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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES AND EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2002

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number: 0-19311

IDEC PHARMACEUTICALS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**33-0112644**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3030 Callan Road, San Diego, California	**92121**
(Address of principal executive offices)	(Zip code)

(858) 431-8500
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: **None**

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $0.0005 par value
(Title of class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes ☒ No o

As of June 30, 2002, the aggregate market value of the voting stock held by non-affiliates of the Registrant was approximately $5,202,590,172. (Based upon the "closing" price as reported by The Nasdaq Stock Market on June 28, 2002). This number is provided only for the purposes of this report and does not represent an admission by either the Registrant or any such person as to the status of such person.

As of January 31, 2003, the Registrant had 154,677,126 shares of its common stock, $0.0005 par value, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for its Annual Meeting of Stockholders held on May 19, 2003 are incorporated by reference into Part III.

Explanatory Note

This Form 10-K/A is being filed solely for the purpose of re-filing the redacted Commercial Supply Agreement dated June 1, 2002 by and between Baxter Pharmaceutical Solutions LLC and the Registrant and does not reflect any events occurring after the date of filing of the original Form 10-K or otherwise modify or update any of the information contained therein.

PART IV

Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K.

a. (1) and (2) Consolidated Financial Statements and Schedule:

See Index to Consolidated Financial Statements and Schedule at page 60.

(3) Exhibits:

The following exhibits are referenced or included in this Form 10-K/A.

Exhibit Number	Description
1.1(19)	Purchase Agreement for $300,000,000 Liquid Yield Option Notes due 2019 (Zero Coupon—Subordinated) dated as of February 9, 1999 between the Registrant and Merrill Lynch, Pierce, Fenner & Smith Incorporated.
3.1(20)	Amended and Restated Certificate of Incorporation of the Registrant.
3.2(1)	Bylaws of the Registrant.
3.3(27)	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant.
4.1	Reference is made to Exhibit 3.1.
4.2	Reference is made to Exhibit 3.2.
4.3(2)	1992 Amended and Restated Registration Rights Agreement of IDEC California.
4.4(1)	Specimen Common Stock Certificate of the Registrant.
4.5	Reference is made to Exhibit 10.46.
4.6(7)	1995 Registration Rights Agreement of the Registrant.
4.8(18)	Preferred Share Purchase Rights.
4.9(19)	First Amendment to the Preferred Share Purchase Rights Agreement, dated July 22, 1997.
4.10(19)	Indenture dated as of February 16, 1999 between the Registrant and Chase Manhattan Bank and Trust Company, National Association.
4.11	Reference is made to Exhibit 1.1
4.12(10)	Form of Registered Liquid Yield Option™ Note due 2019.
4.13(26)	Amended and Restated Rights Agreement dated as of July 26, 2001 between us and Mellon Investor Services LLC.
4.14(31)	Indenture, dated as of April 29, 2002, between IDEC Pharmaceuticals Corporation and JP Morgan Trust Company, N.A.
4.15(31)	Registration Rights Agreement, dated as of April 29, 2002, between IDEC Pharmaceuticals Corporation and Merrill Lynch, Pierce, Fenner & Smith Incorporated.
4.16(31)	Form of Liquid Yield Option™ Note dated April 29, 2002.

10.1(32)	1988 Stock Option Plan of the Registrant, as amended and restated through October 22, 2002.
10.2(13)	Form of Notice of Grant.
10.3(32)	Form of Option Agreement.
10.4(12)	Letter Agreement between the Registrant and Genentech, Inc., dated May 21, 1996.
10.5(2)	401(k) Plan of the Registrant.
10.6(2)	Form of acceleration of vesting letter agreement between the Registrant and certain officers.
10.7(2)+	License Agreement with Coulter Immunology, dated May 16, 1991.
10.8(3)	Lease Agreement between the Registrant and Torrey Sorrento, Inc., dated July 9, 1992.
10.9(3)+	Collaborative Research and License Agreement between the Registrant and SmithKline Beecham p.l.c., dated October 12, 1992.
10.10(3)	Investment Agreement between the Registrant and S.R. One, Limited, dated October 16, 1992.
10.11(17)	1995 Employee Stock Purchase Plan, as amended and restated through January 20, 1999.
10.12(4)+	Collaborative Development Agreement between the Registrant and Mitsubishi Pharma Corporation, formerly Mitsubishi-Tokyo Pharmaceuticals, Inc., formerly Mitsubishi Chemical Corporation, dated November 11, 1993.
10.14(29)	1993 Non-Employee Directors Stock Option Plan, as amended and restated through March 23, 2001.
10.15(6)+	Collaborative Development Agreement between the Registrant and Seikagaku Corporation dated December 27, 1994.
10.16(6)+	License Agreement between the Registrant and Seikagaku Corporation dated December 27, 1994.
10.27(6)	1994 Registration Rights Agreement.
10.28(6)	Investment Agreement between the Registrant, SmithKline Beecham p.l.c. and SmithKline Beecham Corporation, dated December 28, 1994.
10.29(7)	Master Definitions Agreement between the Registrant and Genentech. Inc.
10.30(7)+	Collaboration Agreement between the Registrant and Genentech. Inc., dated March 16, 1995.
10.31(7)+	Expression Technology Agreement between the Registrant and Genentech. Inc., dated March 16, 1995.
10.32(7)	Preferred Stock Purchase Agreement between the Registrant and Genentech. Inc., dated March 16, 1995.

10.33(7)	Option Agreement between the Registrant and Genentech, Inc., dated March 16, 1995.
10.34(7)	Preferred and Common Stock Purchase Agreement between the Registrant and ML/MS Associates, L.P., dated March 16, 1995.
10.35(9)+	Amendment Agreement between the Registrant and SmithKline Beecham p.l.c., dated January 20, 1993.
10.36(9)+	Modification of the Amendment Agreement between the Registrant and SmithKline Beecham p.l.c., dated June 14, 1993.
10.37(8)	Special Stock Issuance Plan.

10.40(15)	Collaborative Development Agreement between the Registrant and Eisai Co., Ltd. dated December 11, 1995.
10.41(15)	License Agreement between the Registrant and Eisai Co., Ltd. dated December 11, 1995.
10.42(15)	License Agreement between the Registrant, Genentech, Inc., and Zenyaku Kogyo Co., Ltd. dated November 30, 1995.
10.43(15)	Development Agreement between the Registrant, Genentech, Inc., and Zenyaku Kogyo Co., Ltd. dated November 30, 1995.
10.44(15)	Supply Agreement between the Registrant and Zenyaku Kogyo Co., Ltd. dated November 30, 1995.
10.45(15)	Termination Agreement between the Registrant and Zenyaku Kogyo Co., Ltd. dated November 30, 1995.
10.46(15)	Amendment to the Development Agreement between the Registrant, Genentech, Inc., and Zenyaku Kogyo Co., Ltd. dated November 30, 1995.
10.47(15)	Amendment to Collaboration Agreement between the Registrant and Genentech, Inc., dated November 30, 1995.
10.48(11)	License Agreement between the Registrant and Chugai Pharmaceutical Co., Ltd., dated March 31, 1996.
10.49(14)	Lease Agreement between the Registrant and All Spectrum Services, Inc., dated August 13, 1996.
10.50(1)	Form of Indemnification Agreement for Officers and Directors.
10.51(16)+	9-AC Asset Transfer Agreement between the Registrant, Pharmacia & Upjohn S.p.A. and Pharmacia & Upjohn Company, dated February 10, 1997.
10.52(19)	Purchase Agreement for $300,000,000 Liquid Yield Option™ Notes due 2019 (Zero Coupon—Subordinated) dated as of February 9, 1999 between the Registrant and Merrill Lynch, Pierce, Fenner & Smith Incorporated.
10.53(19)	Indenture dated as of February 16, 1999 between the Registrant and Chase Manhattan Bank and Trust Company, National Association.
10.54(21)+	Collaboration & License Agreement between the Company and Schering Aktiengesellschaft, dated June 9, 1999.
10.58(22)+	Amended and Restated Collaborative Research and License agreement between IDEC Pharmaceuticals Corporation and SmithKline Beecham p.l.c., dated February 29, 2000
10.62(24)+	Purchase Agreement and Escrow Instructions dated August 31, 2000 between the Company and Ivey Ranch Development Company, LLC.
10.63(25)+	Isotope Agreement between us and MDS Nordion Inc. as amended by a first amendment on January 21, 2000 and a second amendment on March 16, 2001.
10.64(28)+	Purchase and Sale Agreement and Escrow Instructions between San Dieguito Partnership, L.P. and IDEC Pharmaceuticals Corporation, dated July 17, 2001, and the First, Second and Third Amendments to the Purchase and Sale Agreement and Escrow Instructions dated August 17, 2001, August 24, 2001 and August 29, 2001, respectively.
10.65(28)+	Supply Agreement between DSM Pharmaceuticals, Inc., formerly Catalytica Pharmaceuticals, Inc. and IDEC Pharmaceuticals Corporation dated August 8, 2001.
10.66(28)+	Collaborative Development Agreement between IDEC Pharmaceuticals Corporation and Mitsubishi Pharma Corporation, formerly Mitsubishi-Tokyo Pharmaceuticals, Inc., dated September 21, 2001.

10.67(28)	Amended and Restated IDEC Pharmaceuticals Corporation Deferred Compensation Plan dated September 5, 2001.
10.68(30)+	Third Amendment to Agreement between MDS Canada Inc., MDS Nordion division, successor to MDS Nordion Inc. and IDEC Pharmaceuticals Corporation dated November 12, 2001.
10.69(31)+	Addendum to Collaborative Development Agreement, dated March 22, 2002, between IDEC Pharmaceuticals Corporation and Seikagaku Corporation.
10.70+	Commercial Supply Agreement between Baxter Pharmaceutical Solutions LLC and IDEC Pharmaceuticals Corporation dated June 1, 2002.
12.1	Computation of Ratio of Earnings to Fixed Charges.
22.1(2)	Subsidiaries of the Company.
23.1	Independent Auditors' Consent
31.1	Certifications pursuant to Sections 302 and 906 of the Sarbanes-Oxley Act of 2002
32.1	Certifications pursuant to 18 U.S.C. Section 1350

+ Confidential Treatment has been granted with respect to portions of this agreement.

™ Trademark of Merrill Lynch & Co., Inc.

(1)

Incorporated by reference to exhibit filed with our Registration Statement on Form 8-B filed on June 2, 1997.

(2) Incorporated by reference to exhibit filed with our Registration Statement on Form S-1, File No. 33-40756.

(3) Incorporated by reference to exhibit filed with our Annual Report on Form 10-K for the year ended December 31, 1992.

(4) Incorporated by reference to exhibit filed with our Registration Statement on Form S-1, File No. 33-76080.

(5) Incorporated by reference to exhibit filed with our Registration Statement on Form S-8, File No. 33-93794.

(6) Incorporated by reference to exhibit filed with our Annual Report on Form 10-K for the year ended December 31, 1994.

(7) Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended March 31, 1995.

(8) Incorporated by reference to exhibit filed with our Registration Statement on Form S-8, File No. 33-90738.

(9) Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended June 30, 1995.

(10) Incorporated by reference to exhibit 4.4 filed with our Registration Statement on Form S-3, File No. 333-85339.

(11) Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended March 31, 1996.

(12) Incorporated by reference to exhibit filed with our Registration Statement on Form 8-K, dated May 21, 1996.

(13) Incorporated by reference to exhibit filed with our Registration Statement on Form S-8, File No. 333-81625.

(14) Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.

(15) Incorporated by reference to exhibit filed with our Annual Report on Form 10-K for the year ended December 31, 1995.

(16) Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended June 30, 1997.

(17) Incorporated by reference to exhibit 99.1 to our Registration Statement on Form S-8, File No. 333-65494.

(18) Incorporated by reference to exhibit filed with our Registration Statement on Form 8-A, dated August 1, 1997.

(19) Incorporated by reference to exhibit filed with our Annual Report on Form 10-K for the fiscal year ended December 31, 1998.

(20) Incorporated by reference to exhibit filed with our Proxy Statement filed on November 4, 1999.

(21) Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended June 30, 1999.

(22) Incorporated by reference to exhibit filed with our Annual Report on Form 10-K for the fiscal year ended December 31, 1999.

(23) Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended June 30, 2000.

(24) Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended September 30, 2000.

(25) Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended March 31, 2001.

(26) Incorporated by reference to exhibit 4.1 filed with our Registration Statement on Form 8-A, File No. 333-37128 dated July 27, 2001.

(27) Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.

(28) Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended September 30, 2001.

(29) Incorporated by reference to exhibit filed with our Annual Report on Form 10-K for the fiscal year ended December 31, 2000.

(30) Incorporated by reference to exhibit filed with our Annual Report on Form 10-K for the fiscal year ended December 31, 2001.

(31) Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended March 31, 2002.

(32) Incorporated by reference to exhibit filed with our Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.

b. Reports on Form 8-K. On November 29, 2002, we filed a current report of Form 8-K reporting that William R. Rohn, our President and Chief Operating Officer, informed us that he has established a nondiscretionary sales plan intended to comply with Rule 10b5-1 under the Securities Exchange Act of 1934 in order to gradually diversify his holdings. The sales plan takes effect December 4, 2002 and expires one year later. The sales plan provides for sales of up to 125,000 shares of our common stock per three month period depending on prevailing market prices. The maximum number of shares of our common stock that can be sold under the sales plan is 300,000 shares.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

IDEC PHARMACEUTICALS CORPORATION

Date: October 2, 2003

By: /s/ WILLIAM H. RASTETTER, PH.D.

William H. Rastetter, Ph.D.,
Chairman and Chief Executive Officer

Pursuant to the requirements the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Name	Capacity	Date
/s/ WILLIAM H. RASTETTER, PH.D. William H. Rastetter, Ph.D.	Chairman and Chief Executive Officer (Principal Executive Officer)	October 2, 2003
/s/ EDWARD M. RODRIGUEZ* Edward M. Rodriguez	Vice President, Finance and Controller (Principal Financial and Accounting Officer)	October 2, 2003
/s/ HERBERT BOYER, PH.D.* Herbert Boyer, Ph.D.	Director	October 2, 2003
/s/ ALAN B. GLASSBERG, M.D.* Alan B. Glassberg, M.D.	Director	October 2, 2003
/s/ KAZUHIRO HASHIMOTO* Kazuhiro Hashimoto	Director	October 2, 2003
/s/ FRANKLIN P. JOHNSON, JR.* Franklin P. Johnson, Jr.	Director	October 2, 2003
/s/ ROBERT W. PANGIA* Robert W. Pangia	Director	October 2, 2003
/s/ BRUCE R. ROSS* Bruce R. Ross	Director	October 2, 2003
/s/ LYNN SCHENK* Lynn Schenk	Director	October 2, 2003
/s/ WILLIAM D. YOUNG* William D. Young	Director	October 2, 2003

*By: /s/ WILLIAM H. RASTETTER, PH.D.

William H. Rastetter, Ph.D.
Attorney-in-fact

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Exhibit 10.70

CONFIDENTIAL TREATMENT REQUESTED

CONFIDENTIAL TREATMENT REQUESTED: INFORMATION FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED IS OMITTED AND IS NOTED WITH "[CONFIDENTIAL TREATMENT REQUESTED]." AN UNREDACTED VERSION OF THIS DOCUMENT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

COMMERCIAL SUPPLY AGREEMENT

This Commercial Supply Agreement (this "Agreement") is entered into and effective as of the 1st day of June 2002 ("Effective Date") by and between Baxter Pharmaceutical Solutions LLC (**"BAXTER"**), a Delaware limited liability company having a place of business at 927 South Curry Pike, Bloomington, Indiana 47403, and IDEC Pharmaceuticals Corporation (**"CLIENT"**), a Delaware corporation having a place of business at 3030 Callan Road, San Diego, CA 92121.

RECITALS

1. CLIENT is engaged in the development, bulk production, formulation, sale and distribution of pharmaceutical products;

2. BAXTER is engaged in the filling, labeling and packaging of pharmaceutical products;

3. CLIENT and BAXTER desire to have BAXTER fill, package, inspect, label, and test a certain pharmaceutical product known as Ibritumomab Tiuxetan ("Zevalin") for distribution and sale by CLIENT.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, the parties agree as follows:

Article 1, DEFINITIONS

As used in this Agreement, the following words and phrases shall have the following meanings:

1.1 **"Affiliate"** of a party hereto shall mean any entity that controls or is controlled by such party, or is under common control with such party. For purposes of this definition, an entity shall be deemed to control another entity if it owns or controls, directly or indirectly, at least fifty percent (50%) of the voting equity of another entity (or other comparable ownership interest for an entity other than a corporation).

1.2 **"Batch"** shall mean a specific quantity of a Kit Component or Kit set forth in the Project Plan for such Kit Component or Kit that (a) is intended to have uniform character and quality within specified limits, and (b) is Produced according to a single manufacturing run during the same cycle of Production.

1.3 **"BAXTER SOPs"** shall mean BAXTER's Standard Operating Procedures. Copies of BAXTER's Standard Operating Procedures have been provided by BAXTER to CLIENT prior to the Effective Date. BAXTER shall be1.3 responsible at all times to cause the Product-specific BAXTER SOPs to be consistent with the Product Master Plan.

1.4 **"BLA"** shall mean CLIENT's biologics license application filed with the FDA relating to the Kit and each Kit Component, together with any amendments and supplements to such application as may be filed during the term of this Agreement.

1.5 **"Bulk Conjugated Antibody"** shall mean the bulk form of the active ingredient, 2B8-MX-DTPA conjugated antibody, used as the raw material in the Production of the Kit.

1.6 **"Cancellation Fee"** shall be the applicable fee payable by CLIENT for modification or cancellation of a Firm Purchase Order set forth in Exhibit 1, as amended, supplemented or restated from time to time by mutual written agreement of the parties.

1.7 **"CLIENT Trademarks"** shall mean the proprietary mark(s) for Product owned by CLIENT.

1.8 **"Components"** shall mean all Components, including Bulk Conjugated Antibody, used by BAXTER in the Production of Products under this Agreement. Components are listed in the Kit Component Specifications and Kit Specifications, such Components identified as Components supplied by CLIENT ("CLIENT Supplied Components") and Components supplied by BAXTER ("BAXTER Supplied Components").

1.9 **"Confidential Information"** shall have the meaning set forth in the Confidentiality Agreement.

1.10 **"Confidentiality Agreement"** shall mean the Confidentiality Agreement signed by CLIENT and Baxter Healthcare Corporation on December 10, 2001 and assigned to BAXTER on or about January 1, 2002, as amended hereby and as amended, supplemented or restated hereafter from time to time by mutual written agreement of the parties.

1.11 **"Current Good Manufacturing Practices"** or **"cGMP"** shall mean (a) the good manufacturing practices required by the FDA and set forth in the FD&C Act or FDA Regulations (including without limitation 21 CFR 210 and 211), policies or guidelines, in effect at any time during the term of this Agreement, for the Production and testing of pharmaceutical materials as applied solely to Products, and (b) the corresponding requirements of each applicable Regulatory Authority.

1.12 **"Delivery Date"** shall mean, (i) with respect to a Kit Component, the date that such Kit Component is filled, and (ii) with respect to a Kit, the date that such Kit is delivered to a common carrier designated by CLIENT.

1.13 **"Effective Date"** shall mean the date of this Agreement as set forth above.

1.14 **"FDA"** shall mean the United States Food and Drug Administration or any successor entity thereto.

1.15 **"FD&C Act"** shall mean the United States Federal Food, Drug and Cosmetic Act, as may be amended from time to time.

1.16 **"Kit"** shall mean one (1) reaction vial, one (1) 50mM sodium acetate vial, one (1) formulation buffer vial (U.S. or EU as applicable) and one (1) 2B8-MX-DTPA conjugated antibody vial, labeled, packaged and assembled with secondary packaging components for use either as an imaging agent (a "Labeled Imaging Kit") or as a therapeutic agent (a "Labeled Therapeutic Kit"), as specified in Exhibit 2, as amended, supplemented or restated from time to time in accordance with Section 2.2.2.

1.17 **"Kit Component"** shall mean any one (1) of the individual vials specified in Exhibit 3, as amended, supplemented or restated from time to time in accordance with Section 2.2.2, which is labeled ("Labeled Kit Component") or unlabeled ("Unlabeled Kit Component").

1.18 **"Kit Component Specifications"** shall mean the specifications and testing to be performed for each Kit Component, set forth on Exhibit 3, as amended, supplemented or restated from time to time in accordance with Section 2.2.2.

1.19 **"Kit Specifications"** shall mean the specifications, and testing to be performed for each Kit, set forth on Exhibit 2, as amended, supplemented or restated from time to time in accordance with Section 2.2.2.

1.20 **"Long Range Forecast"** shall be defined in Section 4.1.

1.21 **"Master Batch Record"** shall mean the formal set of instructions for the Production of each Kit Component or the Kit. The Master Batch Record for the Production of the 2B8-MX-DTPA conjugated antibody vial is set forth on Exhibit 4. The Master Batch Record for each other Kit Component shall be the formal set of instructions,1.21 for the Production of such Kit Component, that is mutually acceptable to the parties and (except as the parties otherwise mutually agree in writing) shall contain all contents of the batch record previously provided by CLIENT to BAXTER for such Kit Component. The parties shall use commercially reasonable efforts to complete the Master Batch Record for each other Kit Component within twenty-one (21) calendar days after the Effective Date (but in any event prior to the Production of a Stability/Validation Batch for such Kit Component). The Master Batch Record for each other Kit Component shall be incorporated into Exhibit 4 upon their completion. The Master Batch Record for the Kits shall be the formal set of instructions, for the Production of the Kits, that is mutually acceptable to the parties and (except as the parties otherwise mutually agree in writing) shall contain all content of the batch record previously provided by CLIENT to BAXTER for the Kits. The parties shall use commercially reasonable efforts to complete the Master Batch Record for the Kits within thirty (30) calendar days after the Effective Date (but in any event prior to the Production of a Kit). The Master Batch Record for the Kits shall be incorporated into Exhibit 4 upon their completion. The Master Batch Record for each Kit Component or Kit may be amended, supplemented or restated from time to time by mutual written agreement of the parties.

1.22 **"Produce"** or **"Production"** shall mean the filling, packaging, inspecting, labeling, and testing of a Kit Component or Kit by BAXTER.

1.23 **"Products"** shall mean, collectively, the Kits and the Unlabeled Kit Components.

1.24 **"Product Master Plan"** shall mean, collectively, the following:

- the Quality Agreement;
- the Kit Specifications;
- the Kit Component Specifications;
- the Master Batch Records;
- the Project Plans;
- the Regulatory Authorities and Countries where Products will be sold, set forth on Exhibit 5, as amended, supplemented or restated from time to time in accordance with Section 2.2.2;
- the Regulatory Plan;
- the Cancellation Fees;
- the Purchase Prices; and
- the Shipping Instructions.

1.25 **"Project Plans"** shall mean, collectively, the plans containing the parameters for the Production of Products set forth on Exhibit 6, as amended, supplemented or restated from time to time by mutual written agreement of the parties.

1.26 **"Purchase Order"** shall mean written orders from CLIENT to BAXTER which shall specify (a) the quantity of Kit Component or Kit ordered, (b) Delivery Dates, and (c) delivery destinations.

1.27 **"Purchase Price"** shall mean, with respect to each Kit Component or Kit that is Produced under this Agreement and released by BAXTER's quality assurance department in accordance with the Quality Agreement, the applicable price for such Kit Component or Kit Produced under this Agreement set forth in Part A of Exhibit 7, as amended, supplemented or restated from time to time in accordance with Section 2.2.2 or as the parties otherwise mutually agree in writing. The Purchase Price for each Kit Component or Kit is subject to adjustment from time to time in accordance with Section 5.3.

1.28 **"Quality Agreement"** shall mean the Intercompany Quality Agreement in the form attached as Exhibit 8 to this Agreement entered into by BAXTER and CLIENT as of the Effective Date, as amended, supplemented or restated from time to time in accordance with Section 2.3 or as the parties otherwise mutually agree in writing.

1.29 **"Regulatory Approval"** shall mean all authorizations by the appropriate Regulatory Authority necessary for commercial sale in a jurisdiction, including without limitation, approval of labeling, price, reimbursement and Production.

1.30 **"Regulatory Authority"** shall mean those agencies or authorities responsible for regulation of Products in the United States and overseas. BAXTER shall have no obligation to Produce Products in compliance with the requirements of a Regulatory Authority not specified in Exhibit 5, as amended, supplemented or restated from time to time in accordance with Section 2.2.2.

1.31 **"Regulatory Plan"** shall mean the plan containing regulatory services and support for regulatory submissions and supporting documentation for Production of Products attached as Exhibit 9, as amended, supplemented or restated from time to time by mutual written agreement of the parties.

1.32 **"Released Executed Batch Record"** shall mean the completed batch record (in the form of the applicable Master Batch Record) and associated deviation reports, investigation reports, and Certificates of Analysis (provided in accordance with the Quality Agreement) created for each Batch and approved as released to CLIENT under cGMP by BAXTER's quality assurance department.

1.33 **"Rolling Forecast"** shall be defined in Section 4.1

1.34 **"Shipping Instructions"** shall mean the shipping instructions for Product Produced under this Agreement set forth on Exhibit 10, as amended, supplemented or restated from time to time in accordance with Section 2.2.2.

1.35 **"Stability/Validation Batches"** shall mean (a) with respect to each Kit Component (other than the reaction vial specified in Exhibit 3 (as amended, supplemented or restated from time to time in accordance with Section 2.2.2)), the first **[CONFIDENTIAL TREATMENT REQUESTED]** cGMP batches thereof Produced under this Agreement, and (b) with respect to the reaction vial specified in Exhibit 3 (as amended, supplemented or restated from time to time in accordance with Section 2.2.2), the first cGMP batch thereof Produced under this Agreement.

Article 2, PRODUCT MASTER PLAN

2.1 **Product Master Plan.** Prior to the Effective Date, the parties have mutually agreed upon each of the exhibits attached to this Agreement comprising the Product Master Plan.

2.2 **Amendment of Product Master Plan.**

2.2.1 Except as otherwise set forth in Sections 2.2.2 and 2.3, the Product Master Plan may be amended from time to time, as the parties experience with the Production, testing and use of the applicable Product warrants, only upon mutual written agreement of CLIENT and BAXTER.

2.2.2 At the reasonable request of CLIENT, the parties shall negotiate in good faith modification(s) to the Kit Specifications and/or Kit Component Specifications to address regulatory concerns raised by any Regulatory Authority or reasonably raised by CLIENT. At the reasonable request of CLIENT, the parties shall negotiate in good faith modification(s) to the list of countries where Products will be sold and/or the Regulatory Authorities. The Shipping Instructions may be amended from time to time, in the reasonable discretion of CLIENT effective upon written notice to BAXTER. In the event of any modification(s) to the Kit Component Specifications, Kit Specifications, the Shipping Instructions, the list of countries where Products will be sold and/or the Regulatory Authorities that result in an increase/decrease in the cost to BAXTER to Produce a Kit Component or Kit, then the parties shall negotiate in good faith an adjustment to the Purchase Price for such Kit Component or Kit to reflect such increased/decreased cost.

2.3 **Quality Agreement.** The effectiveness of this Agreement is conditioned upon the parties duly executing and delivering the Quality Agreement on or before the Effective Date. At the reasonable request of either party, the parties shall negotiate in good faith amendment(s) to the Quality Agreement (a) to address matters specific to the Production of Product for sale and use outside the United States, and (b) to address regulatory concerns raised by any Regulatory Authority or reasonably raised by either party.

2.4 **No Amendment of Agreement.** In the event that the terms of the Product Master Plan or Quality Agreement are inconsistent with the terms of this Agreement, this Agreement shall control, unless otherwise explicitly agreed to in writing by the parties. The Product Master Plan and Quality Agreement shall be deemed to be incorporated herein and by reference and made a part of this Agreement.

ARTICLE 3, PURCHASE AND SUPPLY OF PRODUCT

3.1 **Agreement to Purchase and Supply.** Pursuant to the terms and conditions of this Agreement, CLIENT shall purchase from BAXTER, and BAXTER shall Produce and deliver to CLIENT, such quantities of Products as ordered by CLIENT in accordance with Sections 3 and 4 of this Agreement.

3.2 **Reproduction, Rework or Reprocessing.** If any reprocessing, rework, or reproduction is required in order to meet the Kit Component Specifications and/or Kit Specifications, BAXTER shall conduct such reprocessing, rework, or reproduction in compliance with cGMPs and the BLA. Any reprocessing, rework, reproduction, or change which is not covered by the BLA must be approved in writing by CLIENT prior to implementation. All costs of any such reprocessing, rework, reproduction, or change shall be allocated in accordance with Sections 7.2, 13.3 and 13.4.

3.3 **Bulk Conjugated Antibody and Other Components Delivery.** CLIENT, **[CONFIDENTIAL TREATMENT REQUESTED]**, shall deliver or cause to be delivered, (a) a reasonably sufficient amount of Bulk Conjugated Antibody and/or other CLIENT Supplied Components, and (b) any applicable certificate of analysis therefor, all to be delivered to BAXTER at least twenty one (21) calendar days in advance of the scheduled date for the applicable Production. Except as may specifically be set forth in the Product Master Plan, on receipt of the Bulk Conjugated Antibody and/or other CLIENT Supplied Components as set forth above, BAXTER's sole obligation with respect to evaluation of the Bulk Conjugated Antibody and other

CLIENT Supplied Components shall be to review the accompanying certificate of analysis to confirm that the Bulk Conjugated Antibody and/or other CLIENT Supplied Components (as applicable) conform with the Kit Specifications and/or Kit Component Specifications (as applicable). CLIENT at all times shall retain title to all Bulk Conjugated Antibody and other CLIENT Supplied Components, and all accompanying documentation supplied by CLIENT, together with all vials filled with Bulk Conjugated Antibody or other CLIENT Supplied Components.

3.4 **Material Safety.** CLIENT shall provide BAXTER a Material Safety Data Sheet for all Bulk Conjugated Antibody and other CLIENT Supplied Components delivered to BAXTER. BAXTER shall immediately notify CLIENT of any unusual health or environmental occurrence relating to a Product, including, but not limited to any claim or complaint by any employee of BAXTER or any of its Affiliates or third party that the operations of BAXTER pursuant to this Agreement have resulted in any adverse health or safety effect on an employee or third party. BAXTER agrees to advise CLIENT immediately of any safety or toxicity problems of which it becomes aware regarding a Product.

3.5 **Vendor and Supplier Audit and Certification.** CLIENT shall be solely responsible for certifying and auditing all vendors and suppliers of Bulk Conjugated Antibody and Components. All vendors and suppliers of Bulk Conjugated Antibody and Components shall be subject to CLIENT's prior written approval, and may be changed by CLIENT from time to time upon sixty (60) days prior written notice to BAXTER. To the extent such changes result in increased cost to BAXTER, BAXTER may adjust the Purchase Price for Product in accordance with the mechanism set forth in Section 5.3.

3.6 **Purchase of Materials.** BAXTER shall purchase, at BAXTER's expense, all packaging and filling materials listed in the Product Master Plan, primary container Components and secondary packaging materials required to Produce Product. BAXTER shall control packaging materials listed in the Product Master Plan and shall assist CLIENT with evaluation and purchase of modified materials in the event that CLIENT requests, pursuant to Section 2.2, a packaging change in the Kit Specifications and/or Kit Component Specifications. BAXTER shall not initiate any changes to materials without written approval from CLIENT.

3.7 **BAXTER Supplied Components.** BAXTER will purchase the BAXTER Supplied Components in quantities sufficient to meet CLIENT's Purchase Orders for Kit Components or Kits consistent with Section 4. The **[CONFIDENTIAL TREATMENT REQUESTED]** will be **[CONFIDENTIAL TREATMENT REQUESTED]**. Risk of loss and damage to BAXTER Supplied Components shall **[CONFIDENTIAL TREATMENT REQUESTED]**.

3.8 **Importer of Record.** In the event any material or equipment to be supplied by CLIENT, including without limitation CLIENT Supplied Components and Bulk Conjugated Antibody, is imported into the United States for delivery to BAXTER ("Imported Goods"), such Imported Goods shall be imported **[CONFIDENTIAL TREATMENT REQUESTED]**. CLIENT shall be the "Importer of Record" of such Imported Goods. As the Importer of Record, CLIENT shall be responsible for (a) customs and other regulatory clearance of Imported Goods, (b) **[CONFIDENTIAL TREATMENT REQUESTED]** in connection with the importation and delivery of the Imported Goods, and (c) keeping all records, documents, correspondence and tracking information required by applicable laws, rules and regulations arising out of or in connection with the importation or delivery of the Imported Goods.

3.9 **Storage.**

3.9.1 **Product Storage.** In no event shall BAXTER be required to store any Kit Component or Kit for more than **[CONFIDENTIAL TREATMENT REQUESTED]** after such

Kit Component or Kit is released by BAXTER's quality assurance department, without BAXTER's prior written consent and CLIENT's agreement to reimburse BAXTER for at the rate set forth in Part B of Exhibit 7, as amended, supplemented or restated from time to time in accordance with Section 2.2.2 or as the parties otherwise mutually agree in writing.

3.9.2 **Bulk Conjugated Antibody and Other CLIENT Supplied Component Storage.** In no event shall BAXTER be required to store more than a **[CONFIDENTIAL TREATMENT REQUESTED]** supply of Bulk Conjugated Antibody or other CLIENT Supplied Components as calculated using the most recent Rolling Forecast without the prior written consent of BAXTER and CLIENT's agreement to reimburse BAXTER at the rate set forth in Part B of Exhibit 7, as amended, supplemented or restated from time to time in accordance with Section 2.2.2 or as the parties otherwise mutually agree in writing.

3.9.3 **Third Party Storage.** BAXTER shall be permitted to store Kit Components and Kits **[CONFIDENTIAL TREATMENT REQUESTED]** in third party storage facilities only to the extent permitted in the applicable Project Plans, provided in each case that (a) such third 3.9.3 party shall have been previously approved in writing by CLIENT and (b) CLIENT shall have the right to visit, inspect and audit such third party's facilitates and records used in or that otherwise directly affect the storage of any Kit Component or Kit.

Article 4, FORECASTS, ORDERS, AND CAPACITY

4.1 **Forecasts and Order Limits.**

4.1.1 Prior to July 10 of each calendar year after the Effective Date, CLIENT will provide to BAXTER in writing a **[CONFIDENTIAL TREATMENT REQUESTED]** forecast for each calendar year during the remainder of the Term of CLIENT's estimated orders for Products (the "Long Range Forecast"). BAXTER specifically agrees that such Long Range Forecasts submitted by CLIENT will be for general planning purposes only, and shall not be binding on CLIENT or BAXTER.

4.1.2 Prior to the **[CONFIDENTIAL TREATMENT REQUESTED]** of each calendar quarter after the Effective Date, CLIENT will provide BAXTER in writing a **[CONFIDENTIAL TREATMENT REQUESTED]** rolling forecast of CLIENT's forecasted orders for Products (the "Rolling Forecast"). CLIENT shall not **[CONFIDENTIAL TREATMENT REQUESTED]** the quantity forecasted for the **[CONFIDENTIAL TREATMENT REQUESTED]** calendar quarter of each Rolling Forecast to more than **[CONFIDENTIAL TREATMENT REQUESTED]** of the quantity forecasted for the **[CONFIDENTIAL TREATMENT REQUESTED]** calendar quarter of the immediately preceding Rolling Forecast, and shall not decrease the quantity forecasted for the **[CONFIDENTIAL TREATMENT REQUESTED]** calendar quarter of each Rolling Forecast to less than **[CONFIDENTIAL TREATMENT REQUESTED]** of the quantity forecasted for the **[CONFIDENTIAL TREATMENT REQUESTED]** calendar quarter of the immediately preceding Rolling Forecast.

4.1.3 BAXTER shall supply CLIENT with the quantity of each Product ordered by CLIENT for a calendar quarter, unless the quantity ordered for such calendar quarter exceeds **[CONFIDENTIAL TREATMENT REQUESTED]** of the quantity of such Product forecasted for such calendar quarter in the most recent Rolling Forecast, in which event BAXTER shall use commercially reasonable efforts to supply quantities in excess of **[CONFIDENTIAL TREATMENT REQUESTED]** of the quantity of such Product forecasted for such calendar quarter in the most recent Rolling Forecast. In no event shall CLIENT order and purchase in any calendar quarter less than **[CONFIDENTIAL TREATMENT REQUESTED]** of the quantity of such Product forecasted for such calendar quarter in the most recent Rolling Forecast (the "Minimum Quantity"). In the event CLIENT orders and purchases less than the

Minimum Quantity of any Product in any calendar quarter, then within thirty (30) calendar days following the end of such calendar quarter, CLIENT shall pay to BAXTER **[CONFIDENTIAL TREATMENT REQUESTED]**. Notwithstanding anything to the contrary in this Agreement, CLIENT's minimum purchase obligations under this Agreement, other than with respect to the Stability/Validation Batches of Product under this Agreement, shall not commence until the date on which CLIENT obtains the applicable Regulatory Approval to sell Product Produced by BAXTER under this Agreement. Additionally, notwithstanding anything to the contrary in this Agreement, the limitations on CLIENT's ability to adjust forecasts and CLIENT's minimum purchase obligations under this Agreement shall terminate in the event of any one or more of the following events: (a) **[CONFIDENTIAL TREATMENT REQUESTED]** of this Agreement, (b) **[CONFIDENTIAL TREATMENT REQUESTED]** in accordance with Section 4 (subject to the limitations on BAXTER's obligations set forth in Section 4); (c) **[CONFIDENTIAL TREATMENT REQUESTED]** directly affecting the ability of BAXTER to timely Produce and deliver Product hereunder which is **[CONFIDENTIAL TREATMENT REQUESTED]**; (d) the Yield (as defined in Section 13.3.5) for any **[CONFIDENTIAL TREATMENT REQUESTED]** falls below **[CONFIDENTIAL TREATMENT REQUESTED]**; and/or (e) the occurrence of an **[CONFIDENTIAL TREATMENT REQUESTED]**.

4.1.4 Notwithstanding anything to the contrary in the preceding Sections 4.1.2 and 4.1.3, the aggregate quantity of Product forecasted in a Rolling Forecast provided by CLIENT for any calendar quarter following the first anniversary of the Effective Date shall not exceed **[CONFIDENTIAL TREATMENT REQUESTED]** of the aggregate quantity of Product forecasted in the Rolling Forecast provided by CLIENT for the corresponding calendar quarter of the immediately preceding calendar year.

4.2 **Purchase Orders.** Prior to or on the **[CONFIDENTIAL TREATMENT REQUESTED]**, CLIENT shall submit Purchase Orders to BAXTER covering CLIENT's purchases of Kit Components and Kits pursuant to this Agreement. CLIENT shall not, without the written consent of BAXTER, designate (a) a Delivery Date in a Purchase Order for Kits earlier than **[CONFIDENTIAL TREATMENT REQUESTED]** from the date CLIENT submits the Purchase Order therefor, provided that CLIENT has satisfied its obligations under this Agreement to enable sufficient Kit Components to be available, or (b) a Delivery Date in a Purchase Order for Kit Components earlier than **[CONFIDENTIAL TREATMENT REQUESTED]** from the date CLIENT submits the Purchase Order. Within **[CONFIDENTIAL TREATMENT REQUESTED]** after the receipt of a Purchase Order, BAXTER shall provide a confirmation of receipt of such Purchase Order setting forth the Delivery Date that BAXTER will meet and setting forth BAXTER's filling date for such order. Upon CLIENT's receipt of the confirmation, such Purchase Order shall become a "Firm Purchase Order." If BAXTER is unable to meet the specified Delivery Date, except when caused by CLIENT's delay in delivery of Bulk Conjugated Antibody or other CLIENT Supplied Components, BAXTER shall so notify CLIENT and provide to CLIENT an alternative Delivery Date which shall not be more than **[CONFIDENTIAL TREATMENT REQUESTED]** later than the initial Delivery Date designated by CLIENT in its Purchase Order. In the event that CLIENT modifies or cancels a Firm Purchase Order without BAXTER's written consent, CLIENT shall pay the Cancellation Fees as set forth in the Product Master Plan. To the extent of any conflict between Purchase Orders submitted by CLIENT and this Agreement, this Agreement shall control.

4.3 **Bulk Conjugated Antibody and Other Component Delivery Delays.** BAXTER shall have no responsibility for delays in delivery of Product caused by delays in receipt of Bulk Conjugated Antibody or other CLIENT Supplied Components. BAXTER shall have no responsibility for delays in delivery of Product to the extent 4.3 caused by **[CONFIDENTIAL TREATMENT REQUESTED]**, provided that (a) **[CONFIDENTIAL TREATMENT REQUESTED]**.

Notwithstanding anything in this Agreement to the contrary, **[CONFIDENTIAL TREATMENT REQUESTED]** be paid promptly to BAXTER within thirty (30) calendar days following receipt by CLIENT of an invoice therefor, **[CONFIDENTIAL TREATMENT REQUESTED]**.

Article 5, PRICE

5.1 **Kit Component and Kit Purchase Price.** The price to be paid by CLIENT for each Kit Component or Kit that is Produced under this Agreement and released by BAXTER's quality assurance department in accordance with the Quality Agreement shall be the applicable Purchase Price therefor, as set forth in Part A of Exhibit 7, as amended, supplemented or restated from time to time in accordance with Section 2.2.2 or as the parties otherwise mutually agree in writing.

5.2 **Process Development, Validation, Regulatory and Other Services Price.** The price to be paid by CLIENT for process development, validation, regulatory and other services (which price shall exclude the Purchase Price for each Kit Component or Kit that is Produced under this Agreement and released by BAXTER's quality assurance department in accordance with the Quality Agreement) shall be set forth in Part B of Exhibit 7, as amended, supplemented or restated from time to time in accordance with Section 2.2.2 or as the parties otherwise mutually agree in writing.

5.3 **Purchase Price Adjustment.** Upon the **[CONFIDENTIAL TREATMENT REQUESTED]** anniversary of the date of this Agreement and on each anniversary thereafter, the Purchase Price of each Kit Component or Kit may be adjusted to reflect changes in the cost of BAXTER Supplied Components and labor costs paid by BAXTER in connection with the Production of such Kit Component or Kit, not to exceed the change in the **[CONFIDENTIAL TREATMENT REQUESTED]** for which such **[CONFIDENTIAL TREATMENT REQUESTED]** is available. BAXTER shall provide CLIENT with written notice, which notice shall set forth the amount of such Purchase Price adjustment. BAXTER shall provide such notice not later than thirty (30) calendar days following each such anniversary date to be effective, and any increase set forth in such notice shall be effective for Purchase Orders received by BAXTER after such anniversary date.

Article 6, SHIPMENT AND INVOICING

6.1 **Delivery Terms.** BAXTER shall ship Products in accordance with the Product Master Plan, and deliver Products to CLIENT or to a location designated by CLIENT in applicable Purchase Order **[CONFIDENTIAL TREATMENT REQUESTED]** BAXTER's facility in Bloomington, Indiana freight collect, by a common carrier designated by CLIENT in Shipping Instructions, at **[CONFIDENTIAL TREATMENT REQUESTED]** expense; provided, however, subject to Article 13, **[CONFIDENTIAL TREATMENT REQUESTED]** for the loading of Products on departure and **[CONFIDENTIAL TREATMENT REQUESTED]** procure, at its cost, insurance covering damage or loss to Products during shipping.

6.2 **Exporter of Record.** CLIENT shall be the exporter of record for any Product shipped out of the United States, as CLIENT remains the owner of such Product. CLIENT warrants that all shipments of any Product exported from the United States will be made in compliance with all applicable United States export laws and regulations and all applicable import laws and regulations into the country of deportation.

[**CONFIDENTIAL TREATMENT REQUESTED]** necessary for the exportation from the United States. CLIENT shall select and pay the freight forwarder who shall solely be CLIENT's agent. CLIENT and its freight forwarder shall be responsible for preparing and filing the Shipper's Export Declaration and any other applications required for the export. BAXTER shall cooperate with CLIENT by providing reasonable assistance in preparing and filing any necessary documents to support CLIENT's import and export applications.

6.3 **Foreign Corrupt Practices Act.** CLIENT acknowledges it is not the agent of BAXTER and represents and warrants that it has not, and covenants that it will not, pay anything of value to any government employee in connection with the resale of Products.

6.4 **Payment Terms.** BAXTER shall invoice CLIENT for each Kit Component or Kit that is Produced under this Agreement and released by BAXTER's quality assurance department in accordance with the Quality Agreement at the time such Kit Component or Kit is so released; provided, however, that the stated due date of each such invoice shall not be prior to the later of (a) **[CONFIDENTIAL TREATMENT REQUESTED]** following the date of CLIENT's receipt of the applicable Product samples, (b) **[CONFIDENTIAL TREATMENT REQUESTED]** following the date of CLIENT's receipt of the applicable Released Executed Batch Record(s) and related documentation in accordance with the Product Master Plan, or (c) **[CONFIDENTIAL TREATMENT REQUESTED]** following the date of the invoice. BAXTER shall invoice CLIENT for all process development, validation and regulatory services (if any) monthly in arrears, which invoices shall set forth in reasonably specific detail the services performed and the costs therefor. CLIENT shall pay all amounts invoiced on or before the stated due date of the applicable invoice, provided that on the date of such invoice BAXTER shall have (a) sent by facsimile such invoice to CLIENT to such facsimile number as most recently requested in writing by CLIENT for such purpose, and (b) deposited the original of such invoice in the United States mail, first class postage prepaid and addressed to CLIENT at such address as most recently requested in writing by CLIENT for such purpose. Notwithstanding anything to the contrary in this Section, the **[CONFIDENTIAL TREATMENT REQUESTED]**.

Payments shall be made in U.S. dollars by check delivered to BAXTER, or by wire transfer. Each invoice shall be payable by CLIENT in accordance with the terms noted above. Any payment due under this Agreement not received within the times noted above shall bear interest at the lesser of (a) the maximum rate permitted by law, or (b) 1.5% per month on the outstanding balance compounded monthly.

6.5 **Default in Payment Obligations.** In addition to all other remedies available to BAXTER in the event of a CLIENT default, if CLIENT fails to make payments as required hereunder of amounts invoiced (other than amounts contested by CLIENT in good faith), BAXTER may **[CONFIDENTIAL TREATMENT REQUESTED]** until the amount invoiced (other than amounts contested by CLIENT in good faith) is paid in full, **[CONFIDENTIAL TREATMENT REQUESTED]** the foregoing terms of payment, place the account on a letter of credit basis, require **[CONFIDENTIAL TREATMENT REQUESTED]** of Product until the amount invoiced (other than amounts contested by CLIENT in good faith) is **[CONFIDENTIAL TREATMENT REQUESTED]** or until **[CONFIDENTIAL TREATMENT REQUESTED]** to BAXTER. For purposes of this Section 6.5 only, **[CONFIDENTIAL TREATMENT REQUESTED]** shall not constitute good faith grounds for contesting an amount invoiced.

Article 7, ACCEPTANCE OF PRODUCT

7.1 **Product Conformity.** Within the later of **[CONFIDENTIAL TREATMENT REQUESTED]** following the date of CLIENT's receipt of Product samples or **[CONFIDENTIAL TREATMENT REQUESTED]** following the date of CLIENT's receipt of the applicable Released Executed Batch Record(s) and related documentation in accordance with the Product Master Plan, CLIENT shall have the right to determine whether Product conforms to cGMP, to all other applicable United States laws and regulations and all foreign laws and regulations of the countries listed in Exhibit 5 (as amended, supplemented or restated from time to time in accordance with Section 2.2.2), to the applicable Kit Component Specifications and/or Kit

Specifications, and to the applicable Project Plan(s) and the Quality Agreement (collectively the "Product Requirements"). Notwithstanding the foregoing, if CLIENT has conducted at least one test of the applicable Batch

and in good faith has requested in writing, within the time period specified in Section 7.1, additional time to perform additional testing, then such period shall be extended as reasonably necessary for CLIENT, or BAXTER (if requested by CLIENT), to perform such additional testing.

7.1.1 If (a) any Product conforms to the Product Requirements, or (b) CLIENT fails to notify BAXTER within the time period specified in Section 7.1 that any Product does not conform to the Product7.1.1 Requirements, then CLIENT shall be deemed to have accepted such Product and waived its right to revoke acceptance.

7.1.2 If CLIENT believes any Product does not conform to the Product Requirements, it shall give written notice to BAXTER specifying the manner in which such Product fails to meet the Product Requirements. Guidelines for resolving any disputed claims regarding conformity of Product are set forth in Section 7.1.3.

7.1.3 If the parties dispute whether any Product is conforming or non-conforming, the samples of Product will be submitted to a mutually acceptable laboratory or consultant for resolution, whose determination of conformity or non-conformity, and the cause thereof of non-conformity, shall be binding upon the parties. The non-prevailing party shall bear the costs of such laboratory or consultant, except as set forth in Section 7.2.3.

7.2 **Remedies for Non Conforming Product.**

7.2.1 In the event BAXTER agrees that any Product is non-conforming or the laboratory determines that the shipment of Product is non-conforming, BAXTER shall replace such non-conforming Product within the latter of (a) **[CONFIDENTIAL TREATMENT REQUESTED]** from receipt of the applicable replacement CLIENT Supplied Component(s) from CLIENT or (b) **[CONFIDENTIAL TREATMENT REQUESTED]** from the date of determination by the third party of non-conformity or agreement by BAXTER of such non-conformity.

7.2.2 CLIENT shall **[CONFIDENTIAL TREATMENT REQUESTED]**, including the **[CONFIDENTIAL TREATMENT REQUESTED]** and the **[CONFIDENTIAL TREATMENT REQUESTED]** therefor, if the nonconformance results from the **[CONFIDENTIAL TREATMENT REQUESTED]** to conform with the applicable Kit Specifications and/or Kit Component Specifications **[CONFIDENTIAL TREATMENT REQUESTED]** to BAXTER.

7.2.3 In the event BAXTER agrees, or the laboratory or consultant determines, that Product is non conforming **[CONFIDENTIAL TREATMENT REQUESTED]**, then **[CONFIDENTIAL TREATMENT REQUESTED]**, subject to, and except as otherwise set forth in, the provisions of Article 13.

7.3 **Non Conforming Bulk Conjugated Antibody or Other CLIENT Supplied Components.** If Product is rejected by CLIENT, and such Product's failure to meet the Product Requirements is the result of non-conforming Bulk Conjugated Antibody or other CLIENT Supplied Component(s), then such non-conformity shall be deemed not to be non-conforming as a result of the negligence, omission or willful misconduct of BAXTER or BAXTER's breach of its warranties or obligations under this Agreement.

Article 8, TERM AND TERMINATION

8.1 **Term.** This Agreement shall be effective on the Effective Date and shall continue for sixty (60) months thereafter (the "Term"), unless earlier terminated in accordance with the terms of this Agreement.

8.2 **Termination for Breach.** Either party may terminate this Agreement upon the material breach of this Agreement by the other party if such material breach is not cured by the breaching party within ten (10) calendar days for monetary defaults, and thirty (30) calendar days for

non-monetary defaults (or such additional time reasonably necessary to cure such non-monetary default provided the breaching party has commenced a cure within the thirty (30) calendar day period and is diligently pursuing completion of such cure) after receipt by the breaching party of written notice of such default. In the event that the Production or sale of any Product is enjoined due to the alleged infringement by either party of the proprietary rights of a third party such occurrence shall not be deemed a breach of this Agreement by CLIENT or BAXTER.

8.3 **Termination by CLIENT.** CLIENT may terminate this Agreement, at its option in its sole discretion, (a) if CLIENT fails to obtain the applicable Regulatory Approval to sell Product Produced by BAXTER under this Agreement within twelve (12) months following the Effective Date due in whole or in part to any act or omission of BAXTER, or (b) upon the withdrawal of the Kit from the market and termination of the marketing and sales of the Kit by CLIENT.

8.4 **Additional Rights and Remedies.** Subject to Section 13.1, termination under this Section 8 shall be in addition to the other rights and remedies of the terminating party. Termination of this Agreement for any reason shall not relieve any party of any obligations accruing prior to such termination.

8.5 **Non-cancelable Costs and Expenses.** In the event of the termination of this Agreement, except by CLIENT as a result of a breach by BAXTER under Section 8.2, CLIENT shall (a) reimburse BAXTER for all BAXTER Supplied Components ordered prior to termination and not cancelable at no cost to BAXTER, and (b) pay BAXTER the applicable Cancellation Fees (if any) as set forth in the Product Master Plan. In addition, in the event of termination or cancellation for any reason, CLIENT shall pay the applicable Purchase Prices described in Section 5 for (i) all work-in-process commenced by BAXTER and (ii) all finished goods of BAXTER. BAXTER promptly shall deliver such materials to CLIENT pursuant to Section 6.1. CLIENT shall make payment for all expenses described in this Section 8.5 within thirty (30) calendar days from the date of receipt by CLIENT of the applicable invoice.

8.6 **Termination Damages.** In addition to the costs and expenses payable in Section 8.5, (a) in the event of termination of this Agreement by BAXTER under Section 8.2 or (b) in the event of termination of this Agreement by CLIENT under clause (b) of Section 8.3, CLIENT shall pay BAXTER **[CONFIDENTIAL TREATMENT REQUESTED]** of the Purchase Price for the aggregate quantity of Product forecasted by CLIENT in the most recent Rolling Forecast.

8.7 **Survival.** Termination, expiration, cancellation or abandonment of this Agreement through any means or for any reason, except as set forth in Section 13.1, shall be without prejudice to the rights and remedies of either party with respect to any antecedent breach of any of the provisions of this Agreement. The provisions of Sections 8, 12, 13, 14, 15, 16, 17 and 18 hereof shall survive expiration or termination of this Agreement.

8.8 **Files and Records.** Upon the expiration or termination of this Agreement, BAXTER promptly shall make available to CLIENT copies of all manufacturing and process development documents and records relating to Product, shall store the originals or electronic copies of such documents and records according to cGMPs in a safe and secure facility for at least two (2) years after the expiration date of the last Batch Produced by BAXTER under this Agreement, and shall permit the FDA or other Regulatory Authorities access to such documents and records to the extent requested thereby. For a period of twelve (12) months following expiration or termination of this Agreement, BAXTER shall make available to CLIENT for review, from the DMF, any non-confidential information contained therein that is reasonably related to Product that may be used by CLIENT to support any investigational studies or commercial marketing of Product.

Article 9, PRODUCTION OF PRODUCT

9.1 **Production.** BAXTER shall Produce Product in accordance with the Product Requirements. Subject to compliance with reasonable rules and regulations of BAXTER relating to confidentiality, safety and security, CLIENT shall have the right to access the BAXTER facilities directly affecting the Production of Product, and all applicable records related thereto, to oversee Production of Product in accordance with the Quality Agreement and BAXTER's standard visitation policy. CLIENT shall have the right to oversee each Production run of Product (from Component preparation through final labeling and assembly) in accordance with the Quality Agreement. CLIENT shall have the right to render technical advice and direction to BAXTER regarding Production of Product pursuant to their involvement in the generation of the Master Batch Record or direct communication with the Project Manager or Technical Service Representative. BAXTER promptly shall implement all reasonable advice and direction provided that such advice and direction is not inconsistent with the Product Master Plan, BAXTER SOPs, and cGMPs. If CLIENT observes or discovers variances from established standards and methods of9.1 Production of Product, CLIENT shall give written notice thereof to BAXTER, and upon receipt of any such notice, BAXTER promptly shall take all appropriate remedial or corrective action and give written notice to CLIENT describing in reasonable detail such actions taken. If BAXTER disagrees with any such advice and direction, the parties shall discuss in good faith an appropriate resolution.

9.2 **Audits.** CLIENT shall have the right to audit BAXTER's facilities in accordance with the Quality Agreement. Such audits shall be scheduled at mutually agreeable times upon reasonable advance written notice to BAXTER, shall be at CLIENT's expense, and shall not occur more than one (1) time per calendar year unless required by BAXTER's compliance status or CLIENT's obligations as a license holder. If CLIENT requests additional audits which are not due to BAXTER's compliance status and BAXTER agrees to such audits, CLIENT will incur fees as reasonably determined by BAXTER. Such fees shall be paid promptly upon completion of such audits. In connection with performing such audits, CLIENT shall comply with all reasonable rules and regulations promulgated by BAXTER relating to confidentiality, safety and security. All information disclosed or reviewed in such inspections shall be deemed to be the property of BAXTER and BAXTER Confidential Information (subject to the exceptions set forth in Section 1 of the Confidentiality Agreement).

9.3 **Testing.** In accordance with the Quality Agreement, BAXTER shall test, or cause to be tested by third party testing facilities audited by BAXTER, in accordance with the Product Requirements, each Batch of Product Produced pursuant to this Agreement before delivery to CLIENT. A certificate of analysis for each Batch of Product delivered to CLIENT shall set forth the items tested by BAXTER, specifications, and test results in accordance with the Quality Agreement. BAXTER shall send, or cause to be sent, such certificates along with one (1) copy of the Released Executed Batch Record to CLIENT prior to or at the same time of shipment of Product to CLIENT.

As required by the FDA, CLIENT shall assume full responsibility for final release of each lot of Product.

9.4 **Permits and Licenses.** Client shall have sole responsibility, at its expense, for obtaining all permits and licenses necessary or required for the sale, marketing and commercialization of each Product Produced by BAXTER hereunder. BAXTER shall be responsible, **[CONFIDENTIAL TREATMENT REQUESTED]** , to obtain and maintain all permits and licenses required for it to carry out its regulatory and Production obligations hereunder. BAXTER, at CLIENT's request **[CONFIDENTIAL TREATMENT REQUESTED]**, shall cooperate with CLIENT by assisting in preparing and filing any necessary documents to support CLIENT's applications for permits and licenses.

9.5 **Regulatory Requirements.** Each party promptly shall notify the other of new regulatory requirements of which it becomes aware which are relevant to the Production of a Product under this Agreement and which are required by the FDA, any other applicable Regulatory Authority or other applicable laws or governmental regulations, and shall confer with each other with respect to the best means to comply with such requirements. Notwithstanding anything to the contrary in this Agreement, BAXTER shall be responsible for its compliance with all regulatory requirements of the United States and all foreign countries listed in Exhibit 5 (as amended, supplemented or restated from time to time in accordance with Section 2.2.2) that are applicable to BAXTER's facilities and BAXTER's activities in Production, whether or not CLIENT is aware of such requirements and has failed to give notice to BAXTER.

9.6 **Drug Master File.** In accordance with the Product Master Plan, BAXTER shall file and maintain the appropriate Drug Master File ("DMF") and related reference applications (e.g. Site Master File) for its Production of each Product hereunder in accordance with 21 CFR 314.420, as may be amended from time to time, at BAXTER's expense.

9.7 **Changes in Manufacturing**

9.7.1 **Changes to Product Master Plan**. BAXTER agrees to inform CLIENT within **[CONFIDENTIAL TREATMENT REQUESTED]** of the result of any regulatory development that directly affect the Production of a Product or changes to Product-specific BAXTER SOPs. BAXTER shall give written notice to CLIENT of any such changes, and CLIENT and BAXTER will review such development or changes in accordance with the Quality Agreement; provided, however, that (a) BAXTER shall assure that all such changes to the Product-specific BAXTER SOPs are consistent with the Product Master Plan unless the parties otherwise expressly agrees in writing, and (b) any changes to the Product Master Plan shall be made only in accordance with Section 2.2.

9.7.2 **Product-Specific Changes.** If facility, equipment, process or system changes are required of BAXTER as a result of requirements set forth by the FDA or any other Regulatory Authority, and such regulatory changes apply primarily to the Production and supply of a Product, then CLIENT and BAXTER will review such requirements and agree in writing to such regulatory changes in accordance with the Quality Agreement, and CLIENT shall bear **[CONFIDENTIAL TREATMENT REQUESTED]** of the reasonable costs thereof; provided, however, that (a) BAXTER shall assure that all such changes to the Product-specific BAXTER SOPs are consistent with the Product Master Plan unless the parties otherwise expressly agree in writing, and (b) any changes to the Product Master Plan shall be made only in accordance with Section 2.2.

9.8 **Equipment Expenses.** If BAXTER is required to obtain specialized equipment in order to Produce a Product for CLIENT, the costs of such equipment shall be paid by CLIENT. BAXTER shall advise CLIENT of the specialized equipment required and the estimated costs associated with the purchase and installation of such equipment. If CLIENT, in its sole discretion, determines that it does not desire to pay the costs for such equipment, then CLIENT shall have the right to terminate this Agreement with respect to such Product for which such equipment is required only, on ninety (90) calendar days prior written notice to BAXTER. CLIENT shall be invoiced for all approved costs after installation and acceptance of such equipment by BAXTER, and CLIENT shall pay all each such invoice within thirty (30) calendar days following receipt by CLIENT thereof.

9.9 **Ownership and Use of Equipment**. All such equipment paid for by CLIENT shall be owned solely by CLIENT; provided, however, that such equipment shall remain at BAXTER's facility used for Production of Products and shall be available for BAXTER's use solely in connection with the Production of Products for CLIENT. BAXTER shall not use such equipment

for any other purpose, shall not transfer such equipment to any third party or other location, shall not purport to convey or grant to any third party an interest in such equipment, and shall take no action inconsistent with CLIENT's ownership of such equipment. During the term of this Agreement, BAXTER shall be responsible for maintaining, servicing and insuring (including by means of self-insurance) such equipment to the same extent and in the same manner as BAXTER maintains, services and insures (including by means of self-insurance) its own equipment. BAXTER shall maintain appropriate records regarding the use, maintenance and service of such equipment. Upon termination of this Agreement, BAXTER promptly shall deliver such equipment to CLIENT at such location as CLIENT reasonably requests.

Article 10, REGULATORY

10.1 **Regulatory Approvals**. In accordance with the Product Master Plan, CLIENT will diligently pursue Regulatory Approval of marketing licenses for Products Produced by BAXTER hereunder. CLIENT will advise BAXTER of document requirements in support of BLA and similar applications required of foreign governments and agencies including amendments, license applications, supplements and maintenance of such. BAXTER will provide documents and assist CLIENT in preparation of submissions to Regulatory Authorities (both U.S and foreign) designated by CLIENT in support of CLIENT's BLAs, similar applications required of foreign governments and licenses. All regulatory submission preparation and maintenance performed by BAXTER for CLIENT shall be specified in the Product Master Plan.

10.2 **Regulatory Authority Inspections**.

10.2.1 **Interaction with Regulatory Authorities.** All interaction with Regulatory Authorities (both written and oral) that directly affects Product or the Production of Product shall be conducted in accordance with the provisions of this Article 10. At CLIENT's request, BAXTER will authorize Regulatory Authorities to review on CLIENT's behalf applications related to the Production of Products.

10.2.2 **Product Pre-Approval Inspection.** In the case of the Product Pre-Approval Inspection by the FDA related to the Products, the following shall apply: (a) BAXTER immediately shall inform CLIENT of the notice of such inspection; (b) BAXTER shall permit a representative of CLIENT (who shall be selected by BAXTER from a list of senior representatives reasonably provided by CLIENT) to be present at such inspection (but not to participate, except as requested by BAXTER); (c) BAXTER shall permit such representative of CLIENT to be present at, and participate in, each daily wrap up session for such inspection and the post-inspection wrap up session for such inspection; (d) BAXTER promptly shall provide CLIENT with copies of all written materials, including without limitation copies of any Notice of Inspection (FDA Form 482), other notice of inspection, notice of violation, other similar notice, or Inspectional Observations (FDA Form 483) received by BAXTER relating to such inspection, and (e) BAXTER shall provide CLIENT with advance copies of all proposed responses to any such inspections, notices or actions, shall permit CLIENT reasonable opportunity to review and comment on each such response, shall reasonably consider CLIENT's reasonable comments thereon, and shall provide CLIENT with copies of each such response as submitted.

10.2.3 **Other Product Specific Inspections.** In the case of an inspection (other than the Product Pre-Approval Inspection) by a Regulatory Authority that directly affects the Production of Products, the following shall apply: (a) BAXTER immediately shall inform CLIENT of the notice of such inspection; (b) BAXTER shall permit a representative of CLIENT (who shall be selected by BAXTER from a list of senior representatives reasonably provided by CLIENT) to be present at the BAXTER facility that is the subject of such

inspection (but not to be present at the inspection or to participate, except as requested by BAXTER); (c) BAXTER shall permit such representative of CLIENT to be present at, and participate in, each daily wrap up session for such inspection and the post-inspection wrap up session for such inspection; (d) BAXTER promptly shall provide CLIENT with copies of all written materials, including without limitation copies

of any Notice of Inspection (FDA Form 482), other notice of inspection, notice of violation, other similar notice, or Inspectional Observations (FDA Form 483) received by BAXTER relating to such inspection, and (e) BAXTER shall provide CLIENT with advance copies of all proposed responses to any such inspections, notices or actions, shall permit CLIENT reasonable opportunity to review and comment on each such response, shall reasonably consider CLIENT's reasonable comments thereon, and shall provide CLIENT with copies of each such response as submitted.

10.2.4 **Other Inspections.** In the case of an inspection by a Regulatory Authority of a Baxter facility that does not directly affect the Production of Products, the following shall apply: (a) BAXTER promptly shall provide CLIENT with copies of all written materials (with confidential information that does not directly affect the Production of Products redacted therefrom), including without limitation copies of any Notice of Inspection (FDA Form 482), other notice of inspection, notice of violation, other similar notice, or Inspectional Observations (FDA Form 483) received by BAXTER relating to such inspection; and (b) BAXTER promptly shall provide CLIENT with copies of all responses to any such inspections, notices or actions (with confidential information that does not directly affect the Production of Products redacted therefrom).

10.3 **Accelerated Delivery of Kits**. In the event of any adverse regulatory action, including without limitation receipt by BAXTER from the FDA or other Regulatory Authorities of a warning letter, injunction, restraining order, notice of intent to do any of the foregoing, or notice of intent to revoke or suspend any of BAXTER's licenses that directly affect Product or the Production of Product, BAXTER shall deliver to CLIENT, within forty eight (48) hours of a written request from CLIENT and after tender by CLIENT of the applicable Purchase Price, all Kits and Kit Components requested by CLIENT in BAXTER's possession; provided that BAXTER is not prohibited from doing so per any applicable law, regulation, court or agency order, notice, or ruling.

Article 11, TRADEMARKS

11.1 CLIENT grants to BAXTER a non-exclusive, royalty free license to use the CLIENT Trademarks for the sole purpose of allowing BAXTER to fulfill its responsibilities under this Agreement. Such license shall not be transferable in whole or in part.

11.2 CLIENT shall be solely responsible for selecting, registering and enforcing the CLIENT Trademarks used to identify a Product and except as set forth in Section 11.1 and shall have sole and exclusive rights in such CLIENT Trademarks.

Article 12, REPRESENTATIONS AND WARRANTIES

12.1 **Mutual Representations**. Each party hereby represents and warrants to the other party that (a) the person executing this Agreement is authorized to execute this Agreement; (b) this Agreement is legal and valid and the obligations binding upon such party are enforceable by their terms; and (c) the execution, delivery and performance of this Agreement does not violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

12.2 **BAXTER Warranties**. BAXTER represents and warrants that, as of the time of delivery to CLIENT in accordance with this Agreement, all Product Produced under this Agreement

(a) conforms to the Kit Component Specifications and/or Kit Specifications (as applicable), (b) has been Produced in accordance with cGMP and all applicable laws and regulations set forth in the Product Master Plan and in accordance with the applicable Certificates of Analysis (provided in accordance with the Quality Agreement) accompanying each Batch of Product, and (c) is not adulterated or misbranded within the meaning of the FD&C Act. BAXTER represents and warrants that it has obtained (or will obtain prior to Producing Product), and will remain in compliance with during the term of this Agreement, all permits, licenses and other authorizations (the "Permits") which are required under federal, state and local laws, rules and regulations applicable to the Production only of Product as specified in the Product Master Plan; provided, however, BAXTER shall have no obligation to obtain Permits relating to the sale, marketing, distribution or use of Products or with respect to the labeling of Products. BAXTER makes no representation or warranty with respect to the sale, marketing, distribution or use of Bulk Conjugated Antibody, other CLIENT Supplied Components or Products or as to printed materials specified by CLIENT or its consignee. BAXTER represents and warrants that (i) no BAXTER employees performing services on behalf of BAXTER under this Agreement have been debarred under Section 306 of the FD&C Act, and (ii) to its knowledge, no persons (other than BAXTER employees) performing services on behalf of BAXTER under this Agreement have been debarred under Section 306 of the FD&C Act.

12.3 **Disclaimer of Warranties.** Except for those warranties set forth in Sections 12.1 and 12.2 of this Agreement, BAXTER makes no warranties, written, oral, express or implied, with respect to Product or the Production of Product. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT HEREBY ARE DISCLAIMED BY BAXTER. NO WARRANTIES OF BAXTER MAY BE CHANGED BY ANY REPRESENTATIVES OF BAXTER. CLIENT accepts Product subject to the terms hereof.

12.4 **CLIENT Warranties**. CLIENT warrants that it has the right to give BAXTER any information provided by CLIENT hereunder, and that BAXTER has the right to use such information for the Production of Product. CLIENT further warrants that the Bulk Conjugated Antibody and other CLIENT Supplied Components provided to BAXTER hereunder will (1) conform to the applicable Kit Component Specifications and/or Kit Specifications and (2) not be adulterated or misbranded within the meaning of the FD&C Act.

12.5 **Disclaimer of Warranties**. Except for those warranties set forth in Section 12.4 of this Agreement, CLIENT makes no warranties, written, oral, express or implied, with respect to Bulk Conjugated Antibody, other CLIENT Supplied Components or Products. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT HEREBY ARE DISCLAIMED BY CLIENT. NO WARRANTIES OF CLIENT MAY BE CHANGED BY ANY REPRESENTATIVES OF CLIENT. BAXTER accepts Bulk Conjugated Antibody and other CLIENT Supplied Components subject to the terms hereof.

Article 13, LIMITATION OF LIABILITY, WAIVER OF SUBROGATION AND REPLACEMENT OF BULK CONJUGATED ANTIBODY AND OTHER CLIENT SUPPLIED COMPONENTS

13.1 **Limitation of Liability.** Under no circumstances shall either party be liable to the other for loss of use or profits or other collateral, special, consequential, incidental or punitive damages, including but not limited to the cost of a recall, except as set forth in Sections 14 and 16, whether such

claims are founded in tort or contract. Without limiting the generality of the foregoing and notwithstanding anything to the contrary herein, the only liability of BAXTER for any

[CONFIDENTIAL TREATMENT REQUESTED] (i) shall exist in the event of a breach hereof by BAXTER **[CONFIDENTIAL TREATMENT REQUESTED]** issued in accordance with the terms of this Agreement; (ii) shall not include **[CONFIDENTIAL TREATMENT REQUESTED]**; (iii) shall be limited to the **[CONFIDENTIAL TREATMENT REQUESTED]** under this Agreement; and (iv) shall in no event **[CONFIDENTIAL TREATMENT REQUESTED]**.

13.2 **Waiver of Subrogation.** All BAXTER Supplied Components and equipment used by BAXTER in the Production of Product, other than those Components and equipment that are specifically stated in this Agreement to be owned by CLIENT (collectively, "BAXTER Property"), shall at all times remain the property of BAXTER and BAXTER assumes risk of loss for the BAXTER Property until delivery of Product to a common carrier as specified under Section 6.1. BAXTER hereby waives any and all rights of recovery against CLIENT and its Affiliates, and against any of their respective directors, officers, employees, agents or representatives, for any loss or damage to BAXTER Property to the extent the loss of damage is covered or could be covered by insurance (whether or not such insurance is described in this Agreement).

13.3 **Replacement of Bulk Conjugated Antibody.** Risk of loss and responsibility for the cost of lost Bulk Conjugated Antibody shall be as follows:

13.3.1 CLIENT shall be solely responsible for the cost of lost Bulk Conjugated Antibody that results from the failure of such Bulk Conjugated Antibody to conform with the applicable Kit Specifications and/or Kit Component Specifications as of the time of the delivery of such Bulk Conjugated Antibody to BAXTER.

13.3.2 CLIENT shall be solely responsible for the cost of lost Bulk Conjugated Antibody that results from the occurrence of a hazard beyond the control of BAXTER (excluding any loss by reason of inefficiencies of Production, storage or handling by or on behalf of BAXTER).

13.3.3 CLIENT shall be solely responsible for the cost of lost Bulk Conjugated Antibody arising in the course of the Production of the Stability/Validation Batches of such Kit Component under this Agreement.

13.3.4 Except as otherwise set forth in Sections 13.3.1, 13.3.2 and 13.3.3, with respect to Products determined to be non-conforming in any calendar year under Section 7.2, (a) CLIENT shall be responsible for the cost of the Bulk Conjugated Antibody necessary to replace the quantity of non-conforming Products, up to the quantity equal to **[CONFIDENTIAL TREATMENT REQUESTED]** of the aggregate conforming Products Produced and delivered to CLIENT in such calendar year; (b) after CLIENT has satisfied its responsibility for the cost of the Bulk Conjugated Antibody under clause (a), BAXTER shall be responsible, and shall reimburse CLIENT, for the replacement cost of the Bulk Conjugated Antibody necessary to replace the quantity of non-conforming Products, in excess of **[CONFIDENTIAL TREATMENT REQUESTED]** and up to **[CONFIDENTIAL TREATMENT REQUESTED]** of the aggregate conforming Products Produced and delivered to CLIENT in such calendar year; and (c) after CLIENT has satisfied its responsibility for the cost of the Bulk Conjugated Antibody under clause (a) and BAXTER has satisfied its responsibility for the replacement cost of the Bulk Conjugated Antibody under clause (b), CLIENT shall be responsible for the cost of the Bulk Conjugated Antibody necessary to replace the quantity of non-conforming Products, in excess of **[CONFIDENTIAL TREATMENT REQUESTED]** of the aggregate conforming Products Produced and delivered to CLIENT in such calendar year.

13.3.5 Except as otherwise set forth in Sections 13.3.1, 13.3.2 and 13.3.3, BAXTER shall be responsible, and shall reimburse CLIENT, for the replacement cost of Bulk Conjugated Antibody lost in the course of Production, storage or handling in any calendar year by or on

behalf of BAXTER to the extent **[CONFIDENTIAL TREATMENT REQUESTED]** of Bulk Conjugated Antibody in such calendar year **[CONFIDENTIAL TREATMENT REQUESTED]**.

13.3.6 For purposes of this Section 13.3 the replacement cost for Bulk Conjugated Antibody shall be **[CONFIDENTIAL TREATMENT REQUESTED]**; provided, however, that upon the first anniversary of the date of this Agreement and on each anniversary thereafter, the replacement cost for Bulk Conjugated Antibody may be adjusted to **[CONFIDENTIAL TREATMENT REQUESTED]**, not to exceed **[CONFIDENTIAL TREATMENT REQUESTED]**. CLIENT shall provide BAXTER with written notice, which notice shall set forth the amount of such adjustment. CLIENT shall provide such notice not later than thirty (30) calendar days following each such anniversary date to be effective, and any adjustment set forth in such notice shall be effective for Bulk Conjugated Antibody provided by CLIENT for Batches which are the subject of Purchase Orders received by BAXTER after such anniversary date.

13.3.7 Notwithstanding anything to the contrary herein, the **[CONFIDENTIAL TREATMENT REQUESTED]** under this Section 13.3 in any **[CONFIDENTIAL TREATMENT REQUESTED]** shall not **[CONFIDENTIAL TREATMENT REQUESTED]**.

13.3.8 BAXTER shall reimburse CLIENT for all amounts owing under Sections 13.3.4 and 13.3.5 within thirty (30) calendar days after the receipt by BAXTER of an invoice from CLIENT therefor.

13.4 **Replacement of Other CLIENT Supplied Components.** Risk of loss and responsibility for the cost of lost CLIENT Supplied Components, other than Bulk Conjugated Antibody, shall be borne solely by CLIENT.

13.5 This Article 13 sets for the entire liability of BAXTER with respect to any and all losses of Bulk Conjugated Antibody or other CLIENT Supplied Components.

Article 14, INDEMNIFICATION

14.1 **CLIENT Indemnification.** CLIENT shall indemnify, defend and hold harmless BAXTER and its Affiliates and any of their respective directors, managers, members, officers, employees, authorized subcontractors and agents (collectively the "Indemnified Parties") from and against any and all liabilities, obligations, penalties, judgments, disbursements of any kind and nature, losses, damages, costs and expenses (including, without limitation, reasonable attorney's fees and costs) incurred as a result of any claims, demands, actions or other proceedings by unaffiliated third parties against an Indemnified Party to the extent arising out of property damage or personal injury (including without limitation death) of third parties (collectively "Claims"), resulting from (a) CLIENT's storage, promotion, labeling, marketing, distribution, use or sale of Bulk Conjugated Antibody, other CLIENT Supplied Components or Products, (b) CLIENT's negligence, omission or willful misconduct, (c) CLIENT's breach of its representations or obligations under this Agreement, (d) the execution, delivery and performance of this Agreement by CLIENT conflicting with any other agreement of CLIENT relating to the production and supply of Product, or (e) any claim that the use, sale, Production, marketing or distribution of Bulk Conjugated Antibody, other CLIENT Supplied Components or Products by BAXTER in accordance with this Agreement, or by CLIENT, violates the patent, trademark, copyright or other proprietary rights of any third party, except to the extent any of the foregoing (a) or (e) is caused **[CONFIDENTIAL TREATMENT REQUESTED]** by the negligence, omission or willful misconduct of the Indemnified Parties or **[CONFIDENTIAL TREATMENT REQUESTED]** by the breach by BAXTER of its representations or obligations under this Agreement.

14.2 **BAXTER Indemnification**. BAXTER shall indemnify, defend and hold harmless CLIENT and its Affiliates and any of their respective directors, officers, employees, and agents from and against any and all Claims resulting **[CONFIDENTIAL TREATMENT REQUESTED]** from the Indemnified Parties' negligence, omission or willful misconduct, or **[CONFIDENTIAL TREATMENT REQUESTED]** from BAXTER's breach of its representations or obligations under this Agreement.

14.3 **Indemnitee Obligations**. A party (the "Indemnitee") which intends to claim indemnification under this Section 14 shall promptly notify the other party (the "Indemnitor") in writing of any claim, demand, action, or other proceeding in respect of which the Indemnitee intends to claim such indemnification; provided, however, that failure to provide such notice within a reasonable period of time shall not relieve the Indemnitor of any of its obligations hereunder except to the extent the Indemnitor is prejudiced by such failure. The Indemnitee shall permit, and shall cause its Affiliates, and their respective directors, officers, employees, subcontractors and agents to permit, the Indemnitor, at its discretion, to settle any such action, claim or other matter, and the Indemnitee agrees to the complete control of such defense or settlement by the Indemnitor. Notwithstanding the foregoing, the Indemnitor shall not enter into any settlement that would adversely affect the Indemnitee's rights hereunder, or impose any obligations on the Indemnitee in addition to those set forth herein, in order for it to exercise such rights, without Indemnitee's prior written consent, which shall not be unreasonably withheld or delayed. No such action, claim or other matter shall be settled without the prior written consent of the Indemnitor, which shall not be unreasonably withheld or delayed. The Indemnitee, its Affiliates, and their respective directors, officers, employees, subcontractors and agents shall reasonably cooperate with the Indemnitor and its legal representatives in the investigation and defense of any claim, demand, action, or other proceeding covered by the indemnification obligations of this Section 14. The Indemnitee shall have the right, but not the obligation, to be represented in such defense by counsel of its own selection and at its own expense.

Article 15, INSURANCE

15.1 **CLIENT Insurance**. CLIENT shall procure and maintain, during the Term of this Agreement and for a period one (1) year beyond the expiration date of the last Product Produced under this Agreement, Commercial General Liability Insurance, including without limitation, Product Liability and Contractual Liability coverage (the "CLIENT Insurance"). The CLIENT Insurance shall cover amounts not less than twenty million dollars ($20,000,000) combined single limit and shall be with an insurance carrier reasonably acceptable to BAXTER. BAXTER shall be named as an additional insured on the CLIENT Insurance and CLIENT promptly shall deliver a certificate of CLIENT Insurance and endorsement of additional insured to BAXTER evidencing such coverage. If CLIENT fails to furnish such certificates or endorsements, or if at any time during the Term of this Agreement BAXTER is notified of the cancellation or lapse of the CLIENT Insurance, and CLIENT fails to rectify the same within ten (10) calendar days after notice from BAXTER, in addition to all other remedies available to BAXTER hereunder, BAXTER, at its option, may obtain the CLIENT Insurance and CLIENT promptly shall reimburse BAXTER for the cost of the same. Any deductible and/or self insurance retention shall be the sole responsibility of CLIENT.

15.2 **BAXTER Insurance.** BAXTER is, and shall during the Term of this Agreement remain, self-insured for the type of liability that could arise under this Agreement, to the same extent and in the same manner as BAXTER maintains self-insurance for similar activities. Notwithstanding the foregoing, except in the case of an assignment of this Agreement by BAXTER to an Affiliate of Baxter Healthcare Corporation, unless CLIENT otherwise reasonably agrees, any permitted assignee or successor in interest to BAXTER under this Agreement (the "Successor") shall

procure and maintain, during the Term of this Agreement and for a period one (1) year beyond the expiration date of the last Product Produced under this Agreement, Commercial General Liability Insurance, including without limitation, Product Liability and Contractual Liability coverage (the "Successor Insurance"). The Successor Insurance shall cover amounts not less than twenty million dollars ($20,000,000) combined single limit and shall be with an insurance carrier reasonably acceptable to CLIENT. CLIENT shall be named as an additional insured on the Successor Insurance and Successor promptly shall deliver a certificate of Successor Insurance and endorsement of additional insured to CLIENT evidencing such coverage. If Successor fails to furnish such certificates or endorsements, or if at any time during the Term of this Agreement CLIENT is notified of the cancellation or lapse of the Successor Insurance, and Successor fails to rectify the same within ten (10) calendar days after notice from CLIENT, in addition to all other remedies available to CLIENT hereunder, CLIENT, at its option, may obtain the Successor Insurance and Successor promptly shall reimburse CLIENT for the cost of the same. Any deductible and/or self insurance retention shall be the sole responsibility of Successor.

Article 16, RECALL OF PRODUCT

16.1 Each party promptly shall notify the other if any Batch of Product is alleged or proven to be the subject of a recall, market withdrawal or correction. CLIENT shall be responsible for coordinating any recall, market withdrawal or field correction of Product, and recall, market withdrawal or correction shall be conducted in accordance with the provisions of the Quality Agreement. CLIENT shall provide BAXTER with a copy of all documents relating to such recall, market withdrawal or field correction. BAXTER shall cooperate with CLIENT (including providing CLIENT with all data, information and documents requested by CLIENT) in connection with such recall, market withdrawal or field correction, at CLIENT's expense. Unless

such recall is **[CONFIDENTIAL TREATMENT REQUESTED]** , CLIENT shall be responsible for all of the costs and expenses of such recall, market withdrawal or field correction. In the event a recall, market withdrawal or field correction is necessary because both (i) BAXTER has delivered a non-conforming Product to CLIENT, and (ii) such non-conformity is **[CONFIDENTIAL TREATMENT REQUESTED]**, BAXTER will bear all reasonable costs associated with such recall, market withdrawal or field correction (including but not limited to costs associated with receiving and administering the recalled Product and notification of the recall to those persons whom

CLIENT deems appropriate) in accordance with and up to a cumulative total maximum amount set forth in the chart below:

	Recall Class		
Number of Consignees	**I**	**II**	**III**
[CONFIDENTIAL TREATMENT REQUESTED]	**[CONFIDENTIAL TREATMENT REQUESTED]**	**[CONFIDENTIAL TREATMENT REQUESTED]**	**[CONFIDENTIAL TREATMENT REQUESTED]**
[CONFIDENTIAL TREATMENT REQUESTED]	**[CONFIDENTIAL TREATMENT REQUESTED]**	**[CONFIDENTIAL TREATMENT REQUESTED]**	**[CONFIDENTIAL TREATMENT REQUESTED]**
[CONFIDENTIAL TREATMENT REQUESTED]	**[CONFIDENTIAL TREATMENT REQUESTED]**	**[CONFIDENTIAL TREATMENT REQUESTED]**	**[CONFIDENTIAL TREATMENT REQUESTED]**
[CONFIDENTIAL TREATMENT REQUESTED]	**[CONFIDENTIAL TREATMENT REQUESTED]**	**[CONFIDENTIAL TREATMENT REQUESTED]**	**[CONFIDENTIAL TREATMENT REQUESTED]**
[CONFIDENTIAL TREATMENT REQUESTED]	**[CONFIDENTIAL TREATMENT REQUESTED]**	**[CONFIDENTIAL TREATMENT REQUESTED]**	**[CONFIDENTIAL TREATMENT REQUESTED]**

In the event a recall, market withdrawal or field correction is necessary because both (i) BAXTER has delivered a non-conforming Product to CLIENT, and (ii) such non-conformity is due **[CONFIDENTIAL TREATMENT REQUESTED]**, or **[CONFIDENTIAL TREATMENT REQUESTED]** BAXTER's breach of its warranties or obligations under this Agreement, BAXTER additionally will be responsible for the replacement cost of all returned Kits which are the subject of such recall, market withdrawal or field correction **[CONFIDENTIAL TREATMENT REQUESTED]**.

16.2 This Article 16 sets forth the entire liability of BAXTER in the event of a recall, market withdrawal, or field correction.

Article 17, INTELLECTUAL PROPERTY

17.1 **Existing Intellectual Property.** Except as the parties may otherwise expressly agree in writing, each party shall continue to own its existing patents, trademarks, copyrights, trade secrets and other intellectual property, without conferring any interests therein on the other party. Without limiting the generality of the preceding sentence, CLIENT shall retain all right, title and interest arising under the United States Patent Act, the United States Trademark Act, the United States Copyright Act and all other applicable United States and foreign laws, rules and regulations relating to Product, Bulk Conjugated Antibody, CLIENT Supplied Components, labeling and trademarks associated therewith (collectively, "CLIENT's Intellectual Property"). Neither BAXTER nor any third party shall acquire any right, title or interest in CLIENT's Intellectual Property by virtue of this Agreement or otherwise, except to the extent expressly provided herein.

17.2 **Individually Owned Inventions.** Except as the parties may otherwise agree in writing, all Inventions (as defined herein) which are conceived, reduced to practice, or created by a party in the course of performing its obligations under this Agreement shall be solely owned and subject to use and exploitation by the inventing party without a duty to account to the other party. For purposes of this Agreement, "Invention" shall mean any invention, innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable. BAXTER

hereby grants to CLIENT a royalty-free, non-exclusive, worldwide license (with the right to grant sublicenses) under all patent rights and other intellectual property rights covering Inventions which are conceived, reduced to practice, or created by BAXTER in the course of performing its obligations under this Agreement and which relate directly to the Bulk Conjugated Antibody or other CLIENT Supplied Components.

17.3 **Jointly Owned Inventions.** All Inventions which are conceived, reduced to practice, or created jointly by the parties and/or their respective agents (i.e., employees or agents who would be or are properly named as co-inventors under the laws of the United States on any patent application claiming any such Invention) in the course of the performance of this Agreement shall be owned jointly by the parties. Each party shall have full rights, subject to the provisions of this Agreement, to freely exploit, transfer, license or encumber its rights in any such jointly-owned Inventions and the patent rights and other intellectual property rights therein without the consent of, or payment or accounting to, the other party. The parties shall share equally in the cost of mutually agreed patent filings with respect to all such jointly owned Inventions. The decision to file for patent coverage on jointly owned Inventions shall be mutually agreed upon, and the Parties shall select a mutually acceptable patent counsel to file and prosecute patent applications based on such joint Inventions.

17.4 **Disclaimer.** Except as otherwise expressly provided herein, nothing contained in this Agreement shall be construed or interpreted, either expressly or by implication, estoppel or otherwise, as: (i) a grant, transfer or other conveyance by either party to the other of any right, title, license or other interest of any kind in any of its Inventions or intellectual property, (ii) creating an obligation on the part of either party to make any such grant,

transfer or other conveyance or (iii) requiring either party to participate with the other party in any cooperative development program or project of any kind or to continue with any such program or project.

17.5 **Rights in IP**. The party owning any solely-owned Invention shall have the world wide right to control the drafting, filing, prosecution and maintenance of patents covering such solely-owned Invention, including decisions about the countries in which to file patent applications. Patent costs associated with the patent activities described in this Section shall be borne by the sole owner. Each party will cooperate with the other party, at the sole cost of the other party, in the filing and prosecution of patent applications covering Inventions solely owned by the other party. Such cooperation will include, but not be limited to, furnishing supporting data and affidavits for the prosecution of patent applications and completing and signing forms needed for the prosecution, assignment and maintenance of patent applications.

17.6 **Confidentiality of IP**. The protection of each party's Confidential Information is described in Section 18. Any disclosure of information by one party to the other under the provisions of this Section 17 shall be treated as the disclosing party's Confidential Information under this Agreement (subject to the exceptions set forth in Section 1 of the Confidentiality Agreement). It shall be the responsibility of the party preparing a patent application to obtain the written permission of the other party to use or disclose the other party's Confidential Information in the patent application before the application is filed and for other disclosures made during the prosecution of the patent application.

Article 18, CONFIDENTIAL INFORMATION, NONDISCLOSURE AND PUBLICITY

18.1 **Confidentiality.** It is contemplated that in the course of the performance of this Agreement each party may, from time to time, disclose Confidential Information to the other. In accordance with the terms and conditions of the Confidentiality Agreement, each party shall maintain in confidence the Confidential Information of the other party, shall not use or grant the use of the Confidential Information of the other party except as expressly permitted hereby, and

shall not disclose the Confidential Information of the other party except on a need-to-know basis to such party's directors, officers and employees to the extent such disclosure is reasonably necessary in connection with such party's activities as expressly authorized by this Agreement.

18.2 **Prior Confidentiality Agreement.** The Confidentiality Agreement, by reference, is made a part hereof as though fully set forth herein. The Parties acknowledge that BAXTER is the successor by assignment to Baxter Healthcare Corporation under the Confidentiality Agreement, and BAXTER shall be bound by the terms of the Confidentiality Agreement to the same extent as if BAXTER were an original signatory thereto. The Confidentiality Agreement is amended (a) to govern all disclosures by the parties hereunder, and (b) to extend the term thereof (and the term of the obligations of the parties thereunder) until the later of (i) five years after the date of this Agreement, and (ii) seven (7) years after the effective date of the Confidentiality Agreement; provided, however, that Confidential Information which constitutes a trade secret of a party shall be kept confidential indefinitely, subject to the limitations set forth in Sections 18.4 through 18.6.

18.3 **Third Party Disclosure**. Either party may disclose Confidential Information of the disclosing party to those Affiliates, agents and consultants who need to know such information to accomplish the purposes of this Agreement (collectively, "Permitted Recipients"); provided that such Permitted Recipients are bound to maintain such Confidential Information in confidence to the same extent as set forth in Section 18.1.

18.4 **Litigation and Governmental Disclosure**. Each party may disclose Confidential Information hereunder to the extent such disclosure is reasonably necessary for prosecuting or defending litigation, complying with applicable laws, governmental regulations or court orders, or conducting pre-clinical or clinical trials, provided that if a party is required by law or regulation to make any such disclosure of the other party's Confidential Information it will, except where impractical for necessary disclosures, for example in the event of a medical emergency, give reasonable advance notice to the other party of such disclosure requirement and will use good faith efforts to assist such other party to secure a protective order or confidential treatment of such Confidential Information required to be disclosed.

18.5 **Limitation of Disclosure**. The parties agree that, except as otherwise may be required by applicable laws, regulations, rules or orders, including without limitation the rules and regulations promulgated by the United States Securities and Exchange Commission, and except as may be authorized in Section 18.4, no information concerning this Agreement and the transactions contemplated herein shall be made public by either party without the prior written consent of the other.

18.6 **Publicity and SEC Filings.** The parties agree that the public announcement of the execution of this Agreement shall only be by one or more press releases mutually agreed to by the parties. The failure of a party to return a draft of a press release with its proposed amendments or modifications to such press release to the other party within five (5) calendar days of such party's receipt of such press release shall be deemed as such party's approval of such press release as received by such party. Each party agrees that it shall cooperate fully and in a timely manner with the other with respect to all disclosures to the Securities and Exchange Commission and any other governmental or regulatory agencies, including requests for confidential treatment of Confidential Information of either party included in any such disclosure.

Article 19, FORCE MAJEURE

19.1 Any delay in the performance of any of the duties or obligations of either party hereto (except the payment of money), to the extent caused by an event outside the affected party's reasonable control, shall not be considered a breach of this Agreement, and unless provided to the contrary herein, the time required for performance shall be extended for a period equal to the

period of such delay. Such events shall include without limitation, acts of God; acts of public enemies; insurrections; riots; injunctions; embargoes; labor disputes, including strikes, lockouts, job actions, or boycotts; fires; explosions; floods; shortages of material or energy; delays in the delivery of raw materials; acts or orders of any government or agency thereof or other unforeseeable causes beyond the reasonable control and without the fault or negligence of the party so affected. The party so affected shall give prompt written notice to the other party of such cause and a good faith estimate of the continuing effect of the force majeure condition and duration of the affected party's nonperformance, and shall take whatever reasonable steps are appropriate to relieve the effect of such causes as rapidly as possible. If the period of nonperformance by BAXTER because of force majeure conditions

exceeds ninety (90) calendar days, CLIENT may terminate this Agreement by written notice to BAXTER. If the period of nonperformance by CLIENT because of force majeure conditions exceeds ninety (90) calendar days, BAXTER may terminate this Agreement by written notice to CLIENT.

Article 20, NOTICES

20.1 All notices hereunder shall be delivered by facsimile (confirmed by overnight delivery), or by overnight delivery with a reputable overnight delivery service, to the following address of the respective parties:

If to BAXTER: Baxter Pharmaceutical Solutions LLC
927 South Curry Pike
Bloomington, Indiana 47403
Attn: Alisa K. Wright, Vice President of Business Affairs

Telefax No. 812-332-3079
Telephone No. 812-333-0887

With a copy to: Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015-4633
Attn: General Counsel

Telefax No. (847) 948-2450
Telephone No. (847) 948-2600

If to CLIENT: IDEC Pharmaceuticals Corporation
3030 Callan Road
San Diego, California 92121
Attn: President

Telefax No. (858) 431-8755
Telephone No. (858) 431-8500

With a copy to: IDEC Pharmaceuticals Corporation
3030 Callan Road
San Diego, California 92121
Attn: Company Secretary

Telefax No. (858) 431-8755
Telephone No. (858) 431-8500

Notices shall be effective on the day of receipt. A party may change its address listed above by notice to the other party given in accordance with this section.

Article 21, APPLICABLE LAW

21.1 This Agreement is being delivered and executed in the State of Indiana. In any action brought regarding the validity, construction and enforcement of this Agreement, it shall be governed in all respects by the laws of the State of Indiana, without regard to the principals of conflicts of laws.

Article 22, ASSIGNMENT

22.1 Neither party shall assign this Agreement or any part hereof or any interest herein to any third party (or use any subcontractor) without the written approval of the other party. In addition, no consent shall be required (a) in the case of an assignment by BAXTER to an Affiliate of Baxter Healthcare Corporation, or (b) in the case of a transaction involving the merger, consolidation, change in control or sale of all or substantially all of the assets of the party seeking such assignment or transfer and such transaction relates to the business covered by this Agreement and the resulting entity assumes all of the obligations under this Agreement. No assignment shall be valid unless the permitted assignee(s) assumes all obligations of its assignor under this Agreement. No assignment shall relieve any party of responsibility for the performance of its obligations hereunder. Any purported assignment in violation of this section shall be void.

Article 23, ALLIANCES

23.1 Notwithstanding anything to the contrary herein, BAXTER agrees that CLIENT shall have the right to enter into alliances with third parties who may engage in joint (with CLIENT) or unilateral marketing and promoting of Product or any combination of products that includes Product.

Article 24, TAXES

24.1 CLIENT shall pay all national, state, municipal or other sales, use, excise, import, property, value added, or other similar taxes, assessments or tariffs assessed upon or levied against the sale of Product to CLIENT pursuant to this Agreement or the sale or distribution of Product by CLIENT (or at CLIENT's sole expense, defend against the imposition of such taxes and expenses). BAXTER shall notify CLIENT of any such taxes that any governmental authority is seeking to collect from BAXTER, and CLIENT may assume the defense thereof in BAXTER's name, if necessary, and BAXTER agrees to fully cooperate in such defense to the extent of the capacity of BAXTER, at CLIENT's expense. BAXTER shall pay all national, state, municipal or other taxes on the income resulting from the sale by BAXTER of Product to CLIENT under this Agreement, including but not limited to, gross income, adjusted gross income, supplemental net income, gross receipts, excess profit taxes, or other similar taxes.

Article 25, SUCCESSORS AND ASSIGNS

25.1 This Agreement shall be binding upon and shall inure to the benefit of the parties hereto, their successors and permitted assigns.

Article 26, ENTIRE AGREEMENT

26.1 This Agreement, together with the Product Master Plan and the Confidentiality Agreement, constitutes the entire agreement between the parties concerning the subject matter hereof and supersedes all written or oral prior agreements, understandings and representations with respect thereto.

Article 27, SEVERABILITY

27.1 If any term or provision of this Agreement shall for any reason be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other term or provision hereof, and this Agreement shall be interpreted and construed as if such term or provision, to the extent the same shall have been held to be invalid, illegal or unenforceable, had never been contained herein.

Article 28, WAIVER AND MODIFICATION OF AGREEMENT

28.1 No waiver or modification of any of the terms of this Agreement (including the Exhibits hereto), the Product Master Plan or the Confidentiality Agreement, shall be valid unless in writing and signed by an authorized representative of each party. Failure by either party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by either party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

Article 29, INDEPENDENT CONTRACTORS

29.1 BAXTER and CLIENT are acting under this Agreement as independent contractors and neither shall be considered an agent of, or joint venturer with, the other.

IN WITNESS WHEREOF, the parties have caused this Commercial Supply Agreement to be signed by their duly authorized representatives as of the Effective Date written above.

"BAXTER"	**"CLIENT"**
BAXTER PHARMACEUTICAL SOLUTIONS LLC	**IDEC PHARMACEUTICALS CORPORATION**
By: /s/ ALISA K. WRIGHT	By: /s/ WILLIAM ROHN
Name: Alisa Wright	Name: William Rohn
Title: Vice President, Business Affairs	Title: President and COO

Exhibit 1

Cancellation Fees

Timing	**Cancellation Fee**
Cancellation of any batch within **[CONFIDENTIAL TREATMENT REQUESTED]** of the scheduled fill date	**[CONFIDENTIAL TREATMENT REQUESTED]**
Cancellation of any batch within **[CONFIDENTIAL TREATMENT REQUESTED]** of the scheduled fill date	**[CONFIDENTIAL TREATMENT REQUESTED]**
Cancellation of any batch within **[CONFIDENTIAL TREATMENT REQUESTED]** of the scheduled fill date	**[CONFIDENTIAL TREATMENT REQUESTED]**

Exhibit 2

Product Specifications for Release Testing of Product Kits

Labeled and released components will be assembled into the Zevalin radiolabeling kit (111-Indium or 90-Yttrium).

Each kit component (2B8-MX-DTPA Conjugated Antibody, 50 mM Sodium Acetate, Formulation Buffer and Reaction vial) is individually tested and released based upon pre-determined release specifications.

Kits are tested for adequacy of the packaging materials (labels, tray, package insert, overlabels and carton), printing of lot number and expiration date, and identity of the kit components is verified using the following methods:

[CONFIDENTIAL TREATMENT REQUESTED]	**[CONFIDENTIAL TREATMENT REQUESTED]**	**[CONFIDENTIAL TREATMENT REQUESTED]**
[CONFIDENTIAL TREATMENT REQUESTED]	**[CONFIDENTIAL TREATMENT REQUESTED]**	**[CONFIDENTIAL TREATMENT REQUESTED]**
[CONFIDENTIAL TREATMENT REQUESTED]	**[CONFIDENTIAL TREATMENT REQUESTED]**	**[CONFIDENTIAL TREATMENT REQUESTED]**
[CONFIDENTIAL TREATMENT REQUESTED]	**[CONFIDENTIAL TREATMENT REQUESTED]**	**[CONFIDENTIAL TREATMENT REQUESTED]**

[CONFIDENTIAL TREATMENT REQUESTED]

Exhibit 3

Kit Component Specifications
for Release Testing of 2B8-MX-DTPA Conjugated Antibody

	Test Name	Specification
Safety Tests/ Process Related Impurities	Pre-filtration Bioburden	**[CONFIDENTIAL TREATMENT REQUESTED]**
	Particulate Matter	**[CONFIDENTIAL TREATMENT REQUESTED]**
	Bacterial Endotoxins	**[CONFIDENTIAL TREATMENT REQUESTED]**
	Sterility (Bulk)	**[CONFIDENTIAL TREATMENT REQUESTED]**
	Sterility (Finished Product)	**[CONFIDENTIAL TREATMENT REQUESTED]**
Identity	Potency Tests	**[CONFIDENTIAL TREATMENT REQUESTED]**
Strength	Protein Concentration	**[CONFIDENTIAL TREATMENT REQUESTED]**
Quality	Appearance, Color, Clarity	**[CONFIDENTIAL TREATMENT REQUESTED]**
Potency	CD20 Binding Activity	**[CONFIDENTIAL TREATMENT REQUESTED]**
	Radiochemical Purity	**[CONFIDENTIAL TREATMENT REQUESTED]**
Purity/ Product Related Impurities	Percent Monomer by SEC-HPLC	**[CONFIDENTIAL TREATMENT REQUESTED]**
	Chelates per Antibody	**[CONFIDENTIAL TREATMENT REQUESTED]**
	SDS-PAGE, Silver Stain	**[CONFIDENTIAL TREATMENT REQUESTED]**
General Tests	Fill Volume	**[CONFIDENTIAL TREATMENT REQUESTED]**
	pH Determination	**[CONFIDENTIAL TREATMENT REQUESTED]**

[CONFIDENTIAL TREATMENT REQUESTED]

Kit Component Specifications
for Release Testing of 50 mM Sodium Acetate

	Test Name	Specification
Safety Tests/ Process Related Impurities	Pre-filtration Bioburden	**[CONFIDENTIAL TREATMENT REQUESTED]**
	Particulate Matter	**[CONFIDENTIAL TREATMENT**

		REQUESTED]
	Bacterial Endotoxins	**[CONFIDENTIAL TREATMENT REQUESTED]**
	Sterility (Bulk)	**[CONFIDENTIAL TREATMENT REQUESTED]**
	Sterility (Finished Product)	**[CONFIDENTIAL TREATMENT REQUESTED]**
Identity	Sodium Identification	**[CONFIDENTIAL TREATMENT REQUESTED]**
	Acetate Identification	**[CONFIDENTIAL TREATMENT REQUESTED]**
Strength	Sodium Acetate Concentration	**[CONFIDENTIAL TREATMENT REQUESTED]**
Quality	Appearance, Color, Clarity	**[CONFIDENTIAL TREATMENT REQUESTED]**
General Tests	Fill Volume	**[CONFIDENTIAL TREATMENT REQUESTED]**

Kit Component Specifications
for Release Testing of Formulation Buffer

	Test Name	Specification
Safety Tests/ Process Related Impurities	Pre-filtration Bioburden	**[CONFIDENTIAL TREATMENT REQUESTED]**
	Particulate Matter	**[CONFIDENTIAL TREATMENT REQUESTED]**
	Bacterial Endotoxins	**[CONFIDENTIAL TREATMENT REQUESTED]**
	Sterility (Bulk)	**[CONFIDENTIAL TREATMENT REQUESTED]**
	Sterility (Finished Product)	**[CONFIDENTIAL TREATMENT REQUESTED]**
Identity	HSA Identification	**[CONFIDENTIAL TREATMENT REQUESTED]**
Strength	HSA Concentration	**[CONFIDENTIAL TREATMENT REQUESTED]**
	DTPA Concentration	**[CONFIDENTIAL TREATMENT REQUESTED]**
Quality	Appearance, Color, Clarity	**[CONFIDENTIAL TREATMENT REQUESTED]**
General Tests	Fill Volume	**[CONFIDENTIAL TREATMENT REQUESTED]**
	pH Determination	**[CONFIDENTIAL TREATMENT REQUESTED]**

[CONFIDENTIAL TREATMENT REQUESTED]

Kit Component Specifications
for Release Testing of Reaction Vial

	Test Name	Specification
Safety Tests/ Process Related Impurities	Particulate Matter	**[CONFIDENTIAL TREATMENT REQUESTED]**
	Bacterial Endotoxins	**[CONFIDENTIAL TREATMENT REQUESTED]**
	Sterility (Finished Product)	**[CONFIDENTIAL TREATMENT REQUESTED]**
Quality	Appearance, Color, Clarity	**[CONFIDENTIAL TREATMENT REQUESTED]**

[CONFIDENTIAL TREATMENT REQUESTED]

Exhibit 4

[Reserved]

Exhibit 5

Regulatory Authorities and Countries

Regulatory Authority	Country of Distribution
FDA	United States
EMEA	European Union
HPB	Canada

Exhibit 6

[CONFIDENTIAL TREATMENT REQUESTED]

Exhibit 7

Pricing

A. Production

Filling	Batch Size	Theoretical Yield*	Price/Batch**
Conjugated Antibody	**[CONFIDENTIAL TREATMENT REQUESTED]**	**[CONFIDENTIAL TREATMENT REQUESTED]**	**[CONFIDENTIAL TREATMENT REQUESTED]**
Sodium Acetate	**[CONFIDENTIAL TREATMENT REQUESTED]**	**[CONFIDENTIAL TREATMENT REQUESTED]**	**[CONFIDENTIAL TREATMENT REQUESTED]**
Formulation Buffer	**[CONFIDENTIAL TREATMENT REQUESTED]**	**[CONFIDENTIAL TREATMENT REQUESTED]**	**[CONFIDENTIAL TREATMENT REQUESTED]**
Reaction Vial	N/A	**[CONFIDENTIAL TREATMENT REQUESTED]**	**[CONFIDENTIAL TREATMENT REQUESTED]**

* **[CONFIDENTIAL TREATMENT REQUESTED].**

** For Batches manufactured post Stability/Validation Batches

Kitting	Price/Kit***
500—1,000 kits	**[CONFIDENTIAL TREATMENT REQUESTED]**
1,001—2,500 kits	**[CONFIDENTIAL TREATMENT REQUESTED]**
2,501—5,000 kits	**[CONFIDENTIAL TREATMENT REQUESTED]**

*** **[CONFIDENTIAL TREATMENT REQUESTED].**

B. Services

Storage of Bulk Conjugated Antibody and Other Client Supplied Components in excess of a **[CONFIDENTIAL TREATMENT REQUESTED]**	**[CONFIDENTIAL TREATMENT REQUESTED]**
Storage of Kit Component or Kit in **[CONFIDENTIAL TREATMENT REQUESTED]**	**[CONFIDENTIAL TREATMENT REQUESTED]**

Exhibit 8

INTERCOMPANY QUALITY AGREEMENT

IDEC Pharmaceuticals Corporation
San Diego, California 92121
(hereafter called "IDEC")

Approved by: /s/ MICHAEL E. WIEKE Date: 6/14/02

Vice President, Quality, IDEC

AND

Baxter Pharmaceutical Solutions LLC
Bloomington, Indiana 47402
(hereafter called "BAXTER")

Approved by: /s/ [ILLEGIBLE] Date: 6/14/02

Director, Quality, BAXTER

The PRODUCT Listed in the Supply Agreement
(hereafter called "the PRODUCT")
are subject to the following conditions:

History of Revisions

Revision Version	Revision Date	Revised By	Description
0.0	041902	T. Ryskamp	Initial

TABLE OF CONTENTS

1. *QUALITY AGREEMENT*

1.1 Purpose

1.1.1. This agreement defines the roles and responsibilities for BAXTER Quality Operations when providing services for IDEC.

1.1.2. This agreement also defines how BAXTER Quality Operations and IDEC Quality Department will interact with each other.

1.1.3. For purposes of the BLA filing for the PRODUCT described in the Supply Agreement, IDEC is identified as the "manufacturer," the legal entity in the license application assuming responsibility for compliance at BAXTER per 21 CFR 600.3 (t).

1.2 Relationship to Supply Agreement

1.2.1. This agreement shall be incorporated within and constitute a part of the Supply Agreement between the two companies.

1.2.2. In the event of a conflict between any of the provisions of the Quality Agreement and the Supply Agreement, the provisions of the Supply Agreement shall govern.

1.2.3. The definitions set forth in the Supply Agreement are applicable to this Quality Agreement unless otherwise specified.

2. *PRODUCT*

2.1 The PRODUCT prepared for IDEC by BAXTER are described in the Supply Agreement.

3. *ADMINISTRATIVE INFORMATION*

3.1 IDEC contact names: See Appendix I

3.2 BAXTER contact names: See Appendix I

3.3 Emergency contact names and numbers, during and outside working hours:

Michael Wiebe, Ph.D.
Vice President, Quality, IDEC
Work: 858-431-8765

Connie Degen
Director, Quality, BAXTER
Work: 812-333-0887

4. *DURATION OF AGREEMENT*

The agreement will expire with termination of the Supply Agreement. The agreement can be modified as needed with the written approval of both parties.

5. *MANUFACTURING cGMP COMPLIANCE*

5.1 General

5.1.1. The manufacturing operations for the PRODUCT to be performed by BAXTER are defined in the Supply Agreement.

5.1.2. The manufacturing schemes for PRODUCT are generally described in the Product Master Plan. IDEC shall advise BAXTER as soon as commercially reasonable of any proposed material change to the manufacturing schemes that are made and filed on the BLA or license for the PRODUCT. Implementation of these changes will be handled as outlined by

Change Management (see section 10). BAXTER shall advise IDEC of any proposed material change to the manufacturing schemes that are made and filed on the BLA or license for the PRODUCT. Any proposed changes shall be approved by IDEC prior to their implementation

5.2 Premises

5.2.1. BAXTER will manufacture the PRODUCT at the Bloomington, Indiana site. The floor plan of the manufacturing area and corresponding room classifications is available for review during annual audits of the facility.

5.2.2. The premises and equipment used to manufacture the PRODUCT will be maintained according to current domestic and EU regulatory requirements and in accordance with the batch records used to manufacture the PRODUCT, which are approved by IDEC. The production of the PRODUCT will be conducted in a suitably controlled environment and such facilities will be regularly monitored for parameters critical to the process to demonstrate compliance with cGMP guidelines and the Product Master Plan, including the Master Batch Records and Project Plans.

A list of the standard operating procedures that are used to manufacture PRODUCT are shown in Appendix VI.

5.2.3. BAXTER will not sub-contract any portion of the manufacturing operations without prior written approval of IDEC

5.2.4. BAXTER will maintain controlled access to the premises. Baxter will maintain all IDEC confidential information as defined in the Confidentiality Agreement and the Supply Agreement.

5.3 cGMP

5.3.1. The principles detailed in the US Current Good Manufacturing Practices (21 CFR 200, 211, and 600), the "Rules Governing Medicinal Product in The European Community—Volume IV Good Manufacturing Practice for Medicinal Products," and/or "Cooperative Manufacturing Arrangements for Licensed Biologics" FDA-CBER will cover the standards of manufacture of the PRODUCT. cGMP guidelines will cover the standards of quality assurance for the PRODUCT, including any product license requirements as communicated to BAXTER by IDEC.

5.4 Materials

5.4.1. BAXTER will use only chemical materials, packaging, and labeling components approved by IDEC and sampled, tested and stored in accordance with the documentation reviewed by IDEC.

5.4.2. Materials procured by BAXTER

5.4.2.1. BAXTER is responsible for ensuring that all materials and components procured by BAXTER for use in the PRODUCT are in full compliance with the specifications approved by IDEC. Raw materials are given an expiration date upon the satisfactory completion of all initial testing. Testing will be performed at defined time intervals to ensure the chemical and physical stability of the raw materials for the duration of their useful shelf life. BAXTER is responsible for ensuring that all materials are used correctly and, are appropriately tested upon receipt as well as for holding the relevant Certificate of Analysis for the materials.

5.4.3. Materials Provided by IDEC for BAXTER

5.4.3.1. IDEC is responsible for ensuring that the material(s) referenced in the Supply Agreement that are provided by IDEC for use in the PRODUCT are in full compliance with the specifications registered. IDEC will provide BAXTER a Certificate of Analysis for Filling for the conjugated antibody component (bulk monoclonal antibody) and the non-biological components. A list of the specific tests included on the Certificate of Analysis for Filling is illustrated in Appendix III, IV, and V.

5.5 Master Production Records

5.5.1. BAXTER may transcribe the manufacturing information into its own format and will obtain written approval from IDEC for each document version before manufacturing. However, agreed upon changes to documentation will be handled as outlined by Change Management (see section 10).

5.6 Standard Operating Procedures

5.6.1. BAXTER is responsible for maintaining any SOPs required to manufacture, test, and store the PRODUCT at BAXTER and to support cGMPs.

5.7 Batch Numbers

5.7.1. The BAXTER manufacturing batch numbering system begins with the number 800000, with the first batch number assigned as 800001. The batch numbers are then issued sequentially from that point at the time the batch record is issued, independent of specific drug product or fill date. Internal or external sublots may be assigned for process segregations of drug product during processing. Internal (temporary) sublotting occurs when a given batch is segregated during processing and rejoined as one lot at the conclusion of a process. These sublots are assigned a seventh place numeric designator (800001 becomes 8000011). External (permanent) sublotting occurs when a batch is permanently segregated. These batch numbers are assigned a seventh place alpha designator (800001 becomes 800001A). The BAXTER packaging batch numbering system appends a sequential alpha character to the existing manufacturing batch number for each packaging sublot produced.

5.7.2. BAXTER will use internally and as a reference, BAXTER's batch number, but IDEC's lot number will be printed on labels and cartons, and both numbers referenced in intercompany documentation.

5.8 Dates of Manufacture and Expiration

5.8.1. Date of Manufacture—The date of the initiation of sterile filtration for filling of the Conjugated Antibody, Formulation Buffer and Sodium Acetate components, and the date of the initiation of stoppering for the Reaction Vial component determines the date of manufacture of PRODUCT.

5.8.2. Expiration Date—BAXTER will calculate the expiry date from the Date of Manufacture (5.8.1) using the shelf life approved by the FDA or other regulatory agency as appropriate as communicated by IDEC to BAXTER. The expiration date will be the last day of the month computed above.

5.9 Manufacturing and Equipment Data

5.9.1. BAXTER is responsible for keeping records of equipment usage (previous product produced in non-dedicated equipment), cleaning, and any maintenance/calibration performed.

5.9.2. BAXTER is responsible for labeling all PRODUCT dedicated equipment and storing this equipment appropriately to prevent its use for other product(s).

5.10 Storage and Shipment

5.10.1. Storage—BAXTER will store the PRODUCT under conditions approved by IDEC. BAXTER will ensure that during storage before shipping of the PRODUCT there is no possibility of interference, theft, product contamination, or admixture with any other materials. IDEC will provide details of any labeling requirements and container sealing and integrity.

5.10.2. Packaging and Labeling for Transit—The PRODUCT will be suitably packaged and labeled for transit. IDEC is responsible for the configuration of the shipping containers. PRODUCT designated for shipment outside of the United States shall be labeled in accordance with Applicable Laws and Regulations.

5.10.3. Mixing of PRODUCT—BAXTER will maintain proper segregation of the PRODUCT according to systems reviewed by IDEC. Different lots of a single PRODUCT or different product types will not be mixed on a pallet.

5.10.4. Shipment of PRODUCT—IDEC will authorize BAXTER to ship PRODUCT upon submission of a BAXTER shipment request form. Only released, finished, labeled PRODUCT will be shipped by BAXTER to the United States designated distribution center identified by IDEC, except for PRODUCT samples required for testing. BAXTER will ship (in conformity with such methods and procedures as are established by IDEC and BAXTER) finished, unlabeled PRODUCT to IDEC's licensee(s) upon request by IDEC. Any shipment of unapproved PRODUCT (other than test samples) or PRODUCT under Quarantine from BAXTER requires prior written authorization by IDEC and BAXTER Quality. Requests for shipment of unlabeled vials to Europe will include information defining quantity and bulk packaging and labeling instructions.

5.10.5. BAXTER shall ship PRODUCT to designated sites following procedures approved by IDEC which conform to the Supply Agreement and the biologics license for the PRODUCT using shipping containers and temperature controls/recorders validated or otherwise qualified and authorized by IDEC.

6. *QUALITY CONTROL*

6.1 General

6.1.1. The testing activities for the PRODUCT that are to be performed by BAXTER should be in accordance with the Specifications in the Supply Agreement. In general, BAXTER is responsible for performing tests and assays directly related to the filling operation; i.e., identity testing, uniformity by unit weight variation, pre-filtration bioburden, bulk and finished PRODUCT sterility, etc., or as otherwise determined by agreement between IDEC and BAXTER in the Product Master Plan. In general, IDEC is responsible for PRODUCT release and stability assays related to the conjugated antibody component and non-biological PRODUCT kit components. BAXTER is responsible for submitting unlabeled bulk and finished PRODUCT test samples to a mutually agreed upon third-party contract laboratory such as Lancaster Laboratories for sterility testing. BAXTER will not sub-contract any analytical testing without the prior approval of IDEC.

6.2 Materials supplied by BAXTER

6.2.1. Quality control of materials supplied by BAXTER will be undertaken by BAXTER. BAXTER will notify IDEC of any investigations related to the storage and handling of any raw materials used in the manufacturing process for the PRODUCT.

6.3 In-Process and Finished PRODUCT Testing

6.3.1. BAXTER will perform pre-filtration bioburden, bulk and finished PRODUCT sterility, and uniformity by unit weight variation testing as directed by IDEC using approved

specifications and validated, or otherwise qualified, methods of analysis. BAXTER shall provide bulk and unlabeled finished PRODUCT sterility test samples to Lancaster Laboratories or other mutually approved contract laboratory and shall review and approve sterility test results from said laboratory.

6.3.2. A Certificate of Compliance and a Certificate of Analysis confirming that the PRODUCT has been manufactured, packaged and tested, and meets the requirements of the Master Batch Record and appropriate approved specifications will be issued by the BAXTER Quality Unit. The current release documentation information can be found in Appendix II.

6.3.3. IDEC or its licensees may perform testing to confirm or supplement the BAXTER data. IDEC may perform confirmatory testing during the initial term of the Supply Agreement to validate the BAXTER data. Periodically thereafter, IDEC may test material to confirm the BAXTER data. Dispute resolutions of conflicting test data will be handled per Section 9.

6.3.4. Shipping of samples to IDEC or the third party contract laboratory will be per a validated or otherwise qualified shipping method, provided by IDEC.

6.4 Retain Samples

6.4.1. IDEC is responsible for storing retain samples of formulated bulk and finished PRODUCT per 21 CFR 211.170.

6.5 Routine Stability Program

6.5.1. IDEC is responsible for maintaining a routine stability-testing program for the PRODUCT. BAXTER will label and ship samples of PRODUCT to IDEC for placement on the stability program, as directed by IDEC by submission of a sample request form. IDEC is responsible for identifying the batch number and quantity of samples for each lot to be shipped.

6.6 Out-of-Specification (OOS) Investigations

6.6.1. BAXTER is responsible for investigating any testing performed by BAXTER that fails to meet specifications and notifying IDEC within 24 hours of the initiation of any investigation. Each investigation will be reviewed by BAXTER's designated Quality representative, and will follow the procedures recommended by regulatory agencies and as defined in appropriate BAXTER SOPs for OOS Investigations. All completed investigation reports will be included in the released, executed batch record that will be provided to IDEC.

7. *QUALITY ASSURANCE*

7.1 Deviations (Variances) and Investigations

7.1.1. Deviations and Investigation Reports—Any deviation from the process during manufacture, including but not limited to, batch record execution, and environmental monitoring excursions or aseptic processing procedures, must be carefully explained and documented in the batch records. They must be justified and approved by BAXTER Quality Assurance and the affected area management, and included in the document package. Investigations will be communicated to IDEC within 24 hours of the initiation of the investigation. Batch records that contain process deviations will be highlighted to IDEC. All investigations related to PRODUCT shall be forwarded to IDEC for review as part of the released, executed batch record. IDEC may review such investigation reports and has final disposition of any batch of PRODUCT.

7.1.2. Failure Investigations—BAXTER is responsible for investigating any test result or in-process test, which fails to meet specifications. Each investigation will be reviewed and

approved by BAXTER's designated quality representative. The investigation must document that any failure has not jeopardized the safety, identity, strength, purity, or quality of the PRODUCT. As PRODUCT experts, IDEC may conduct its own independent failure investigation, and may participate in the BAXTER Failure Investigation, as applicable.

7.1.3. IDEC will authorize the destruction of any batch of PRODUCT aborted or rejected by BAXTER.

7.1.4. BAXTER will provide verbal notification to IDEC if any problems are discovered, including review of media fills and environmental monitoring trending, that may impact PRODUCT batch(es) previously shipped to IDEC or its distributor(s) or licensee(s) within 24 hours of initiation of the investigation and will follow with written notification promptly thereafter.

7.1.5. Some deviations/failures may require that additional testing, stability, or validation be conducted. This work may be performed by IDEC and/or BAXTER as agreed by both parties.

7.2 Batch Disposition

7.2.1. For each batch, BAXTER will provide the documentation required in Appendix II.

7.2.2. Certificate of Compliance

BAXTER is responsible for ensuring and certifying that the PRODUCT has been manufactured according to the specifications/procedures documented in the Master Batch Records.

BAXTER QA Representative will sign a Certificate of Compliance confirming that the PRODUCT has been manufactured and tested according to the requirements as defined in Appendix II and the Master Batch Record.

7.3 Product Release

7.3.1. Release of the PRODUCT is the absolute responsibility of IDEC and will be undertaken by IDEC based on IDEC's internal procedures, the full document package provided by BAXTER (Appendix II), and completion of any release testing required by IDEC.

7.3.2. Any problem discovered by IDEC likely to cause rejection of the PRODUCT will be communicated to BAXTER within the later of 15 days from receipt of the full release documentation package or within 45 calendar days following receipt of PRODUCT Samples (see Appendix II). If these conditions cannot be met, IDEC will notify BAXTER and provide a new target date for completion and justification for the extension.

7.3.3. IDEC will communicate within 15 days, any problem confirmed by IDEC that is a change in acceptability of a previously IDEC supplied material received at BAXTER. BAXTER will evaluate the status change for impact to BAXTER systems.

7.4 Product Complaints and Recalls

7.4.1. Product Complaints—IDEC is responsible for receiving and initially investigating any PRODUCT complaints. IDEC will notify BAXTER within 2 days of discovery of any problems thought to be due to manufacture, which are found during the distribution of the

PRODUCT. When requested by IDEC, BAXTER will promptly perform investigations for these problems. Investigation reports will be forwarded to IDEC within 30 days or BAXTER will notify IDEC and provide a new target date for completion and justification for the extension

7.4.2. Product Recall—IDEC is responsible for instituting a PRODUCT recall that IDEC deems necessary. IDEC will notify BAXTER of any recall within 2 days of initiation, which may be due to the manufacturing of PRODUCT. BAXTER will provide a rapid initial response and/or an interim report within five (5) working days of such notice.

7.5 Records Retention

7.5.1. BAXTER will initially retain batch production records for the PRODUCT and materials for one year after expiration, then electronically archive and send the original and an electronic copy to IDEC.

7.5.2. BAXTER will not destroy any batch production records without first obtaining written approval from IDEC.

7.6 Manufacturing and Quality Presence in the Manufacturing Facility

7.6.1. BAXTER will maintain adequate, qualified Manufacturing and Quality personnel in the manufacturing facility during the manufacture of the PRODUCT to ensure compliance with cGMPs and the consistent manufacture of PRODUCT.

7.6.2. BAXTER will permit IDEC presence in the manufacturing facility during the manufacture and testing of the PRODUCT and on-site presence for purposes of record and data review.

7.7 Adverse Events

7.7.1. IDEC shall advise BAXTER of any adverse medical event or adverse drug event within two days of IDEC's receipt of notice thereof if determined to be related to manufacturing.

8. *REGULATORY COMPLIANCE*

8.1 Regulatory Inspections

8.1.1. **[CONFIDENTIAL TREATMENT REQUESTED]**.

[CONFIDENTIAL TREATMENT REQUESTED].

8.1.2. BAXTER will secure the agreement of IDEC prior to making any commitment to a regulatory agency regarding PRODUCT. IDEC shall be provided with draft responses to regulatory observations that directly involve the PRODUCT and its manufacture prior to submission to the regulatory authorities and BAXTER shall permit IDEC's input into responses and corrective actions. BAXTER shall retain the final authority for the content of the responses to the regulatory authority.

8.1.3. BAXTER will promptly forward to IDEC any observations and responses from a routine regulatory inspection relating to the facility where IDEC's PRODUCT is manufactured.

8.1.4. IDEC will inform BAXTER in writing of any regulatory issue that impacts BAXTER's ability to manufacture the PRODUCT.

8.1.5 BAXTER will forward to IDEC a redacted summary of any observations and responses from other clients' product inspections to the extent that such observations and responses relate directly to PRODUCT or directly to BAXTER's ability to supply PRODUCT; provided, however, BAXTER is not required to disclose any client confidential information.

8.2 Regulatory Actions

8.2.1. IDEC will notify BAXTER of any regulatory actions related to the PRODUCT that will impact BAXTER.

8.2.2. BAXTER is responsible for supporting all batch record investigations associated with regulatory actions.

8.2.3. Each party agrees to supply the other with any manufacturing, testing, or storage data within 48 hours, if requested, as the result of a regulatory inspection, or a potential regulatory exposure such as a recall or significant product complaint.

8.3 Right to Audit

8.3.1. BAXTER will allow representatives from IDEC to have access to their manufacturing, warehousing, laboratory premises, records, regulatory filings (e.g., DMF) and communications (e.g., FDA483s) for audit purposes listed below in 8.3.2 through 8.3.4; provided, however, BAXTER has the obligation to protect the confidential information of its clients.

8.3.2. BAXTER will permit IDEC to conduct preparatory audits of cGMP manufacture of the PRODUCT for pre-approval inspection for PRODUCT.

8.3.3. BAXTER will permit IDEC to conduct audits to address significant PRODUCT quality or safety problems as discovered through PRODUCT failures or complaints related to BAXTER's manufacturing of the PRODUCT.

8.3.4. BAXTER will permit IDEC to perform two standard cGMP compliance audits per year.

8.3.5. IDEC may audit any vendors, contractors, or subcontractors that are utilized by BAXTER. BAXTER will use reasonable efforts to cause such vendors, contractors or subcontractors to allow such audits.

8.3.6. Subject to the execution of a confidential disclosure agreement among BAXTER, IDEC and IDEC's licensee(s), BAXTER will permit access by IDEC's licensees to BAXTER's premises for audit purposes, consistent with the limitations listed in 8.3.2 through 8.3.4. IDEC will accompany the licensees during each audit, provided the audit is directly related to IDEC's PRODUCT.

8.4 Audit Closeout

8.4.1. An exit meeting will be held with representatives from BAXTER and IDEC to discuss significant audit observations.

8.4.2. IDEC will provide a written report of all observations within 30 days to BAXTER. Within 30 days of the audit report receipt, BAXTER will provide a written response to all findings that details corrective action to be implemented. BAXTER will follow up to ensure that all corrective actions are implemented.

8.5 Disclosure of Information and Regulatory Report

8.5.1. The Parties recognize that the holder of a Biologics License Application or Regulatory Approval may be required to submit information and file reports with various governmental agencies. To ensure that IDEC will be able to fulfill such obligations, BAXTER agrees that it will promptly disclose to IDEC any and all relevant information, data or changes (prior to implementation) that impact PRODUCT or global regulatory filings. In addition, BAXTER further agrees that it will report in writing all changes (other than nonmaterial

changes which would not affect regulatory approvals or submissions) related to PRODUCT regarding facilities (areas), equipment, procedures/documentation and personnel at least once annually. Such reports will include any contemplated efforts to manufacture or process compounds other than those related to PRODUCT in areas or employing equipment that is used to provide PRODUCT. In the event that no changes related to PRODUCT are contemplated or implemented during any particular year, BAXTER shall file a report attesting to that fact.

9. *DISPUTE RESOLUTION*

9.1 Non-Conformity Dispute

9.1.1. In the event that a dispute arises between BAXTER and IDEC in the non-conformity of a batch of the PRODUCT, the heads of Quality from both companies shall in good faith promptly attempt to reach an agreement. Whatever the outcome, IDEC retains the absolute right to determine product release status. Financial liability is determined in the Supply Agreement.

9.2 Test Result Dispute

9.2.1. In the event that a dispute arises between BAXTER and IDEC in the testing performed by BAXTER for the PRODUCT, the resolution will proceed in stages. The first stage requires direct communication between Quality management from both parties to determine that the methods of analysis are the same and are being executed in the same manner at the applicable sites. Second, carefully controlled and split samples should be sent from one site to another in an attempt to reach agreement. Should there be a failure to achieve resolution, QC Management from the parties will be required to meet to work through the analysis of a mutually agreeable sample. If these actions fail to achieve resolution, and only after these avenues have been exhausted, a qualified referee laboratory will be used to achieve resolution. This laboratory must be agreeable to both parties prior to use. The results from this referee laboratory will be used as final authority to determine responsibilities, but whatever the outcome, IDEC retains the right to determine product release status. Financial liability is determined in the Supply Agreement.

10. *CHANGE MANAGEMENT*

10.1 All proposed changes go through a technical, regulatory, and cGMP impact assessment by the BAXTER expert groups. The documents that contain IDEC's intellectual property or changes that may affect IDEC's regulatory submissions will also go through IDEC's assessment for regulatory advice and implementation requirements, as per the agreements between IDEC and BAXTER.

10.2 The scope of such a Change Management process includes Chemical Manufacturing, Pharmaceutical Manufacturing and Packaging processes. The associated changes may relate to: the Master Batch Records (e.g. Master Formulas, Filling, Packaging); Bills of Materials; Specifications and Test Methods (for Raw Materials and Finished PRODUCT); Purchase Specifications (for Raw Materials and Packaging Components); CLIENT specific Validated Equipment; Facilities; Utilities; or Computer Systems.

10.3 The Parties will assess changes within 15 working days and those changes marked urgent within 5 working days.

11. *PRODUCT AND PROCESS VALIDATION*

11.1 Process Validation—IDEC and BAXTER are responsible for ensuring that the manufacturing process is validated. BAXTER is responsible for ensuring that the facilities, utilities

and support systems are validated. The validation should ensure that the process is capable of consistently achieving the PRODUCT acceptance specification. BAXTER shall provide adequate resources to execute process validations as per mutually approved protocols.

11.2 Cleaning Verification/Validation—BAXTER is responsible for ensuring that adequate cleaning of product contact parts used in the manufacture of PRODUCT is carried out between batches of different product to prevent contamination. IDEC will provide information (i.e. LD50, toxicity, solubility, batch size, fill volume, product max human dose (MHD)) to establish cleaning limits. Until such time as the cleaning procedure and analytical methodology is validated, IDEC will purchase new product contact equipment; including but not limited to, glass receiving vessels and filling needles, to be used in the manufacture of all PRODUCT batches.

11.3 Equipment, Computer, Facility, and Utilities Qualification—BAXTER is responsible for all equipment, computer, facility, and utility qualification activities associated with the PRODUCT consistent with applicable regulatory requirements.

11.4 Laboratory Qualification—BAXTER is responsible for ensuring that all laboratories are in compliance with cGMPs and are qualified in all of the methodology associated with the PRODUCT. If PRODUCT specific analytical work is performed at BAXTER then IDEC will provide any relevant analytical documentation to assist in methods transfer or methods validation. BAXTER is responsible for third party laboratory qualification and assurance that analytical methods are validated. IDEC shall have the right to participate in vendor audits along with BAXTER, as IDEC deems necessary.

12. *NOTIFICATION OF NEW PRODUCT CLASSIFICATION*

12.1 BAXTER will notify IDEC prior to introducing a new product, either approved or unapproved, into the preparation, formulation, and filling area used for the manufacture of PRODUCT. IDEC and BAXTER will assure that appropriate regulatory approvals will be obtained prior to actual introduction of the new product into the manufacturing facility.

13. *ANNUAL PRODUCT REVIEW, ANNUAL REPORT AND DRUG LISTING*

13.1 Product Review

13.1.1. BAXTER will perform an Annual Product Review for the PRODUCT and will issue a report to IDEC. This report will cover all manufacturing and testing activities performed by BAXTER. It will consist of a review of any changes at BAXTER in the manufacturing, testing, storage, shipping or validation of the PRODUCT in the previous calendar year and a summary of lots made, released, and rejected. Also, control charting and summarizing of key PRODUCT parameters will be performed. Any abnormalities will be explained in the annual review. BAXTER will provide the requested information to IDEC annually commencing with the start of commercial production. Trend analysis of environmental data will be available for review during annual audits.

13.2 Annual Report

13.2.1. IDEC is responsible for preparing any Annual Report as required by applicable regulations, including 21 CFR 314.7(g)(3), 314.81(b)(2), and/or 601.12(d), (f)(3). At least 90 calendar days before the Annual Report due date, IDEC shall request in writing from BAXTER the chemistry, manufacturing, and controls data required for submission of the Annual Report. BAXTER will provide the requested information to IDEC within 30 days.

13.3 Drug Listing

13.3.1. BAXTER is responsible for drug listing as the manufacturer of the PRODUCT, while IDEC is responsible for drug listing as the distributor of the PRODUCT. IDEC will provide BAXTER with all information needed by them for their listing, including date of approval and PRODUCT launch to the market within three days of such dates, as and to the extent required by Applicable Laws and Regulations.

APPENDIX I—List of Quality Contacts
(Name, phone, fax, e-mail)

ISSUE	IDEC	BAXTER
Product Release	Fanzia Mohammed Ph: (858) 431-8505 Fax: (858) 431-8152 fmohammed@idecpharm.com	Carol Winnefeld Ph: (812) 333-0887 Fax: (812) 333-3079 carol_winnefeld@baxter.com
QC Testing	Mark Rosen Ph: (858) 431-8537 Fax: (858) 431-8751 mrosen@idecpharm.com	Bryan Hudson/Dan Larrimore Ph: (812) 333-0887 Fax: (812) 333-3079 Bryan_Hudson@baxter.com Dan_larrimore@baxter.com
Investigations	Fanzia Mohammed Ph: (858) 431-8505 Fax: (858) 431-8152 fmohammed@idecpharm.com	Susan Easton/ Jennifer Walls Ph: (812) 333-0887 Fax: (812) 333-3079 Susan_Easton@baxter.com Jennifer_walls@baxter.com
Stability	Roya Ravan Ph: (858) 431-8587	Bryan Hudson Ph: (812) 333-0887

	Fax: (858) 431-8751 rravan@idecpharm.com	Fax: (812) 333-3079 Bryan_Hudson@baxter.com
Validation	Kathleen Houck Ph: (858) 431-8605 Fax: (858) 431-8152 khouck@idecpharm.com	Dave Abram Ph: (812) 333-0887 Fax: (812) 333-3079 Dave_abram@baxter.com
Compliance Audits	Neno Segura Ph: (858) 431-8678 Fax: (858) 431-8751 nsegura@idecpharm.com	Aaron Turner Ph: (812) 333-0887 Fax: (812) 333-3079 Aaron_turner@baxter.com
Product Complaints	Fanzia Mohammed Ph: (858) 431-8505 Fax: (858) 431-8152 fmohammed@idecpharm.com	Carol Winnefeld Ph: (812) 333-0887 Fax: (812) 333-3079 Carol_winnefeld@baxter.com
Change Management	Mikel Edwards Ph: (858) 431-8683 Fax: (858) 431-8751 medwards@idecpharm.com	Jennifer Walls/Kelly Davis Ph: (812) 333-0887 Fax: (812) -333-3079 Jennifer_walls@baxter.com Kelly_davis@baxter.com
CMC Regulatory Issues	Art Blum Ph: (858) 431-8341 Fax: (858) 431-8889 ablum@idecpharm.com	Kelly Davis Ph: (812) 333-0887 Fax: (812) 333-3079 Kelly_davis@baxter.com

APPENDIX II—Release Documentation

A Certificate of Analysis (C of A)

This document will include the name of the PRODUCT, the batch number and the date of manufacture. The C of A will list the finished PRODUCT test results and PRODUCT disposition.

A Certificate of Compliance (C of C)

This document will attest to the fact that the batch of PRODUCT was made in accordance with applicable SOPs, Batch Record and the Product Master Plan. It will state that all deviations were documented and, if necessary, investigated

Raw Data

In addition to the foregoing, BAXTER will provide a copy of the raw data for the in-process QC tests and release tests to IDEC.

Executed Batch Records and Environmental Monitoring Data

BAXTER will provide copies of environmental monitoring data related to the manufacture of PRODUCT, and the executed Batch Records including investigation reports and process deviation reports.

APPENDIX III—Certificate of Analysis for Filling: Conjugated Antibody Component

Zevalin 2B8-MX-DTPA Bulk

TEST CODE	TEST NAME	SPECIFICATION	RESULT
QBC-102	Protein Concentration	**[CONFIDENTIAL TREATMENT REQUESTED]**	
QGM-001	PH	**[CONFIDENTIAL TREATMENT REQUESTED]**	
QBC-120	Bacterial Endotoxins	**[CONFIDENTIAL TREATMENT REQUESTED]**	
QMB-038	Bioburden	**[CONFIDENTIAL TREATMENT REQUESTED]**	

Prepared By: _____ Date: _____

o All tests passed
o Not all tests passed

Date:

Quality Control

APPENDIX IV—Certificate of Analysis for Filling: Formulation Buffer Component

Formulation Buffer Bulk

TEST CODE	TEST NAME	SPECIFICATION	RESULT
QMB-038	Bioburden	**[CONFIDENTIAL TREATMENT REQUESTED]**	
QGM-001	pH Determination	**[CONFIDENTIAL TREATMENT REQUESTED]**	
QRM-056	HSA Concentration	**[CONFIDENTIAL TREATMENT REQUESTED]**	
QBC-120	Bacterial Endotoxins	**[CONFIDENTIAL TREATMENT REQUESTED]**	

Prepared By: Date:

o All tests passed
o Not all tests passed

Date:

Quality Control

APPENDIX V

Certificate of Analysis for Filling: Sodium Acetate Component

50 mM Sodium Acetate Bulk

TEST CODE	TEST NAME	SPECIFICATION	RESULT
QMB-038	Bioburden	**[CONFIDENTIAL TREATMENT REQUESTED]**	
QBC-120	Bacterial Endotoxins	**[CONFIDENTIAL TREATMENT REQUESTED]**	

Prepared By: Date:

o All tests passed
o Not all tests passed

Date:

Quality Control

APPENDIX VI

List of Standard Operating Procedures utilized in the Manufacture of PRODUCT

[Omitted]

EXHIBIT 9

Regulatory Plan

IDEC and
BAXTER PHARMACEUTICAL SOLUTIONS LLC (BAXTER)
May 8, 2002

Primary Contact— Art Blum
Sr. Director of Regulatory Affairs
IDEC
3030 Callan Road
San Diego, CA 92121
Ph: 858-431-8341
Fax: 858-431-8889
E-mail: ablum@idecpharm.com

Secondary Contact— Hector Tamburini
Director of Pharmaceutical Product and Development
Ph: 858-431-8494
Fax: 858-431-8750
E-mail: htamburini@idecpharm.com

Contact at BAXTER— Kelly A. Davis
Regulatory Affairs Supervisor
Ph: 812-333-0887
Fax: 812-332-3079
E-mail: kelly davis@baxter.com

Judy Salyer
Project Manager
Ph: 812-333-0887
Fax: 812-332-3079
E-Mail: judy salyer@baxter.com

Product Description— Zevalin/Formulation Buffer/Reaction Vial/50 mM Sodium Acetate/2B8-MX-DTPA Conjugated Antibody

This product is for the treatment of non-Hodgkins lymphoma.

Purpose of Plan— The following services are available to IDEC and will be billed only if and when specifically requested in writing by IDEC to Baxter. Nothing in this Regulatory Plan shall be construed as committing IDEC to accepting any of the following services without IDEC first giving the appropriate written notice therefor.

Raw Materials & Components— Refer to the appropriate Project Plan.

BAXTER Regulatory

In accordance to the 21 CFR 601.12, Changes to an Approved Application, and as agreed upon by both parties, BAXTER will supply documentation to support the Zevalin Biologic License Application (BLA). The BLA documentation will consist of two primary parts; the chemistry, manufacturing and control information and the establishment description information. This documentation may include **one** copy of each of the following:

Part 1—Product Description Section

1.0 Description of Manufacturer

1.1 Name and Address

1.2 List of biological products manufactured (reference Type V DMF)

2.0 Composition of the Drug Product

3.0 Methods of Manufacturing and Packaging

3.1 Description of Manufacturing Process Flow (Narrative and Diagrams)

3.1.1 Raw Material Flow

3.1.2 Formulation Flow

3.1.3 Container/Stopper/Filling Equipment Flow

3.1.4 Filling Flow

3.1.5 Transfer From Building A to Building B

3.1.6 Inspection Flow

3.1.7 Labeling/Packaging Flow

3.2 Environmental Monitoring

3.2.1 Description of Environmental Monitoring

3.2.2 Environmental Monitoring Specifications

3.2.3 Environmental Monitoring Results during Production Batches

3.2.4 Environmental Controls

3.2.4.1 Sanitation Procedure

3.2.4.2 Area Classifications

3.2.4.3 Description of Procedure for Exceeded Limits

4.0 Specifications and Test Methods

4.1 Certificates of Analysis—Raw Materials

4.2 Certificates of Analysis—Primary Packaging Components

4.3 Certificates of Analysis—Finished Product

4.4 Finished Product and Raw Material Sampling Procedures

5.0 Container/Closure System

6.0 Microbiology

6.1 Depyrogenation/Sterilization Validation of Containers/Closures/Filling Equipment

6.2 Description of Filter Components

6.3 Critical Holding Periods

6.4 Description of Media Fills

6.5 Media Fill Environmental Monitoring

6.6 Description of Procedure for Media Fill Failures

7.0 Executed Production Batch Records

Part 2—Establishment Description Section

1.0 General Information

1.1 Floor diagram of the facility

1.2 Product, personnel, equipment, waste and air flows (narrative and diagrams)

1.3 Indication of areas which are served by each air handling unit (narrative and diagram)

2.0 Water Systems

2.1 General Description

2.2 Validation Summary

2.2.1 Description of the validation protocol

2.2.2 Dates of IQ and OQ completion

2.2.3 Length of the validation period

2.2.4 Parameters monitored and tests performed

2.2.5 Frequency of monitoring of each point of use during the validation period

2.2.6 Validation data summary

2.2.7 Explanation of all excursions during validation

2.3 Routine Monitoring Program

2.3.1 Tests performed and specifications

2.3.2 Frequency of tests

2.3.3 Description of action to be taken when limits are exceeded

3.0 Heating, Ventilating and Air Conditioning Systems (HVAC)

3.1 General Description

3.2 Validation Summary

3.2.1 Description of the validation protocol

3.2.2 Dates of IQ, OQ and current filters certifications

3.2.3 Length of the validation period

3.2.4 Validation data summary

3.2.5 Explanation of all excursions during validation

3.3 Routine Monitoring Program

3.3.1 Tests performed and specifications

3.3.2 Frequency of tests

3.3.3 Description of action to be taken when limits are exceeded

4.0 Contamination/Cross Contamination Issues

4.1 Cleaning Procedures and Validations for Dedicated Equipment

4.2 Cleaning Procedures and Validations for Shared Equipment

4.3 Containment Features

4.3.1 Description of segregation and containment procedures for areas, manufacturing operations, personnel, equipment and waste materials

4.3.1.1 Personnel gowning procedures

4.3.1.2 Sanitization procedures

4.3.1.3 Aseptic technique and training

4.3.2 Air pressure differentials between adjacent manufacturing areas

4.3.3 Segregation of air handling units

4.3.4 Air supply and return

4.3.5 Use of airlocks

5.0 Computer Systems

5.1 Narrative of the validation process

5.2 Dates of IQ and OQ

5.3 Description of parameters monitored and tests performed

5.4 Validation data summary

5.5 Explanation of all excursions and deviations

References:

Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description information for a Biological in Vitro Diagnostic Product (1999)

Submission of Documentation for Sterilization Process Validation in Applications for human and Veterinary Drug Products (1994)

Submitting Documentation for Packaging for Human Drugs and Biologics (1987)

Submission Timeline:

If requested by CLIENT, a final draft of the supplement documentation will be submitted by BAXTER to CLIENT by a date determined by mutual agreement of the parties, for review by CLIENT. CLIENT will provide BAXTER with its comments on such draft as soon as practicable after receipt and BAXTER will thereafter provide CLIENT with final supplement documentation, incorporating CLIENT's comments complete and ready for submission to the FDA, by not later than thirty (30) days after receipt by BAXTER of CLIENT's comments.

Required from CLIENT: To the extent that CLIENT requests services under this Regulatory Plan from BAXTER,

1. CLIENT is responsible for keeping BAXTER supplied with the most current methods and specifications

2. CLIENT will summarize and provide written comments from one primary contact. These comments will be reflective of CLIENT'S entire internal comments.

3. BAXTER will be allowed at least 5 working days from date of receipt to respond to CLIENT written comments. **If 5 working days are not allowed, regardless of the reason, a fee of *at least* $2500 per occurrence may be assessed which is dependent on the amount of effort required by BAXTER.**

4. CLIENT will provide one copy of the BAXTER portion of the final submission.

Project Price:

1. Total estimated regulatory support is **[CONFIDENTIAL TREATMENT REQUESTED]**. Any requested support outside the confines of the agreement will be billed separately at a rate of **[CONFIDENTIAL TREATMENT REQUESTED]**.

Exhibit 10 - A
Temperature Controlled Product
Shipping Requirements Document

IDEC Pharmaceuticals
Product Description: Zevalin™ Indium Kit (IDEC-154)

Ship to Account:	IDEC Pharmaceuticals
Ship to Customer:	ICS / IDEC Pharmaceuticals
Ship to Contact:	ICS, Jenny Brian
Ship to Phone:	502-964-3300
Ship to Fax:	502-966-4166
Ship to Address:	5051 Commerce Crossing Drive Louisville, KY 40229

Designated Carrier: Federal Express Custom Critical, White Glove Service

Transit Time: 3 hours

Special Shipping Conditions: Truck temperature set-point [CONFIDENTIAL TREATMENT REQUESTED] with temperature recorder. Temperature Range [CONFIDENTIAL TREATMENT REQUESTED]

Special Shipping Services:

- Carrier Booked by Baxter Shipping Department

- Baxter Shipping Department to request temperature control truck with a minimum length of 20 feet and not to exceed 24-feet in length with temperature recorder. The carrier must provide the shipper calibration documentation on temperature monitoring/recording equipment.

- Carrier's Bill of Lading must state: "Must Call ICS at 502-964-3300 for delivery appointment" and "Ship Temperature Control [CONFIDENTIAL TREATMENT REQUESTED] set-point."

The Shipment of *Zevalin™ Indium Kits* from Baxter Pharmaceuticals Solutions is to be made per the following instructions

Comments:

Record information in each section as indicated and then initial and date when complete. Have a second person verify the information and then initial and date when complete

Comments:

PRODUCTION BATCH

Lot Number: Packaging Order Number:

Initials & date Initials & date Initials & date Initials & date

Lot Number: Packaging Order Number:

Initials & date Initials & date Initials & date Initials & date

Lot Number: Packaging Order Number:

Initials & date Initials & date Initials & date Initials & date

TEMPERATURE DATA LOGGER

Manufacturer: Sensitech
Model: Temptale3, 2K, Single Use, without probe
Number Required per Shipment: 2
Note: If product is shipped with IDEC Yttrium Kits (IDEC 156) on the same truck, a total of two Temptale3 devices are required per truck.

Temperature Recorder

Serial Number: Initials & date Initials & date

Serial Number: Initials & date Initials & date

SHIPPING PACKAGING MATERIALS

Not Applicable

REFRIGERANT

Not Applicable

Comments:

PACK OUT PROCEDURE:

Not Applicable

PALLETIZATION REQUIREMENTS

None. Product is palletized during packaging operations.

PRE LOADING PROCEDURE

Verify that the truck has current calibration documentation for its temperature recorder.
Initials & date _____ Initials & date _____

Verify the temperature recorder is operational.
Initials & date _____ Initials & date _____

Photocopy the temperature recorder calibration documentation
Initials & date _____ Initials & date _____

Attach the temperature recorder calibration documentation to the appendix.
Initials & date _____ Initials & date _____

Verify that the trailer temperature set point is 41° F (5° C)
Initials & date _____ Initials & date _____

Verify that the trailer is within 5° F(3°C) of the temperature set point.
Initials & date _____ Initials & date _____

LOADING PROCEDURE

The load configuration must be a minimum of 1 pallet and a maximum of 8 pallets.

Comments: _____

Pallets of product must be:

- [CONFIDENTIAL TREATMENT REQUESTED]
- [CONFIDENTIAL TREATMENT REQUESTED]
- [CONFIDENTIAL TREATMENT REQUESTED]
- [CONFIDENTIAL TREATMENT REQUESTED].
- [CONFIDENTIAL TREATMENT REQUESTED].
- [CONFIDENTIAL TREATMENT REQUESTED]

Initials & date _____ Initials & date _____

Verify that the temperature data recorder has been pre-configured

Initials & date _____ Initials & date _____

Activate the temperature data recorder

Initials & date _____ Initials & date _____

Place the temperature data recorder per the following instructions:

Once loading of the truck is complete, place the two Temptale3 devices on the selected pallets above the pallet label and secure the Temptale3 to the pallet. Apply a layer of shrink-wrap over the temperature-recording device.

Initials & date _____ Initials & date _____

Review the documentation for completeness

Print Name _____ Print Name _____

Signature _____ Signature _____

Date _____ Date _____

Comments: _____

Exhibit 10 - B
Temperature Controlled Product
Shipping Requirements Document

IDEC Pharmaceuticals
Product Description: Zevalin™ Yttrium Kit (IDEC-156)

Ship to Account:	IDEC Pharmaceuticals
Ship to Customer:	ICS / IDEC Pharmaceuticals
Ship to Contact:	ICS, Jenny Brian
Ship to Phone:	502-964-3300
Ship to Fax:	502-966-4166
Ship to Address:	5051 Commerce Crossing Drive Louisville, KY 40229

Designated Carrier: Federal Express Custom Critical, White Glove Service

Transit Time: 3 hours

Special Shipping Conditions: Truck temperature set-point **[CONFIDENTIAL TREATMENT REQUESTED]** with temperature recorder. Temperature Range **[CONFIDENTIAL TREATMENT REQUESTED**]

Special Shipping Services:

- Carrier Booked by Baxter Shipping Department
- Baxter Shipping Department to request temperature control truck with a minimum length of 20 feet and not to exceed 24-feet in length with temperature recorder. The carrier must provide the shipper calibration documentation on temperature monitoring/recording equipment.
- Carrier's Bill of Lading must state: "Must Call ICS at 502-964-3300 for delivery appointment" and "Ship Temperature Control **[CONFIDENTIAL TREATMENT REQUESTED]** set-point."

The Shipment of *Zevalin™ Yttrium Kits* from Baxter Pharmaceuticals Solutions is to be made per the following instructions

Comments:

Record information in each section as indicated and then initial and date when complete. Have a second person verify the information and then initial and date when complete.

Comments:

PRODUCTION BATCH

Lot Number:				Packaging Order Number:			
Initials & date		Initials & date		Initials & date		Initials & date	
Lot Number:				Packaging Order Number:			
Initials & date		Initials & date		Initials & date		Initials & date	
Lot Number:				Packaging Order Number:			
Initials & date		Initials & date		Initials & date		Initials & date	

TEMPERATURE DATA LOGGER

Manufacturer: Sensitech
Model: Temptale3, 2K, Single Use, without probe
Number Required per Shipment: 2
Note: If product is shipped with IDEC Indium Kits (IDEC 154) on the same truck, a total of two Temptale3 devices are required per truck.

Temperature Recorder

Serial Number:		Initials & date		Initials & date	
Serial Number:		Initials & date		Initials & date	

SHIPPING PACKAGING MATERIALS

Not Applicable

REFRIGERANT

Not Applicable

Comments:

PACK OUT PROCEDURE:

Not Applicable

PALLETIZATION REQUIREMENTS

None. Product is palletized during packaging operations.

PRE LOADING PROCEDURE

Verify that the truck has current calibration documentation for its temperature recorder.
Initials & date Initials & date

Verify the temperature recorder is operational.
Initials & date Initials & date

Photocopy the temperature recorder calibration documentation
Initials & date Initials & date

Attach the temperature recorder calibration documentation to the appendix.
Initials & date Initials & date

Verify that the trailer temperature set point is 41° F (5° C)
Initials & date Initials & date

Verify that the trailer is within 5° F(3°C) of the temperature set point.
Initials & date Initials & date

LOADING PROCEDURE

The load configuration must be a minimum of 1 pallet and a maximum of 8 pallets.

Comments:

Pallets of product must be:

- **[CONFIDENTIAL TREATMENT REQUESTED]**
- **[CONFIDENTIAL TREATMENT REQUESTED]**
- **[CONFIDENTIAL TREATMENT REQUESTED]**

- **[CONFIDENTIAL TREATMENT REQUESTED].**
- **[CONFIDENTIAL TREATMENT REQUESTED].**
- **[CONFIDENTIAL TREATMENT REQUESTED]**

Initials & date _____ Initials & date _____

Verify that the temperature data recorder has been pre-configured

Initials & date _____ Initials & date _____

Activate the temperature data recorder

Initials & date _____ Initials & date _____

Place the temperature data recorder per the following instructions:

Once loading of the truck is complete, place the two Temptale3 devices on the selected pallets above the pallet label and secure the Temptale3 to the pallet. Apply a layer of shrink-wrap over the temperature-recording device.

Initials & date _____ Initials & date _____

Review the documentation for completeness

Print Name _____ Print Name _____

Signature _____ Signature _____

Date _____ Date _____

Comments: _____

QuickLinks

Exhibit 10 - B Temperature Controlled Product Shipping Requirements Document

The Shipment of Zevalin™ Yttrium Kits from Baxter Pharmaceuticals Solutions is to be made per the following instructions

QuickLinks -- Click here to rapidly navigate through this document

EXHIBIT 31.1

CERTIFICATIONS

I, William H. Rastetter, Ph.D., certify that:

1. I have reviewed this annual report on Form 10-K/A of IDEC Pharmaceuticals Corporation;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

   a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

   c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: October 2, 2003

/s/ WILLIAM H. RASTETTER, PH.D.

William H. Rastetter, Ph.D.
Chairman of the Board and Chief Executive Officer
(Principal Executive Officer)

I, Edward M. Rodriguez, certify that:

1. I have reviewed this annual report on Form 10-K/A of IDEC Pharmaceuticals Corporation;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

   a)

designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: October 2, 2003

/s/ EDWARD M. RODRIGUEZ

Edward M. Rodriguez
Vice President, Finance and Controller
(Principal Financial and Accounting Officer)

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EXHIBIT 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350

In connection with the accompanying Annual Report on Form 10-K/A of IDEC Pharmaceuticals Corporation for the year ended December 31, 2002 (the "Report"), I, William H. Rastetter, Ph.D., Chairman of the Board and Chief Executive Officer of IDEC Pharmaceuticals Corporation, hereby certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge and belief, that:

(1) such Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in such Report fairly presents, in all material respects, the financial condition and results of operations of IDEC Pharmaceuticals Corporation.

/s/ WILLIAM H. RASTETTER

William H. Rastetter, Ph.D., Chairman of the Board and Chief Executive Officer

October 2, 2003

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350

In connection with the accompanying Annual Report on Form 10-K/A of IDEC Pharmaceuticals Corporation for the year ended December 31, 2002 (the "Report"), I, Edward M. Rodriguez, Vice President, Finance and Controller of IDEC Pharmaceuticals Corporation, hereby certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge and belief, that:

(1) such Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in such Report fairly presents, in all material respects, the financial condition and results of operations of IDEC Pharmaceuticals Corporation.

/s/ EDWARD M. RODRIGUEZ

Edward M. Rodriguez, Vice President, Finance and Controller

October 2, 2003

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