

FORM 10-K/A

SCHERING PLOUGH CORP - sgp

Filed: May 03, 2004 (period: December 31, 2003)

Amendment to a previously filed 10-K

10-K/A - AMENDMENT TO FORM 10-K

PART I

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

SIGNATURES

Exhibit Index

EX-10.U (DISTRIBUTION AGREEMENT)

EX-31.1 (CERTIFICATION)

EX-31.2 (CERTIFICATION)

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

Form 10-K/A

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

For the fiscal year ended December 31, 2003

Commission File No. 1-6571

SCHERING-PLOUGH CORPORATION

(Exact name of registrant as specified in charter)

New Jersey (State of incorporation)	I.R.S. Employer Identification No. 22-1918501
2000 Galloping Hill Road <u>Kenilworth, N.J. 07033</u> (Address of principal executive offices)	(908)298-4000 (Registrant's telephone number)
Securities registered pursuant to section 12(b) of the Act:	
Title of each class	Name of each exchange on which registered
Common Shares, \$.50 par value	New York Stock Exchange
Preferred Share Purchase Rights*	New York Stock Exchange
*At the time of filing, the Rights were not traded separately from the Common Shares	S.
Indicate by check mark whether the registrant has filed all reports required to be filed Exchange Act of 1934 during the preceding 12 months and has been subject to such files ■ NO □	
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regular be contained, to the best of registrant's knowledge, in definitive proxy or information of this Form 10-K or any amendment to this Form 10-K. □	
Indicate by check mark whether the registrant is an accelerated filer (as defined in Ru	le 12b-2 of the Exchange Act). YES ⊠ NO □
Aggregate market value of common shares held by non-affiliates computed by reference last sold as of June 30, 2003 (the last business day of the registrant's most recently co	
Common shares outstanding as of January 31, 2004: 1,471,196,309	
Documents incorporated by reference Schering-Plough Corporation Proxy Statement for the Annual Meeting of Shareholders on April 27, 2004	Part of Form 10-K <u>incorporated into</u> Part III

TABLE OF CONTENTS

Item 6. Exhibits and Reports on Form 8-K SIGNATURES
Item 6. Exhibits and Reports on Form 8-K DISTRIBUTION AGREEMENT CERTIFICATION
CERTIFICATION

Explanatory Note:
This amendment to Schering-Plough Corporation's 2003 Form 10-K is being filed solely to include a new version of Exhibit 10(u).
That Exhibit omits certain information for which Schering-Plough Corporation has requested confidential treatment by the SEC. No other portions of the 10-K are being amended.

- Item 15. Exhibits, Financial Statement Schedules, and Reports on Form 8-K
 - (a) 3. Exhibits The following Exhibits are filed with this Amendment:

Exhibit Number 10(u)	Description Distribution Agreement between the Company and Centocor, Inc., dated April 3, 1998.*
31.1	Sarbanes-Oxley Act of 2002, Section 302 Certification for Chairman of the Board, Chief Executive Officer and President
31.2	Sarbanes-Oxley Act of 2002, Section 302 Certification for Executive Vice President and Chief Financial Officer

^{*}Note that information is omitted from Exhibit 10(u) pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

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.

Schering-Plough Corporation (Registrant)

DateApril 29, 2004

By /s/ Thomas H. Kelly

Thomas H. Kelly Vice President and Controller

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

Fred Hassan Chairman of the Board, C and President	Chief Executive Officer
/s/ Robert J. Bertolini	
Robert J. Bertolini Executive Vice President Chief Financial Officer	and
/s/ Thomas H. Kelly	
Thomas H. Kelly Vice President and Contr and Principal Accounting	
	*
Hans W. Becherer Director	
	*
Philip Leder, M.D. Director	
	*
Eugene R. McGrath Director	
	*
Carl E. Mundy, Jr. Director	
	*
Richard de J. Osborne Director	

Patricia F. Russo				
Director				
	*			
Kathryn C. Turner Director				
	*			
Robert F. W. van Oor Director	dt			
	*			
Arthur F. Weinbach Director				
y: /s/ Thomas H. Kell	ly		Date:	April 29, 2004
Thomas H. Kelly Attorney-in-fact				
		- 4 -		

Exhibit Index

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^{*}Note that information is omitted from Exhibit 10(u) pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

SCHERING-PLOUGH CORPORATION REDACTED VERSION. [***] Indicates information omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

DISTRIBUTION AGREEMENT

This Distribution Agreement (hereinafter "Agreement") is made as of April 3, 1998, by and between Centocor, Inc., a Pennsylvania corporation ("Centocor"), and Schering-Plough Ltd., a Swiss corporation ("Schering-Plough").

Centocor has developed an anti-TNF chimeric monoclonal antibody product (cA2, infliximab, Avakine/(TM)/) (the "Product") for use as an agent in the treatment of (a) inflammatory bowel diseases, including Crohn's Disease (collectively referred to as "Inflammatory Bowel Disease"); (b) rheumatoid arthritis; and (c) new indications to be defined. A description of the Product is set forth in the attached Appendix A. The Product also includes Improvements, if any, as defined in Section 1.9.

Subject to obtaining necessary Regulatory Approvals, Centocor and Schering-Plough wish to set forth the manner in which, and the terms under which, they have agreed to commercialize the Product.

Therefore, the parties, for good and valuable consideration, the receipt and adequacy of which is hereby acknowledged by each of them, and intending to be legally bound, agree as follows.

ARTICLE I

DEFINITIONS

For purposes of this Agreement, the following terms, when used with initial capital letters, will have the meaning set forth below. Other terms are defined elsewhere in this Agreement and those terms, when used with initial capital letters, will also have the defined meanings whenever they appear in this Agreement. As to the terms defined and used herein, the singular will be understood to include the plural and vice-versa, unless the context clearly indicates to the contrary.

- 1.1 "Affiliate" means any person or entity directly or indirectly Controlling, Controlled by or under common Control with a party hereto. Any reference in this Agreement to Centocor or Schering-Plough includes the Affiliates of that party unless the context clearly indicates to the contrary.
- 1.2 "Agreement Year" means, initially, the period from the Effective Date of this Agreement through December 31, 1998, or the earlier termination of this Agreement, and thereafter, each calendar year during the term of this Agreement or part thereof which ends at the point of expiration or termination of this Agreement.
- 1.3 "Commercial Sales" means, for any applicable period, the amount invoiced for Product sold by Schering-Plough or its Affiliates to unaffiliated parties, exclusive of intercompany transfers.
 - 1.4 "Control" means the ability of any entity (the

"Controlling" entity), directly or indirectly, through ownership of securities, by agreement or by any other method, to direct the manner in which more than fifty percent (50%) of the outstanding voting rights of any other entity (the "Controlled" entity), whether or not represented by securities, shall be cast, or the right to receive over fifty percent (50%) of the profits or earnings of, or to otherwise control the management decisions of, such other entity (also a "Controlled" entity).

- 1.5 "Core Co-Promotion Territory" shall mean all of the following countries: Germany, France, Italy, Spain and the United Kingdom.
- 1.6 "Cost of Goods Sold" means: (a) the costs of direct material purchased for use in the production process; (b) depreciation, repair, maintenance and operating costs of the production facilities utilized in the production of the Product; (c) the costs of quality, stability and in-process controls; (d) building operating costs, other than any included in subpart (b) above; (e) direct labor costs and overheads calculated in conformity with U.S. generally accepted accounting principles; (f) the costs of mutually agreed, noncapitalized manufacturing process improvement and cost reduction efforts; and (g) the costs of filling, finishing and packaging; provided, however, that the Cost of Goods Sold for the finished Product will not exceed [***] per gram of labelled Product. "Cost of Goods Sold" excludes the costs of research batches. This definition of "Cost of Goods Sold" is intended to be consistent with Appendix B.
 - 1.7 "Effective Date" means the date first set forth above.
- 1.8 "EMEA Approval" means the issuance by the European Agency for the Evaluation of Medicinal Products (the "EMEA") of the marketing authorization (excluding any pricing approvals) necessary for the sale of Product within the European Community for one or more indications.
- 1.9 "Improvement" means any change with respect to the Product, including, without limitation, any change in the formulation, dosage, mode of delivery or new indications for the Product, any change in the Product resulting from a change in the manufacturing process, and any chimeric or humanized anti-TNF monoclonal antibody or fragment thereof, other than the Product as described in Appendix A, developed by or licensed to Centocor.
- 1.10 "Marketing Approval" means Regulatory Approval, pricing approval and reimbursement approval, where applicable.
- 1.11 "Marketing Expenses" means(a) [***] marketing expenses (including [***] and [***] expenses), and (b) [***] expenses allocable to [***] of the Product (including those of [***] and [***]. With respect to [***] related expenses, "Marketing Expenses" includes [***] and [***] expenses and excludes [***] expenses.
- 1.12 "Net Sales" means, for each applicable period, the Commercial Sales for that period, less reasonable and customary deductions from such gross amounts, including: (a) normal and customary trade, cash and quantity discounts, allowances and credits; (b) credits or allowances actually granted for damaged goods, returns or rejections of Product and retroactive price reductions; (c) sales or similar taxes when included in billing (including duties or other governmental charges levied on, absorbed or otherwise imposed on

the sale of Product including, without limitation, value added taxes or other governmental charges otherwise measured by the billing amount); (d) charge back payments and rebates granted to managed health care organizations or their agencies, and purchasers and reimbursers or to trade customers, including but not limited to, wholesalers and chain and pharmacy buying groups; (e) commissions paid to third parties other than sales personnel and sales representatives, sales agents or distributors; and (f) rebates (or equivalents thereof) granted to or charged by national, state or local governmental authorities in a country in the Territory, to the extent specifically associated with Commercial Sales of the Product.

- 1.13 "Product" means the anti-TNF chimeric monoclonal antibody product (cA2, infliximab, Avakine/(TM)/) developed by Centocor for use as an agent in the treatment of (a) inflammatory bowel diseases, including Crohn's Disease (collectively referred to as "Inflammatory Bowel Disease"); (b) rheumatoid arthritis; and (c) new indications to be defined. A description of the Product is set forth in the attached Appendix A. The Product also includes Improvements, if any, as defined in Section 1.9.
- 1.14 "Product Development Costs" means all external costs, including external product development costs, incurred by Centocor and Schering-Plough after the Effective Date in connection with the clinical development (including pre-clinical, toxicology, pharmacology and pharmacodynamic studies and clinical trials, except as limited by the last sentence of this definition) and clinical support of regulatory filings with respect to the Product. "Product Development Costs" also includes the cost of goods for material used in clinical trials, which cost will be calculated based on Centocor's Cost of Goods Sold, or, if Centocor contracts with a third party for manufacture of the Product, will be the actual cost paid by Centocor to that third party. "Product Development Costs" also includes such costs of the development of improvements of manufacturing and control processes as are incurred after the Product has received a first EMEA Approval. All internal costs of Centocor or Schering-Plough, including but not limited to salaries, payroll taxes, bonuses and benefits incurred with respect to their employees and office, administration and overhead expenses, are specifically excluded from the definition of "Product Development Costs," unless otherwise agreed by the parties. Excluded from "Product Development Costs" are costs incurred with respect to clinical trials or other studies undertaken solely to support applications for Regulatory Approval outside the Territory.
- 1.15 "Regulatory Approval" means, as to the United States and each country in the Territory in which approval may be required, the issuance by the relevant governmental body or bodies or other organization or organizations of all licenses, approvals and registrations necessary for the sale of the Product within such country for a particular indication or indications (excluding any pricing approvals).
- 1.16 Subject to Section 2.2(a), "Territory" means the world except for the United States, Japan, Taiwan, Indonesia and the People's Republic of China (including Hong Kong).

ARTICLE II

DISTRIBUTION AND PROMOTION OF THE PRODUCT

2.1 Distribution and Promotion Plan. Subject to the further terms and conditions described below, Centocor and Schering-Plough agree on the following distribution and promotion plan for the Product, all subject to the receipt of the necessary Regulatory Approvals, wherever required.

(a) Exclusive Distribution by Schering-Plough. Centocor will sell the Product to Schering-Plough on an exclusive basis for resale by Schering-Plough in each country within the Territory in which Schering-Plough may lawfully sell the Product. Subject to any regulatory restrictions on price in any of the countries in the Territory, Schering-Plough will set the selling price of the Product in the Territory to unaffiliated parties. In those countries in which governmental approval of pricing is required or desirable, Schering-Plough will have the responsibility for seeking such approval; and Centocor will appoint Schering-Plough to act as its agent in seeking such approval and will otherwise cooperate with and provide reasonable assistance to Schering-Plough. Notwithstanding any other provision of this Agreement, Schering-Plough will not have any obligation to launch the sale of the Product in any country in the Territory in which governmental approval of pricing is required or desirable, but in which Schering-Plough is unable to obtain approval of pricing which is satisfactory in the view of the Product Committee. Schering-Plough will, on an exclusive basis, distribute (or cause the distribution of) and, subject to Section 2.1(b), market the Product in all countries in the Territory in which Marketing Approval for the Product has been granted. Centocor will participate in promotional support and educational support activities with respect to the Product in the Territory in a manner to be discussed and approved from time to time by the Product Committee.

(b) Co-Promotion of the Product in the Territory. If, at the conclusion of the third full Agreement Year after both of the milestones set forth in Section 3.3 have been achieved, Net Sales of the Product in the Territory are less than [***] in that third full Agreement Year, Centocor shall thereafter have the option to co-promote the Product with Schering-Plough, using its own resources or resources contracted from others, in the Core Co-Promotion Territory. Centocor may exercise its co-promotion option by providing written notice to Schering-Plough to that effect; provided, however, that Centocor's co-promotion option will expire on the last day of the [***] full Agreement Year after the milestones set forth in Section 3.3 have been achieved. Upon exercising the co-promotion option, Centocor shall be obligated to perform fifty percent (50%) of the details (as determined by the Product Committee) in the Core Co-promotion Territory. Centocor's co-promotion option shall be contingent upon Centocor having in place at the time the option is exercised an adequate field sales force to perform such activities. The remaining terms pursuant to which Centocor and Schering-Plough will co-promote the Product should this contingency arise, including the potential expansion of the Core Co-Promotion Territory, will be determined by the Product Committee, subject to the terms of Section 6.2(e)(iii). If one or both of the milestones set forth in Section 3.3 are not achieved but the Product nevertheless has received Marketing Approval and has been sold for Crohn's Disease and rheumatoid arthritis indications for three full Agreement Years in the Core Co-promotion Territory and Net Sales in the Territory in that third full Agreement Year are less than [***], the Product Committee shall discuss whether Centocor should have the option to co-promote the Product, at a minimum in the Core Co-promotion Territory and possibly in other countries in the Territory.

(c) Other Indications. The parties, through the Product Committee, may from time to time consider development of the Product for indications other than Inflammatory Bowel Disease or rheumatoid arthritis. In the event that the Product Committee determines to pursue the development of the Product for any such other indication, the parties will share [***] the Product Development Costs for such new indication incurred after the date of the Product Committee's determination. Following Regulatory Approval, Schering-Plough shall have the exclusive rights in the Territory to market, promote, distribute, offer for sale and sell the Product for such new indications. In the Territory, the Contribution Income split with respect to Commercial Sales for such new

indication will be as set forth in Section 6.2.

For any such new indications, Centocor may, at its discretion, grant to Schering-Plough's United States Affiliate, Schering Corporation, an option to co-promote the Product in the United States for any such new indication. Such option must be exercised by providing written notice to Centocor no later than ninety (90) days after the successful completion of one or more Phase II clinical trials establishing proof of efficacy for the Product for such indication which supports undertaking a Phase III clinical study. During the ninety (90) day period prior to the date Schering Corporation must exercise the option, Schering Corporation will conduct any due diligence review reasonably necessary to enable Schering Corporation to determine whether or not to exercise its option rights. If Schering Corporation elects to exercise its option, it will make a payment to Centocor or offer to Centocor United States co-promotion rights to a Schering Corporation product. The amount of such payment, or the Schering Corporation product to be co-promoted by Centocor and the terms of such co-promotion by Centocor, will be negotiated at the time Schering Corporation exercises its option. If Schering Corporation elects to exercise its option, the parties will enter into a suitable agreement under essentially the same terms as set forth herein and will share equally the Contribution Income, as that term is defined in Section 6.2, from Commercial Sales in the United States for such new indication; however, in the Territory the Contribution Income split with respect to Commercial Sales for such new indication will be as set forth in Section 6.2. If Schering Corporation elects not to exercise its option, Centocor will retain one hundred percent (100%) of Contribution Income from Commercial Sales in the United States for such new indication.

The parties will discuss in good faith whether the term of this Agreement as set forth in Section $8.1\ \mathrm{will}$ apply or be extended in respect of such new indication.

In the event that, for any reason, the Product Committee cannot agree as to whether or not the Product should be developed for a new indication and one party but not the other would nevertheless like to pursue that indication, the parties will negotiate the terms under which that indication may be pursued and the Product could be developed and commercialized in the Territory for that indication. In so doing, the parties agree as follows:

(i) In the event that Centocor independently proceeds to develop the Product for such indication it shall notify Schering-Plough upon successful completion of the first Phase IIb clinical trial establishing proof of efficacy for the Product for such indication. Schering-Plough shall have sixty (60) days from the date of such notice in which to acquire the rights to such indication in the Territory by reimbursing Centocor for [***] of its out-of-pocket costs for development of such indication, whereupon the parties shall continue the development and commercialization of such indication under this Agreement. If Schering-Plough does not acquire the rights to such indication in the Territory, Centocor or one or more third parties designated by Centocor shall have exclusive rights to sell the Product for such indication in the Territory but only if it is a different formulation or in a different dosage form than the Product the parties are selling under this Agreement and if it is sold under a separate and distinct trademark from that used for the Product in the Territory by Schering-Plough under this Agreement; and Centocor and such third party or third parties shall retain one hundred percent (100%) of the Product revenue derived from such new indication.

(ii) In the event that Schering-Plough independently proceeds to develop the Product for such indication it shall notify Centocor upon successful completion of the first Phase IIb clinical trial establishing proof

of efficacy for the Product for such indication. Centocor shall have sixty (60) days from the date of such notice in which to notify Schering-Plough of its intent to share Contribution Income in the Territory and shall reimburse Schering-Plough for [***] of its out-of-pocket costs for development of such indication, whereupon the parties shall continue the development and commercialization of such indication under this Agreement. If Centocor does not provide such notice to Schering-Plough, Schering-Plough may sell the Product for such indication in the Territory only if it is a different formulation or in a different dosage form than the form of the Product the parties are selling under this Agreement and if it is sold under a separate and distinct trademark from that used for the Product in the Territory by Schering-Plough under this Agreement; and Schering-Plough shall retain one hundred percent (100%) of the Product revenue derived from such new indication. If Schering-Plough proceeds to develop and sell the Product for such new indication, it shall purchase its requirements of Product for the clinical development and commercial sales for such new indication from Centocor, [***], and subject to Centocor's ability to manufacture the Product for such purposes.

 $\hbox{2.2 Schering-Plough's Commercialization Efforts with Respect to the Product.}$

(a) Within the Territory, as to all indications for which Marketing Approval has been obtained, Schering-Plough will market, promote, distribute and sell the Product in accordance with the applicable Country Marketing Plans (as described in Section 4.2) and in a manner consistent with accepted business practices and applicable legal requirements. For purposes of this Agreement, promotion includes, but is not limited to, sales presentations to prescribing physicians by sales representatives which include the use of written promotional materials, presentations at scientific and medical meetings using promotional materials, and other personal and non-personal efforts. Such promotional activities, including detailing, will be carried out through Schering-Plough's sales force, wherever feasible, or third party sales forces contracted by Schering-Plough, the members of which will have received the necessary training and support and have the necessary skills and resources to promote the Product. The number of face-to-face sales presentations by Schering-Plough for the promotion and detailing of the Product in the countries to which the EMEA Approval applies shall be consistent with the level of such activities Schering-Plough would apply to the promotion of its other pharmaceutical products of comparable commercial status, potential and value in such countries. In promoting and detailing the Product, Schering-Plough shall present the Product in the primary position for the approved indication(s), (i.e., Crohn's Disease and/or rheumatoid arthritis) until the commercial launch by Schering-Plough of another product for substantially the same indication(s) developed by Schering-Plough alone or in conjunction with a third party licensor, licensee or collaborator, including, without limitation Interleukin-10 (hereinafter a "Schering-Plough Product"). Commencing with the commercial launch of a Schering-Plough Product, to the extent that the approved indications and patient populations for the Product and such Schering-Plough Product overlap, Schering-Plough shall devote an [***] share of primary details and support, marketing and promotion to the Product and the Schering-Plough Product in the Territory. Activities performed by Schering-Plough with respect to the Product pursuant to this Section, including detailing, advertising and other promotional support, will in any case be consistent with the level of effort Schering-Plough would ordinarily employ for a product with similar market potential, commercial value and status. Centocor shall have the right to audit Schering-Plough's internal call reporting records to ascertain compliance with this Section. Such

audit shall be conducted in the manner set forth in Section 2.2(d).

(b) In the event that Schering-Plough fails to meet its diligence obligations under Section 2.2(a) then Centocor shall have the right to give Schering-Plough written notice thereof stating in reasonable detail the particular failure. Schering-Plough shall have a period of sixty (60) days from the receipt of such notice to correct the failure. Schering-Plough shall, within thirty (30) days of its receipt of such failure notice from Centocor, provide written notice to Centocor setting forth: (i) the steps Schering-Plough is undertaking to cure such failure; or (ii) Schering-Plough's intention to dispute the allegation that it has failed to meet its diligence obligations. If Schering-Plough fails to correct the failure, Centocor shall have the right to terminate this Agreement. In the event of a dispute as to whether or not Schering-Plough has failed to exercise due diligence under Section 2.2(a), such dispute shall be resolved through binding arbitration in accordance with the terms of this Agreement. The time periods set forth in this Section 2.2(b) shall be suspended during the pendency of such arbitration proceedings.

(c) The foregoing obligations of Schering-Plough with respect to development and commercialization of the Product are expressly conditioned upon the continuing absence of adverse conditions or events which, in the aggregate, warrant a delay in commercialization of the Product including, but not limited to, an adverse condition or event relating to safety or efficacy, or unfavorable pricing, pricing reimbursement, labeling or lack of Regulatory Approval. Schering-Plough's obligation to develop and market the Product shall be delayed or suspended so long as in the mutual agreement of the parties any such condition or event exists.

(d) Schering-Plough represents and warrants, on behalf of itself and its Affiliates, with respect to Germany, France, Italy, Spain and the United Kingdom, that the personnel responsible for the performance of its diligence obligations hereunder with respect to the Product in such markets shall constitute a distinct and separate business unit from those personnel who belong to the business unit involved in the development and commercialization of Schering-Plough's INTEGRILIN product(s). For purposes of this Section 2.2(d), the term "business unit" shall refer to the sales personnel, product management staff and support staff responsible for the commercialization of the Product or Schering-Plough's INTEGRILIN products, as appropriate. In those countries in the Territory in which Schering-Plough does not maintain separate business units, Schering-Plough shall use diligent efforts to ensure that its field sales force and medical affairs personnel engaged in marketing and promoting INTEGRILIN do not market and promote the Product. Schering-Plough and its Affiliates shall keep complete and accurate records of its operations in sufficient detail to enable Centocor to confirm the separation of its Product operations from those relating to INTEGRILIN. Upon forty-five (45) days prior written notice from Centocor, Schering-Plough shall permit a firm of independent auditors of nationally recognized standing selected by Centocor and reasonably acceptable to Schering-Plough, at Centocor's expense, to have access during normal business hours to examine pertinent records and facilities of Schering-Plough and/or its Affiliates as may be reasonably necessary to confirm the separation of Schering-Plough's Product and INTEGRILIN operations. An examination under this Section 2.2(d) shall not occur more than once in any calendar year. Schering-Plough may designate competitively sensitive information which such auditors may not disclose to Centocor, provided, however, that such designation shall not encompass the auditor's conclusions. The auditors shall disclose to Centocor only whether Schering-Plough's representations with respect to its operations are correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to Centocor. All such auditors shall sign a confidentiality agreement (in form and substance reasonably acceptable to Schering-Plough) as to any of Schering-Plough's or its

Affiliates' confidential information which they are provided, or to which they have access, while conducting any audit pursuant to this Section 2.2(d).

2.3 Change in Territory.

- (a) If Centocor [***] from [***] its rights to the Product in [***] and [***] or one or more such countries, Centocor will immediately notify Schering-Plough. Schering-Plough will then have the [***] right to [***] for a [***] period commencing with the date of Centocor's notification to Schering-Plough of the [***] upon which such countries, or any one or more of them if Centocor [***] its rights in less than all of them, should be included in the definition of "Territory" for purposes of this Agreement. In the event Schering-Plough and Centocor reach agreement within such period, the country or countries involved will be included within the definition of "Territory" on the terms and conditions reached by the parties. In the event no agreement is reached within such period, Centocor [***] within such country or countries for [***].
- (b) In the case that Centocor decides to seek an arrangement with another party for co-promotion of the Product in the United States for rheumatoid arthritis indications, Centocor will immediately notify Schering-Plough. Schering-Plough's United States Affiliate, Schering Corporation, will then have the exclusive right to negotiate with Centocor for a [***] period commencing with the date of Centocor's notification to Schering-Plough of the terms and conditions (including payments upon execution of any agreement) upon which Schering Corporation would acquire such rights. In the event no agreement on commercial terms is reached within such period, Centocor will be free to enter into an agreement with another party to co-promote the Product in the United States for rheumatoid arthritis, provided that the terms thereof shall be no less favorable to Centocor than those last offered by Centocor to Schering Corporation.
- 2.4 Non-Compete. During the term of this Agreement, and for a period of [***] years immediately following the termination of this Agreement, Schering-Plough will not promote, market, manufacture, sell or distribute any anti-TNF (alpha) antibody or small molecule mimicking anti-TNF (alpha) antibody activity by binding to the TNF (alpha) receptors known as p55 and/or p75,i.e., having as its main action the direct inhibition of the binding of TNF (alpha) to the TNF (alpha) receptors p55 and/or p75 by binding to TNF (alpha) or such receptors, other than the Product or an Improvement, in the Territory; provided, however, that in the case of any country within the European Union or European Free Trade area, this obligation not to compete shall cease upon termination of this Agreement. If Schering Corporation commences to co-promote the Product in the United States pursuant to either Section 2.1(c) or Section 2.3(b) herein, the terms of this Section 2.4 thereafter shall be applicable to Schering Corporation in the United States. The parties acknowledge that during the term of this Agreement, Schering-Plough may promote, market, manufacture, sell and distribute Interleukin-10 in the Territory.

ARTICLE III

PAYMENTS BY SCHERING-PLOUGH TO CENTOCOR

3.1 Payments upon Execution. Schering Plough will make a non-refundable payment of [***] to Centocor by wire transfer within ten (10)

business days of the Effective Date.

- (a) Twenty million dollars (\$20,000,000) of such payment will be in recognition of the efforts and expenditures by [***] to date.
- (b) [***] of such payment will be in recognition of Centocor's ongoing internal research and development efforts with respect to the Product for the remainder of 1998.
- 3.2 Additional Payments. Schering-Plough will make an additional payment of [***] to Centocor by wire transfer on or before [***].
- 3.3 Milestone Payments. Schering-Plough will pay to Centocor the following non-refundable additional amounts, in each instance by wire transfer within twenty (20) days of Centocor providing written notification of the Product Committee's determination of the occurrence of the event which triggers the payment and an invoice to Schering-Plough:
- (a) [***] upon the first EMEA Approval for therapeutic use of the Product for the treatment of patients with Crohn's Disease, including labeling consistent with that sought by Centocor in its initial EMEA application as set forth on the attached Appendix C (i.e., to reduce signs and symptoms in patients with moderate to severe disease activity for whom conventional therapies are inadequate and to close enterocutaneous fistulae, or similar wording that does not further restrict the patient population which may be treated as a result of such labeling).
- (b) [***] upon the Product receiving EMEA Approval for therapeutic use in the treatment of rheumatoid arthritis (i.e., for the reduction of signs and symptoms of rheumatoid arthritis in patients who have an inadequate response to methotrexate with no restriction as to disease severity, or similar wording that does not further restrict the patient population which may be treated as a result of such labeling).
- (c) The foregoing notwithstanding, no milestone payment will be due under Sections 3.3(a) or 3.3(b) to the extent that the Product is subject to [***]. For this purpose, [***] shall mean an [***]. The parties agree that the language in [***] does not constitute a [***] which would preclude payment of the milestones under Sections 3.3(a) and 3.3(b). If either milestone is not initially paid because of [***], such milestone will subsequently be paid in accordance with Section 3.3(a) or 3.3(b) if [***].

ARTICLE IV

COMMITTEES AND MARKETING PLANS

 $\,$ $\,$ To facilitate the achievement of their commercialization objectives, the parties agree as follows.

4.1 Committees. Within thirty (30) days following the Effective Date, the parties will establish a Product Committee and an Oversight Committee.

(a) Product Committee. The Product Committee shall have overall responsibility to monitor, coordinate and oversee the parties' activities relating to the Product in the Territory, including, without limitation, the specific responsibilities set forth in Sections 4.1(a)(i) and 4.1(a)(ii). Each party will appoint three (3) representatives to the Product Committee, or such greater number as the Product Committee may determine from time to time; provided that two (2) representatives from each party shall constitute a quorum. These representatives shall have appropriate technical credentials and knowledge, and shall be senior representatives selected from each of the following areas: clinical development, marketing/general management and regulatory. Each party from time to time may substitute one or more of its representatives, in its sole discretion, effective upon notice to the other party of such change. The Product Committee may from time to time and in its sole discretion create ad hoc sub-committees and delegate certain aspects of its responsibilities to such sub-committees.

The Product Committee will meet on a quarterly basis, or more frequently if necessary, at mutually agreeable times and locations, to discuss any matters or issues involving the Product, including, but not limited to, matters arising under Sections 4.1(a)(i) and 4.1(a)(ii), the manufacture of the Product and the ways and means of most effectively implementing this Agreement. The Product Committee shall be co-chaired by a representative of Centocor and a representative of Schering-Plough. The Co-Chairpersons shall be responsible for calling meetings, preparing agendas and preparing and issuing minutes of each meeting within thirty (30) days thereafter. Meeting minutes will be countersigned by a Product Committee representative from each of Schering-Plough and Centocor. All decisions of the Product Committee shall be made with a quorum of the members present, and shall be based on an unanimous vote with Schering-Plough and Centocor each having one (1) vote.

Additional non-voting representatives or consultants may from time to time be invited by either party to attend and participate in Product Committee meetings (e.g., to evaluate and advise on business or scientific issues). Each party shall ensure that any of its third party consultants attending a Product Committee meeting have entered into a suitable agreement containing confidentiality and non-use provisions substantially the same as those contained in this Agreement.

In September or October of each Agreement Year, the Product Committee will hold an annual planning meeting to review and comment on the Country Marketing Plans, and to approve the clinical development plans and the budget for the following year. If at any time agreement is not reached within the Product Committee, the matter in question will be referred to the Oversight Committee should either party deem it to be of sufficient importance to warrant a further effort to reach agreement.

(i) Clinical Development and Regulatory Approvals. Centocor will have primary responsibility for the conduct of pre-clinical studies, clinical trials and regulatory submissions. Nevertheless, the Product Committee will review and discuss the Product's clinical and regulatory development including, but not limited to, the design and implementation of clinical trials, budgets, the content and status of regulatory filings and approvals, and Adverse Event Reports. Communications between the parties concerning such matters will be directed through the parties' representatives to the Product Committee or their designees.

(ii) Marketing. Subject to Section 2.1(c), the Product Committee will also discuss indications for which Regulatory Approvals will be

sought, the countries in which Regulatory Approval will be sought, and the promotion, detailing, marketing, distribution and sales of the Product including, but not limited to, the Country Marketing Plans and selected core Marketing Materials (hereinafter defined). Communications between the parties concerning such matters will be directed through the parties' representatives to the Product Committee or their designees.

(b) Oversight Committee/Dispute Resolution. The parties will also establish an Executive Oversight Committee (the "Oversight Committee") consisting of two (2) senior management representatives of each party. The initial representatives of the Oversight Committee will be:

Centocor Schering-Plough

Joseph C. Scodari Thomas C. Lauda Harlan F. Weisman, M.D. Jonathan R. Spicehandler, M.D.

The Oversight Committee will meet as necessary, but no less than one time per year at mutually agreeable times and locations to discuss strategic issues of interest to the parties and to resolve disputes arising under this Agreement, including those referred to it by the Product Committee. Decisions by the Oversight Committee will be made by the unanimous consent of its members. In the event that the Oversight Committee fails to resolve any dispute, then either party may submit such dispute to binding arbitration in accordance with the terms of Section 12.7.

4.2 Marketing Plans. Schering-Plough will prepare Country Marketing Plans for each country (or, where appropriate, groups of countries) within the Territory substantially in the form set forth in Appendix D (the "Country Marketing Plans"), and will present the Country Marketing Plans for the United Kingdom, Canada, Germany, France, Italy and Spain, as well as the Schering-Plough Strategic Marketing Plan, to the Product Committee for comment. Each Country Marketing Plan will establish the strategy and tactics designed to maximize Commercial Sales in that country or group of countries. To enable Schering-Plough to coordinate its marketing efforts in the Territory, Centocor will present information regarding its U.S. marketing plans to the Product Committee, provided, however that Schering-Plough may not provide any of such information to any line management (excluding executive management) employee of Schering Corporation or any of its Affiliates who are engaged in any effort relating to the commercialization of Interleukin-10 in the United States.

4.3 Marketing and Promotional Materials; Trademarks; Labels.

(a) Marketing Materials. Schering-Plough will have primary responsibility for the preparation of all Product marketing and promotional materials (collectively, the "Marketing Materials") for use in the Territory. However, selected core Marketing Materials, i.e., those prepared by or on behalf of Schering-Plough's Global Marketing group for use throughout the Territory, will be submitted to the Product Committee for its review and comment. Schering-Plough acknowledges that Centocor, as the license holder, is responsible for regulatory compliance as it relates to all aspects of the Product, including compliance with regulations relating to promotional materials. Notwithstanding this fact, under the terms of this Agreement, Centocor assigns responsibility to Schering-Plough to ensure that its local Affiliates are in compliance with all local laws and regulatory requirements governing promotional materials in the Territory. In addition, for the United Kingdom, Canada, Germany, France, Italy and Spain, Schering-Plough will provide copies of primary sales aids and journal advertisements intended for use in these markets to Centocor's regulatory affairs department for its review and approval as to their compliance with regulatory requirements. Centocor will review and approve these marketing materials in a timely manner (generally not

to exceed three (3) business days). Schering-Plough indemnifies Centocor for any damages resulting from regulatory non-compliance in those circumstances where Centocor's regulatory affairs department has not undertaken a prior review. Centocor retains the right to audit Schering-Plough's compliance with local laws and regulations regarding promotion. Such audit shall be conducted in the manner set forth in Section 2.3(d).

(b) Trademarks. Centocor has applied for the AVAKINE trademark for the Product in the United States and in certain countries in the Territory (the "Trademark"). Centocor shall be responsible for filing, prosecuting, registering, maintaining and protecting the Trademark in all countries in the Territory. Schering-Plough recognizes that the Trademark is a trademark of Centocor and that Schering-Plough has no right or interest in the Trademark other than those rights explicitly granted in this Agreement. Centocor hereby grants to Schering-Plough the royalty-free right, exclusive even as to Centocor, to use during the term of this Agreement, the Trademark in the Territory for the purpose of co-promoting, marketing, selling and distributing the Product purchased by Schering-Plough from Centocor under the terms of this Agreement. To the extent that Schering-Plough is processing, packaging and labeling the Product pursuant to Section 5.1, Centocor further grants to Schering-Plough the right to use the Trademark for the purpose of processing, packaging and labeling the Product for use in the Territory. If Centocor commences co-promotion of the Product in the Core Co-promotion

Territory and any other countries in the Territory pursuant to Section 2.1(b), Schering-Plough shall grant back to Centocor the right to use the Trademark in those countries for the purposes of co-promoting the Product. All rights of Schering-Plough under this Section will terminate immediately upon the termination or expiration of this Agreement.

When packaged for sale in the Territory, the Product will bear the Trademark, the Schering-Plough trade dress and the name and/or logo of the appropriate Schering-Plough local entity as permitted under applicable laws and regulations. Schering-Plough will assist Centocor as may be necessary (including by executing any necessary documents) in recording Schering-Plough as a licensee of any registration of the Trademark and Schering-Plough hereby agrees that such recording may be cancelled by Centocor on termination of this Agreement for whatever reason and that it will assist Centocor to the extent reasonably necessary to achieve such cancellation including by executing any necessary documents.

In the event that the Trademark cannot be used in one or more countries in the Territory, or if it is agreed by the Product Committee that a different trademark is to be used other than or in addition to the Trademark in any country in the Territory, then the parties shall agree on a trademark and Centocor shall determine the availability and shall diligently file for and prosecute such trademark, which shall thereafter be treated as the Trademark for the purposes of this Agreement. If the trademark selected by the parties is already owned by Schering-Plough, then the parties shall enter into a suitable agreement pursuant to which Schering-Plough shall assign all of its rights, title and interest in and to said trademark to Centocor in return for a payment of [***]. If the trademark is acquired from a third party, then Centocor shall be responsible for acquiring said trademark.

(c) Labels. When offered for sale in the Territory, the Product will be packaged with Schering-Plough trade dress and, to the extent permitted by local regulatory requirements, will include the Schering-Plough logo and/or name of the appropriate Schering-Plough local entity. The labeling will state that the Product is manufactured by or on behalf of Centocor. Where permissible, such labels will give equal prominence to the Centocor and Schering-Plough names.

ARTICLE V

SUPPLY OF PRODUCT

5.1 Purchase and Supply. Centocor agrees to supply to Schering-Plough, and Schering-Plough agrees to purchase from Centocor all of Schering-Plough's requirements of the Product for Commercial Sales. Centocor further agrees to supply all quantities of Product for use as free samples or for compassionate use programs in the Territory, which quantities shall be provided to Schering-Plough by Centocor [***].

Product supplied by Centocor to Schering-Plough for Commercial Sales will be in final labelled and packaged vials. Alternatively, Schering-Plough shall have the option, exercisable by providing written notice to Centocor, to purchase its requirements for Product from Centocor in the form of bulk Product and to perform the final processing, packaging and labeling of such material into finished Product for Commercial Sales in the Territory. Such option shall only be exercisable by Schering-Plough if Schering-Plough can reasonably demonstrate that the parties will enjoy a net financial benefit or that it is cost neutral to the parties for Schering-Plough to perform such activities. If Schering-Plough exercises its option to perform such activities, Schering-Plough's cost of performing such activities will be included in [***]

as if Centocor had incurred such costs and delivered finished Product to Schering-Plough.

Within ninety (90) days of the Effective Date, the parties will negotiate and enter into a separate Manufacture and Supply Agreement more fully setting forth the terms under which Product will be manufactured for and supplied to Schering-Plough by Centocor, the terms of which shall conform to the terms of this Agreement. The Manufacture and Supply Agreement will be appended to this Agreement as Appendix E.

5.2 Manufacturing. Centocor will manufacture the Product and use diligent efforts to satisfy Schering-Plough's requirements for the Product. All Product manufactured for Schering-Plough for use and/or sale in the Territory shall be manufactured in an approved facility. Centocor shall provide to Schering-Plough, concurrently with each shipment of Product supplied to Schering-Plough under this Agreement (whether in the form of finished Product or in bulk) a Certificate of Analysis setting forth the analytical results and specifications for the batch. In order to ensure the required supply of Product for sale pursuant to this Agreement, Centocor may contract with a third party acceptable to Schering-Plough to manufacture the Product.

In the event that Schering-Plough elects to exercise its option under Section 5.1 to purchase the Product in bulk, Centocor shall cooperate with and provide reasonable assistance to Schering-Plough, at Schering-Plough's expense, to make available to Schering-Plough any Product specific know-how necessary to enable Schering-Plough to perform the final processing and packaging of the Product in its facilities and to obtain any necessary regulatory or manufacturing approvals for such facilities.

5.3 Forecasts. Beginning on a date to be determined by the Product Committee and within ten (10) business days following the end of each calendar quarter thereafter during the term of this Agreement, Schering-Plough will supply to Centocor, for planning purposes, a non-binding twenty-four (24) month rolling forecast of projected requirements in units of Product for Commercial Sales in the Territory broken down by country or groups of countries. The forecast may be expressed in terms of a reasonable range. Centocor will promptly notify Schering-Plough if it anticipates that it will be unable to meet any portion of the forecasted requirements. In the event of a temporary shortfall, Centocor's available supplies of Product will be allocated proportionately according to Centocor's forecasted demand for the United States on one hand and

Schering-Plough's forecasted demand for the Territory on the other hand. The allocation will be monitored by the Product Committee and will end as soon as supply permits.

- 5.4 Firm Orders; Inventory Levels. Schering-Plough will provide orders for Product to Centocor at least [***] days prior to requested date of shipment. Schering-Plough will consolidate the orders for itself and its Affiliates. Within fourteen (14) days of receipt of an order, Centocor will send to Schering-Plough a written confirmation of such order, at which point such order will be binding upon Schering-Plough and Centocor. In determining the amount of its orders, Schering-Plough will order such quantities as are necessary to maintain at all times a minimum inventory of Product sufficient to fulfill Schering-Plough's next [***] months expected requirements of the Product for Commercial Sales. Centocor will use all reasonable efforts to ensure dispatch to Schering-Plough of the requisite quantity of Product to fulfill such orders.
- 5.5 Terms. All shipments of Product to Schering-Plough will be F.C.A. (Incoterms 1990) Centocor's place of shipment, by an approved carrier selected from a list of approved carriers to be agreed upon from time to time by Schering-Plough and Centocor. Shipments will be made to such locations as Schering-Plough directs. Payment terms will be net thirty (30) days, upon receipt of Centocor's invoice, in United States Dollars by wire transfer to Centocor.
- 5.6 Product Recall. Schering-Plough will review with Centocor the Schering-Plough product recall procedures and Schering-Plough agrees to maintain and to implement the same, subject to the provisions herein. Schering-Plough and Centocor have the responsibility to notify each other within twenty-four (24) hours of a situation which could lead to a recall or withdrawal of the Product in the Territory. Within forty-eight (48) hours after such notice, the parties' representatives from business, medical, regulatory, quality assurance and legal functions, and any others deemed necessary (the "Recall Team"), will consult to determine if any Product shall be withdrawn or recalled from the market. If the Recall Team agrees to conduct a recall, then the Recall Team shall also consult with respect to the timing of the recall, the breadth, extent and level of customer to which the recall shall reach, and what strategies and notifications should be used. If agreement as to whether a recall should be conducted cannot be reached between the Schering-Plough and Centocor representatives on the Recall Team, the Oversight Committee shall be immediately consulted. If the Oversight Committee cannot agree, then the party holding the marketing authorizations for the Product in the Territory shall have final decision making authority with respect to any recall in the Territory and Centocor shall have final decision making authority with respect to countries outside the Territory. The license holder for the Product will be responsible for formal notification of the regulatory authorities; however, Centocor and Schering-Plough will coordinate with each other on the notification of regulatory authorities. In the Territory, Schering-Plough will be responsible to implement any Product withdrawal or recall from the market.
- (a) In the event that any Product recall or withdrawal occurs in the Territory as a result of adverse event or other safety reasons for which neither Centocor nor Schering-Plough are at fault, the parties shall share equally all reasonable costs and expenses of such Product recall or withdrawal in the Territory, including, without limitation, the expenses incurred for the investigation, notification, regulatory reporting, destruction and/or return of the recalled Product, the cost of the manufactured Product recalled, Schering-Plough's costs relating to the testing, packaging, shipping and supplying the Product recalled, expenses or obligations to third parties, and the cost of notifying users (hereinafter the "Recall Expenses"). For purposes of calculating Recall Expenses under this Section 5.6(a) and under Sections 5.6(b) and (c), Centocor shall issue a credit to Schering-Plough for the full cost paid

by Schering-Plough to Centocor for the manufactured Product recalled, and that cost of the manufactured Product recalled shall be included in Recall Expenses at Centocor's cost of goods. Centocor and Schering-Plough each acknowledge that the obligations of the other under this Section do not extend to expenses or obligations of either to third parties or to any claim by either for loss of anticipated profits, goodwill, reputation, business receipts or contracts, or losses or expenses resulting from third party claims or for any indirect or consequential losses suffered by either, howsoever caused, and each hereby waives any claim to such expenses or losses or which may arise as a result of any such obligations.

- (b) In the event that any Product recall occurs as a result of (i) a breach of this Agreement by Centocor, or (ii) any wrongful act or omission whether negligent or otherwise of Centocor, Centocor will bear all reasonable Recall Expenses incurred by Schering-Plough. Recall Expenses under this Section 5.6(b) shall be calculated as set forth in Section 5.6(a). Schering-Plough acknowledges that Centocor's obligations under this Section do not extend to expenses or obligations of Schering-Plough to third parties or to any claim by Schering-Plough for loss of anticipated profits, goodwill, reputation, business receipts or contracts, or losses or expenses resulting from third party claims or for any indirect or consequential losses suffered by Schering-Plough, howsoever caused, and hereby waives any claim to such expenses or losses or which may arise as a result of any such obligations.
- (c) In the event that any Product recall occurs as a result of (i) a breach of this Agreement by Schering-Plough, or (ii) any wrongful act or omission, whether negligent or otherwise of Schering-Plough, Schering-Plough will bear all reasonable Recall Expenses incurred by Centocor. Recall Expenses under this Section 5.6(c) shall be calculated as set forth in Section 5.6(a). Centocor acknowledges that Schering-Plough's obligations under this Section do not extend to expenses or obligations of Centocor to third parties or to any claim by Centocor for loss of anticipated profits, goodwill, reputation, business receipts or contracts, or losses or expenses resulting from third party claims or for any indirect or consequential losses suffered by Centocor, howsoever caused, and hereby waives any claim to such expenses or losses or which may arise as a result of any such obligations.
- $5.7\,$ Product Warranties. Centocor warrants good title to the Product and warrants that upon delivery of Product in accordance with this Agreement, the Product:
- (a) will have been manufactured, stored and shipped in accordance with all applicable good manufacturing practices, all other applicable laws, rules, regulations and regulatory requirements in the country of manufacture and in the Territory, and will conform to the specifications set forth in Appendix F;
- (b) shall not be adulterated or misbranded as provided for under any applicable law, order or regulation in effect in the country of manufacture and the Territory;
- (c) shall conform to the specifications for the Product in the then current Regulatory Approvals of each country in the Territory;
- (d) shall, when stored at 2-8 degrees Celsius, have a shelf life of at least [***] months from the completion of lyophilization and shall be delivered within [***] days of the completion of lyophilization; and
- (e) will be labeled, packaged and shipped in accordance with labeling, packaging and distribution standards mutually agreed upon by the parties and in accordance with all applicable laws and regulatory requirements

in the Territory; provided that where Schering-Plough is responsible under the terms of this Agreement for obtaining any Regulatory Approval, any requirements for labeling and packaging of the Product specified in such approvals have been fully communicated to Centocor.

EXCEPT FOR THE FOREGOING WARRANTIES, CENTOCOR MAKES NO OTHER WARRANTIES AS TO THE PRODUCT, EITHER EXPRESS OR IMPLIED, AND SPECIFICALLY, MAKES NO IMPLIED WARRANTY AS TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

5.8 Inspection and Right of Return of Product. If Schering-Plough determines upon receipt and inspection of the Product that any of the Product does not meet any of the standards warranted in Section 5.7, Schering-Plough will notify Centocor of the non-conformance within forty-five (45) days of receipt of shipment; provided, however, that if the defect is a Hidden Defect, Schering-Plough will notify Centocor of the non-conformance within fifteen (15) days of Schering-Plough's discovery of the defect. Centocor and Schering-Plough will confer on the matter and, within fifteen (15) days after receipt of Schering-Plough's notice, Centocor will notify Schering-Plough as to whether or not it concurs with Schering-Plough's determination. If Centocor concurs with Schering-Plough's determination (or fails to timely notify Schering-Plough of a disagreement with the determination), Centocor will replace the rejected Product, free of charge, as soon as practicable thereafter, and in any event within forty (40) days after receipt of Schering-Plough's notice, and Schering-Plough will, at Centocor's request and expense, return the rejected Product. If Centocor timely disagrees with Schering-Plough's determination, the parties will attempt to resolve the issue in accordance with the provisions of Section 4.1(b). If Schering-Plough does not provide a notice of non-conformance within forty-five (45) days of receipt of shipment (or within fifteen (15) days after Schering-Plough's discovery of a Hidden Defect), Schering-Plough will not have the right to return the shipment pursuant to this Section. Except as set forth in this Section and in Section 5.7 and Section 10.1, Centocor will have no obligation to Schering-Plough for breach of any of the warranties as to the quality of the Product set forth in Section 5.7. For purposes of this Section, "Hidden Defect" means a defect which prevents use of the Product for its normal application and which could not have been discovered by Schering-Plough upon routine inspection following its receipt of the Product.

ARTICLE VI

PAYMENTS BASED ON SALES; OTHER PAYMENTS

- 6.1 Centocor Sales to Schering-Plough. The parties estimate that the initial price per vial will be [***] of the forecasted average Schering-Plough net selling price for sales of the Product in the Territory, which forecasted average net selling price will be determined by Schering-Plough will be communicated to Centocor by Schering-Plough. From time to time the Product Committee will review the transfer price and adjust it as necessary. For this purpose, the unit at the outset of Commercial Sales is a vial containing one hundred milligrams (100 mg) of active ingredient Product.
- 6.2 Division of Contribution Income. The parties will divide Contribution Income in the manner provided herein and in Section 2.1(b).
- (a) "Contribution Income" is defined as [***] less (i) Marketing Expenses, (ii) [***] expenses (including [***] and [***] and (iii) [***] where [***] equals [***] less (A) Cost of Goods Sold, (B) all [***] on account of the Product in an aggregate amount not to [***], (C) all [***] and (D) Cost of a [***].
- $\,$ (i) A list of third party agreements providing for the payment of royalties, as of the Effective Date, is attached as Appendix G. For purposes of

calculating Contribution Income, [***] pursuant to subpart (B) above will not include any [***] in excess of [***]. The parties agree that Centocor shall have the right to [***]. Except as agreed by the parties, no other [***] associated with [***] shall be included in the calculation of Contribution Income. As of the Effective Date, Centocor shall not enter into any other additional agreements with third parties that include provisions requiring the payment of license fees, milestones, royalties or other payments relating to commercialization of Product in the Territory without the prior written approval of Schering-Plough.

(ii) For purposes of calculating Contribution Income, Marketing Expenses and [***] expenses do not include [***] such as [***] or [***] incurred with respect to [***] or [***] or [***] incurred by the parties, except as specified in Section 1.11. Each party will bear the [***] and [***] incurred with respect to [***], except as specified in Section 1.11. Expenses related to [***] will be borne by [***] and will be [***].

(iii) As set forth in Section 6.3, Product Development Costs are excluded from Contribution Income. Also excluded from the Contribution Income calculation is the cost of Product supplied by Centocor to Schering-Plough in the Territory for distribution as free samples or for compassionate use programs pursuant to Section 5.1.

(b) For purposes of documenting Marketing Expenses and [***] expenses which are included in the Contribution Income calculation, each party will maintain adequate and reasonable records containing information to quantify the activities and costs and qualify the activities under the programs approved in accordance with Article IV; and will provide the other party's independent representative access to such records in accordance with Section 6.4. To enable Centocor to comply with its quarterly financial reporting obligations, Schering-Plough will provide to Centocor on a monthly basis no later than ten (10) business days after the end of each month its actual Net Sales for such month. In addition, Schering-Plough will provide to Centocor on a quarterly basis no later than fifteen (15) business days after the end of each calendar quarter, or with respect to the fourth calendar quarter in any calendar year within thirty (30) days of the last day of such calendar year, a summary of its actual Net Sales and an estimate of its Marketing Expenses and [***] expenses for that quarter, and estimates of Net Sales, Marketing Expenses, and [***] expenses for the next calendar quarter.

(c) Contribution Income with respect to any Agreement Year is to be divided [***] to Schering-Plough and [***] to Centocor on the first [***] of Net Sales in such Agreement Year. For Net Sales in excess of [***] in each Agreement Year, Contribution Income is to be divided [***] to Schering-Plough and [***] to Centocor. An example of the quarterly Contribution Income Calculation is set forth in Appendix H.

(d) The calculation of Contribution Income will commence at the time of the first Commercial Sale in the Territory. On or after the date which is sixty (60) days prior to that first Commercial Sale, the [***] incurred in any country in the Territory will be [***] in the calculation of the Contribution Income. Expenses relating to [***] will be [***] the calculation of Contribution Income from the time they have been [***]. Expenses relating to [***] incurred after the Effective Date will be [***] the calculation of Contribution Income.

follows:

(i) Within forty-five (45) days after the end of each calendar quarter (or portion thereof), the parties will calculate and agree upon the amount of Contribution Income for that quarter and Centocor will remit to Schering-Plough, or Schering-Plough will remit to Centocor, upon submission of an invoice, a quarterly equalization payment within thirty (30) days of receipt of such invoice.

(ii) If, for any period, the Contribution Income calculation results in a net loss, the parties will share the loss in the same proportions that they share Contribution Income.

(iii) Notwithstanding the foregoing, to the extent that Centocor is co-promoting the Product in one or more countries in the Territory pursuant to the provisions of Section 2.1(b), then commencing in the calendar quarter of the Agreement Year in which Centocor begins co-promoting the Product in the Territory, the division of Contribution Income will be [***] to Schering-Plough and [***] to Centocor solely with respect to Contribution Income attributable to Net Sales in the country or countries in which Centocor is co-promoting the Product.

6.3 Product Development Costs. All Product Development Costs are expressly excluded from the Contribution Income sharing concept and, subject to Section 2.1(c) above, shall be shared by the parties as follows.

(a) Subject to variances in patient accrual rates, the parties agree that the anticipated budget for Product Development Costs in calendar year 1998 shall not exceed [***]. The parties further agree that, subject to variances in patient accrual rates, the anticipated budget for Product Development Costs in calendar year 1999 for the clinical trials already in progress or ready to be started and for the ACCENT study is estimated at [***]. Schering-Plough shall make a payment of [***] to Centocor by wire transfer on or before June 30, 1999. Schering-Plough's obligation to pay for Product Development Costs incurred during 1998 and 1999 with respect to such studies shall be capped, unless the Product Committee elects to initiate additional clinical studies during such calendar years or the Product Committee otherwise approves additional Product Development Costs to be incurred in such calendar years. To the extent that either party exceeds the agreed upon budgeted Product Development Costs for such activities without the prior written approval of the Product Committee, such party shall be solely responsible for such excess expenditures which shall be excluded from Product Development Costs.

(b) In each successive Agreement Year after 1999 during the term of this Agreement, the parties shall agree upon a budget setting forth the estimated Product Development Costs for their respective development activities. To the extent that either party exceeds the agreed upon budgeted Product Development Costs for such activities without the prior written approval of the Product Committee, such party shall be solely responsible for such excess expenditures which shall be excluded from the calculation of any Excess Amount under Section $6.3 \, (c)$.

(c) Within thirty (30) days following the end of each calendar quarter, each party will provide a written summary to the other party of its respective Product Development Costs for such calendar quarter. Such summary will include adequate and reasonable information to quantify the activities and costs and qualify the activities under the programs approved in accordance with Article IV. With respect to any such calendar quarter, the

amount by which the total of one party's Product Development Costs exceeds the total of the other party's Product Development Costs is referred to herein as the "Excess Amount," and the party whose total Product Development Costs are less than the other party's total Product Development Costs is referred to herein as the "Paying Party." Commencing in calendar year 2000, within sixty (60) days following the end of each calendar quarter, upon submission of an invoice, the Paying Party will pay to the other party an amount equal to one-half of the Excess Amount for such calendar quarter.

(d) With respect to calendar years 1998 and 1999 in the aggregate, Schering-Plough will not be required to pay Centocor unless the Product Committee has approved spending of total Product Development Costs in excess of [***] and [***] of the Excess Amount payable by Schering-Plough is greater than [***], in which event Schering-Plough will pay Centocor the amount by which [***] of the Excess Amount exceeds [***]. If the total of both parties' Product Development Costs is [***] or less and [***] of the Excess Amount is less than [***], then (1) if Schering-Plough would otherwise be the Paying Party as defined above, Schering-Plough shall make no payment to Centocor and Centocor shall pay Schering-Plough the amount by which [***] exceeds [***] of the Excess Amount; and (2) if Centocor is the Paying Party as defined above, Centocor shall pay Schering-Plough [***] plus [***] of the Excess Amount. The parties will within thirty (30) days after the end of calendar year 1999 exchange information relating to Product Development Costs for 1998 and 1999, determine whether any payment is due from one party to the other party under this Section 6.3(d), and issue an appropriate invoice to the party owing such payment, if any. Any such payment shall be made within sixty (60) days after the end of calendar year 1999.

6.4 Access to Information. Each party will have the right, upon forty-five (45) days prior written notice and during normal business hours, through an independent third party representative (who will agree to be bound by confidentiality provisions substantially similar to those set forth in Sections 11.1 and 11.2 hereof), to review and inspect the other party's books and records which relate to such other parties's operations under this Agreement including, but not limited to, records concerning Commercial Sales, Net Sales, Product Development Costs, [***], sales presentations, [***], and other costs. The inspection shall be limited to pertinent books and records for any year ending not more than [***] months prior to the date of such request. An inspection under this Section 6.4 shall not occur more than once in any calendar year. The party whose records are being inspected may designate competitively sensitive information which the representative may not disclose to the other party, provided, however, that such designation shall not encompass the representative's conclusions. Such representative shall only report inaccuracies in amounts payable under this Agreement. With respect to inspection of Schering-Plough's books and records, Schering-Plough may request that an independent auditor familiar with Schering-Plough's record keeping systems be present at the inspection to assist Centocor's auditor in using Schering-Plough's internal record management system. Likewise, with respect to inspection of Centocor's books and records, Centocor may request that an independent auditor familiar with Centocor's record keeping systems be present at the inspection to assist Schering-Plough's auditor in using Centocor's internal record management system. Each party shall bear the costs and expenses of its representative for inspections conducted under this Section, unless a variation or error producing an underpayment in amounts payable exceeding [***] of the amount paid for any period covered by the inspection is established in the course of any such inspection, whereupon all costs relating to the inspection for such period and any unpaid or overpaid amounts that are discovered will be paid or credited as appropriate by the party in whose favor the deviation occurred. This Section will survive the expiration or the termination of the Agreement for a period of two (2) years.

6.5 Currency Translation. For the purpose of computing the Commercial Sales or Net Sales of Product sold in a currency other than United States Dollars, for the purpose of computing costs for calculating Contribution

Income where the costs are incurred in a currency other than United States Dollars, and for the purpose of determining Centocor Product Development Costs or Schering-Plough Product Development Costs which are incurred in a currency other than United States Dollars, such currency shall be converted into United States Dollars at the rates of exchange used by Schering Corporation to report its sales for public, financial reporting purposes. A copy of the current policy used by Schering-Plough and its Affiliates for bookkeeping exchange rates is attached hereto as Appendix I. Schering-Plough shall treat the Product in a manner consistent with its standard practices used for its own products, in order to minimize foreign currency exposure.

6.6 Withholding. If at any time, any jurisdiction within the Territory requires the withholding of income taxes or other taxes imposed upon payments set forth in this Article VI, the party required to make such withholding payment shall make the payment and subtract such withholding payments from the payments set forth in this Article VI. The party required to make any such payment shall provide to the other party documentation of such withholding and payment in a manner that is satisfactory for purposes of the U.S. Internal Revenue Service. Any withholdings paid when due hereunder shall be for the account of the party liable for such taxes and shall not be included in the calculation of Net Sales or Contribution Income. Withholding payments made by either party pursuant to this Section 6.6 shall be made based upon financial information provided to the party making the payment by the other party; to the extent that such information is incorrect, the party providing such information shall be liable for any deficiency, and any fine, assessment or penalty imposed by any taxing authority in the Territory for any deficiency in the amount of any such withholding or the failure to make such withholding payment. If either party is required to pay any such deficiency, or any fine, assessment or penalty for any such deficiency, the party liable for such payment shall promptly reimburse the other party for such payment, which shall not be included in the calculation of Net Sales or Contribution Income.

6.7 Failure to Agree. In the event the parties fail to agree on any payment due from one party to the other under this Agreement, such dispute shall be resolved in accordance with the provisions of Section 4.1(d).

ARTICLE VII

REGULATORY MATTERS

7.1 Regulatory Approvals and Clinical Studies. Prior to the Effective Date, Centocor will fully inform Schering-Plough of, and provide full access to information to Schering-Plough regarding, all Product clinical studies in progress as of the Effective Date. Following the Effective Date, Centocor and Schering-Plough, through the Product Committee, will coordinate such in-progress clinical studies. Centocor and Schering-Plough will, through the Product Committee, jointly propose, develop and coordinate all clinical studies for the Product to be initiated after the Effective Date. In some instances, management of clinical studies may be delegated to Schering-Plough, although Centocor, as the party responsible for obtaining and maintaining Regulatory Approvals, will ultimately be responsible for all pre-clinical and clinical studies. The parties acknowledge their mutual intent that, subject to locally applicable laws in each country of the Territory, Centocor will hold all marketing authorizations in its name. Notwithstanding the foregoing, Centocor shall promptly take all steps necessary to ensure that as of the date of Marketing Approval in each country in the Territory Schering-Plough shall have the right to market, promote, distribute, import, export, offer for sale and sell the Product in the Territory under the Trademark and using Schering-Plough's trade dress (including, without limitation, the transfer of the relevant marketing authorizations to Schering-Plough and/or its designated Affiliate, if necessary).

7.2 Licenses, Filings, Registrations, Permits and Regulatory Approvals. In collaboration with Schering-Plough, Centocor will be responsible for obtaining and maintaining all licenses, registrations, permits and any other required Regulatory Approvals relating to the Product; provided, however, that Schering-Plough, with Centocor's support, will be responsible for obtaining and maintaining those licenses, registrations, permits and regulatory approvals required to be obtained by Schering-Plough to enable Schering-Plough to act as the exclusive distributor of the Product in the Territory pursuant to this Agreement. Each of the parties will cooperate with the other in making all regulatory filings that may be necessary or desirable in connection with the execution, delivery and performance of this Agreement and each will use all reasonable efforts to obtain any regulatory approvals related thereto. To enable Schering-Plough to assist Centocor in obtaining regulatory approvals, Centocor will provide Schering-Plough access to Centocor's regulatory filing documentation, with the exception of the manufacturing master file. On expiration or termination of this Agreement, for whatever reason, Schering-Plough will use all reasonable efforts to effect the transfer of any such licenses, registrations, permits or approvals as may be in its name in relation to the Product to Centocor or such other entity as Centocor may nominate. If the Agreement is terminated upon Schering-Plough's fault, the cost of such transfer will be borne by Schering-Plough. If the Agreement is terminated upon Centocor's fault, the cost of such transfer will be borne by Centocor. In all other cases the cost will be equally shared by Centocor and Schering-Plough.

7.3 Adverse Event Reporting and Drug Safety Information. As the license holder, Centocor will have ultimate responsibility for adverse event reporting and drug safety information in the United States and in those countries in the Territory in which Centocor holds the relevant marketing authorizations. Schering-Plough shall have such responsibility in those countries in the Territory where it holds the relevant marketing authorizations and/or is otherwise required by law to report adverse events. Promptly after the Effective Date, the drug safety departments of Centocor and Schering-Plough shall agree upon suitable protocols and procedures to further delineate each party's obligations with respect to adverse event reporting which shall be incorporated into a separate written agreement of the parties. (The outline of such adverse event reporting and drug safety agreement contained in Appendix J as of the Effective Date will be the basis for finalizing such new agreement, which new agreement will supersede and replace the outline.) In any event, during the term of this Agreement, each party will, within the time periods and in accordance with procedures set forth in Appendix J, notify the other party of all information coming into its possession concerning side effects, injury, toxicity or sensitivity reactions, including unexpected increased incidence or severity thereof, associated with commercial or clinical uses, studies, investigations or tests with the Product, inside or outside the Territory, whether or not determined to be attributable to the Product.

7.4 Communication with Agencies. Centocor, as the party responsible for obtaining and maintaining Regulatory Approvals, will have the primary responsibility for communications with various regulatory agencies but will do so in collaboration with Schering-Plough. Schering-Plough will have the right to have representatives present at all meetings with regulatory agencies in the Territory concerning the Product. The foregoing notwithstanding, to the extent that Schering-Plough holds the market authorizations and Marketing Approvals in a country in the Territory, Schering-Plough shall have primary responsibility for such communications, and will do so in collaboration with Centocor, with Centocor having the right to have representatives present at any meetings with regulatory agencies in such countries concerning the Product. Each party will provide the other with copies of any significant communications (which are known to the party to exist and which the party can obtain copies of) with any regulatory agency throughout the world concerning the Product, including but not limited to reports of Adverse Events, but excluding communications pertaining to or included in the manufacturing master file.

ARTICLE VIII

TERM OF AGREEMENT

8.1 Term. This Agreement is effective on the Effective Date. It will continue for a term of fifteen (15) years from the date of the first Commercial Sale in the Territory, unless earlier terminated pursuant to the provisions of this Agreement.

8.2 Termination.

(a) Breach of Obligation. In the event of a material breach of this Agreement by either party, the non-breaching party will give the breaching party written notice requiring it to remedy such breach. If, after sixty (60) days following such notice, the breach is neither fully remedied nor a plan to remedy it has been agreed by the parties, the non-breaching party will, in addition to having the right to seek an arbitration award under Section 12.7 for any damages to which it may be entitled, be entitled to terminate this Agreement with immediate effect upon written notice thereof to the breaching party.

(b) Insolvency. This Agreement may be terminated by either party upon written notice to the other should the other party (i) become insolvent; or (ii) file a voluntary petition under any bankruptcy or insolvency law; or (iii) have any such petition filed against it which is not stayed within sixty (60) days of such filing; or (iv) has a receiver appointed for its business or property; or (v) makes a general assignment for the benefit of its creditors. Such termination shall be made effective the date notice of termination is given. In the event of Centocor's insolvency, Centocor shall provide to Schering-Plough access to Centocor's drug master file in order to enable Schering-Plough to undertake manufacture of the Product.

(c) Change in Control. If either party is acquired by a third party or otherwise comes under Control (as defined in Section 1.4 above) of a third party, it will promptly notify the other party not subject to such change of control. The party not subject to such change of control will have the right, however not later than thirty (30) days from such notification, to notify in writing the party subject to the change of Control of the termination of the Agreement taking effect immediately. As used herein "Change of Control" shall mean (i) any merger, reorganization, consolidation or combination in which a party to this Agreement is not the surviving corporation; or (ii) any "person" (within the meaning of Section 13(d) and Section 14(d)(2) of the Securities Exchange Act of 1934), excluding a party's Affiliates, is or becomes the beneficial owner, directly or indirectly, of securities of the party representing more than fifty percent (50%) of either (A) the then-outstanding shares of common stock of the party or (B) the combined voting power of the party's then-outstanding voting securities; or (iii) if individuals who as of the Effective Date constitute the Board of Directors of the party (the "Incumbent Board") cease for any reason to constitute at least a majority of the Board of Directors of the party; provided, however, that any individual becoming a director subsequent to the Effective Date whose election, or nomination for election by the party's shareholders, was approved by a vote of at least a majority of the directors then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of a person other than the Board; or (iv) approval by the shareholders of a party of a complete liquidation or the complete dissolution of such party.

8.3 Effect of Expiration and Termination.

- (a) Accrued Obligations. Expiration or termination of this Agreement for any reason will not release any party hereto from any obligation and any liability which, at the time of such expiration or termination, has already accrued to the other party or which is attributable to a period prior to such expiration or termination, nor will it preclude either party from pursuing all rights and remedies it may have hereunder with respect to any breach of this Agreement.
- (b) Outstanding and New Orders. Upon delivery of a termination notice by either party, the parties will seek agreement to what extent outstanding orders, and whether new orders of Schering-Plough addressed to Centocor, will be fulfilled. In any case, Centocor acknowledges (i) that Schering-Plough's supply obligations to its customers will be taken into consideration, and (ii) that Schering-Plough has no obligation to accept delivery of the Product to the extent its ability or authority to import, distribute and/or sell the Product has expired for practical or for legal reasons.
- (c) Stock of Product. Upon expiration of the Agreement and upon termination of the Agreement by either party for any reason other than a material breach by Schering-Plough, to the extent that Schering-Plough then holds in its inventory a quantity of Product the purchase price of which exceeds the value of Centocor's work-in-process and finished inventory of Product intended for shipment to Schering-Plough pursuant to firm orders, Centocor will repurchase or have repurchased by an entity of its choice at the per unit price paid by Schering-Plough to Centocor according to Section 6.1 and under terms analogous to Section 5.5, a quantity of Product such that following such repurchase, the amount paid by Schering-Plough for its remaining inventory of Product will equal the cost of Centocor's work-in-process and finished inventory of Product intended for shipment to Schering-Plough pursuant to firm orders; provided, however, that in no event will Centocor be required to repurchase any inventory with a remaining shelf life of less than twelve (12) months.
- (d) Product Sell Off. Upon expiration or termination of this Agreement for any reason, Schering-Plough shall have the right to continue to sell its existing inventory of Product in the Territory for a period of six (6) months from the effective date of such expiration or termination. The parties will continue to share the Contribution Income arising from any such sales in accordance with the terms of this Agreement. If such termination is the result of a material breach of this Agreement by Centocor, Centocor shall be obligated to repurchase from Schering-Plough all unsold quantities of Product in Schering-Plough's inventory, unless Schering-Plough notifies Centocor in writing at the time of the termination that it elects to sell its existing inventory for a period of six (6) months. If Schering-Plough elects to sell its existing inventory following termination due to a material breach of this Agreement by Centocor, Centocor shall not be obligated to repurchase product with a shelf life of less than [***] months.

ARTICLE IX

REPRESENTATIONS AND COVENANTS

- 9.1 Representations of Centocor. Centocor represents and warrants to Schering-Plough as follows:
- (a) Organization and Good Standing. Centocor is a corporation duly organized, validly existing and in good standing under the laws of the Commonwealth of Pennsylvania.
 - (b) Authority. Centocor has the corporate power to enter into

this Agreement and to carry out the transactions contemplated hereby. The execution, delivery and performance of this Agreement have been duly and validly authorized and approved by all necessary corporate action on the part of Centocor and this Agreement has been duly executed by and constitutes the legally binding obligation of Centocor, enforceable in accordance with its terms (except that such enforcement may be limited by applicable bankruptcy, insolvency, reorganization, moratorium and other similar laws affecting the enforcement of creditors' rights, as from time to time in effect, and general principles of equity). The execution and delivery of this Agreement do not, and the consummation by Centocor of the transactions contemplated hereby will not, violate the provisions of, constitute a default under or give rise to rights of any entity under (i) any laws applicable to Centocor, (ii) Centocor's Articles of Incorporation or bylaws, (iii) any judgment, decree or order of any court or governmental agency applicable to Centocor or (iv) any agreements, contracts or commitments to which Centocor is a party.

- (c) Governmental Consents. Apart from Regulatory Approvals and except for the subjects addressed in Section 12.15, no consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state or local governmental authority is required in connection with the consummation by Centocor of the transactions contemplated by this Agreement.
- (d) Access to Data. Centocor has provided to Schering-Plough for its review all relevant information except certain information relating to the manufacturing of the Product. Centocor has also provided to Schering-Plough details of all adverse events known to it relating to the Product.
- (e) Patent Infringement. To Centocor's knowledge, there exists no valid and enforceable patent owned by a third party which would prevent: (i) the use, manufacture or sale of the Product in the United States or the Territory; or (ii) the import, export, marketing, promotion, distribution, offering for sale or sale of the Product in the Territory by Schering-Plough and/or its Affiliates.
- (f) Centocor Licenses. The consummation of the transactions contemplated by this Agreement by Schering-Plough will not require additional licenses under any third party patent licensed to Centocor.
 - 9.2 Centocor Covenants.
- (a) Centocor covenants to Schering-Plough that it will take such actions as are necessary to enable Schering-Plough to import, export, market, promote, distribute, use and sell the Product in all countries in the Territory, as of the date of Marketing Approval in each such country, under the Trademark and using Schering-Plough's trade dress.
- (b) Centocor covenants to Schering-Plough that: (i) it will comply fully with all laws applicable to Centocor and its activities under this Agreement; and (ii) it will notify Schering-Plough promptly in writing of any material civil, criminal or administrative action brought against Centocor, its directors, officers, employees or agents which is likely to have a material adverse effect on Centocor's pharmaceutical business or Centocor's business reputation, or is likely adversely to affect Centocor's ability to perform its obligations under this Agreement, and promptly to provide Schering-Plough with reasonably detailed information regarding Centocor's handling and disposition of any such action; and (iii) except as mutually agreed by the parties, during the term of this Agreement, it will not enter into any distributorship agreements, marketing arrangements, licenses or similar arrangements granting any third party the right to distribute, market, promote or sell the Product in the Territory.
 - (c) Centocor covenants to Schering-Plough that it will (i)

use diligent efforts not to diminish the rights under "Patent Rights" held by Centocor and/or granted to Schering-Plough hereunder or under the License Agreement attached hereto as Appendix L, including without limitation, by not committing or permitting any actions or omissions which would cause the breach of any agreements between itself and third parties which provide for intellectual property rights applicable to the manufacture, use or sale of the Product, (ii) provide Schering-Plough promptly with notice of any such alleged breach, and (iii) as of the Effective Date, it is in compliance in all material respects with any such agreements with third parties. For purposes of this Section 9.2(c), the term "Patent Rights" shall mean any and all patents and patent applications (which for the purposes of this Agreement shall be deemed to include certificates of invention and applications for certificates of invention) which during the term of this Agreement are owned or controlled by Centocor (wherein control means the ability to grant licenses and/or sublicenses) and have claims covering (A) the Product and/or any Improvements, (B) any materials, methods or processes used in the manufacture of the Product and/or any Improvements, or (C) any methods of use or new indications for the Product and/or Improvements, as well as any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates or the like, of any of the foregoing.

- $9.3\ \mbox{Representations}$ of Schering-Plough. Schering-Plough represents and warrants to Centocor as follows:
- (a) Organization and Good Standing. Schering-Plough is a corporation duly organized, validly existing and in good standing under the laws of Switzerland.
- (b) Authority. Schering-Plough has the corporate power to enter into this Agreement and to consummate the transactions contemplated by this Agreement. The execution, delivery and performance of this Agreement have been duly and validly authorized and approved by all necessary corporate action on the part of Schering-Plough and this Agreement has been duly executed by and constitutes the legally binding obligation of Schering-Plough enforceable in accordance with its terms (except that such enforcement may be limited by applicable bankruptcy, insolvency, reorganization, moratorium and other similar laws affecting the enforcement of creditors' rights generally, as from time to time in effect, and general principles of equity). The execution and delivery of this Agreement by Schering-Plough do not, and the consummation by Schering-Plough of the transactions contemplated hereby will not, violate the provisions of, constitute a default under or give rise to rights of any entity under (i) any laws applicable to Schering-Plough, (ii) the Articles or Certificate of Incorporation or other charter documents or bylaws of Schering-Plough, (iii) any judgment, decree or order of any court or governmental agency applicable to Schering-Plough or (iv) any agreements, contracts or commitments to which Schering-Plough is a party.
- (c) Governmental Consents. Except for the subjects addressed in Section 12.15, no consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state or local governmental authority is required in connection with the consummation by Schering-Plough of the transactions contemplated by this Agreement.
- (d) Access to Data. In entering into this Agreement, Schering-Plough is relying solely upon its independent investigation of Centocor's business and its independent consultation with such professional, legal and accounting advisors as it deems necessary, and is not acting in reliance on any statements, instruments, certificates, documents, representations or warranties other than those contained or referred to in this Agreement.

9.4 Schering-Plough Covenants. Schering-Plough covenants to Centocor that it will: (i) comply fully with all laws applicable to Schering-Plough and its activities under this Agreement; (ii) notify Centocor promptly in writing of any material civil, criminal or administrative action brought against Schering-Plough, its directors, officers, employees or agents which is likely adversely to affect Schering-Plough's ability to perform its obligations under this Agreement, and promptly to provide Centocor with reasonably detailed information regarding Schering-Plough's handling and disposition of any such action; and (iii) except as provided in Section 7.2, not initiate any voluntary communications with regulatory agencies relating to the Product without Centocor's prior consent.

ARTICLE X

INDEMNIFICATION AND INSURANCE

10.1 Centocor Indemnification. Centocor will defend and indemnify Schering-Plough, its Affiliates and their respective directors, officers, employees and agents against all claims, losses, damages, liabilities, and expenses, including reasonable attorneys' fees (collectively "Losses") arising out of or resulting from: (i) any product liability or similar claim relating to the Product (except to the extent any such Losses are caused by the negligence, willful misconduct or illegal acts of Schering-Plough); (ii) any other claim relating to the Product to the extent such Losses are caused by the negligence, willful misconduct or illegal acts of Centocor; (iii) any breach by Centocor of any of its representations and covenants contained in Sections 9.1 and 9.2 hereof; or (iv) any claim of patent or trademark infringement relating to the Product (and in the case of trademark infringement, where Centocor is the holder of the trademark).

10.2 Schering-Plough Indemnification. Schering-Plough will defend and indemnify Centocor, its Affiliates and their respective directors, officers, employees and agents against any Losses arising out of or resulting from: (i) a claim made against Centocor relating to the Product, but only to the extent such Losses are caused by the negligence, willful misconduct or illegal acts of Schering-Plough or any of its directors, officers, employees or agents in connection, in any manner, with the sale, distribution or promotion of the Product by Schering-Plough or other transactions contemplated by this Agreement; (ii) any breach by Schering-Plough of any of its representations and covenants contained in Sections 9.3 and 9.4 hereof; or (iii) any claim of trademark infringement relating to the Product where Schering-Plough is the holder of the trademark.

10.3 Conditions to Indemnification. The obligations of the indemnifying party under Sections 10.1 and 10.2 are conditioned upon the delivery of written notice to the indemnifying party of any potential Losses within sixty (60) days after the indemnified party becomes aware of such potential Losses. The indemnifying party shall have the right to assume the defense of any suit or claim related to the Losses if it has assumed responsibility for the suit or claim in writing; however, if in the reasonable judgment of the indemnified party, such suit or claim involves an issue or matter which could have a materially adverse effect on the business operations or assets of the indemnified party, the indemnified party may waive its rights to indemnity under this Agreement and control the defense or settlement thereof, but in no event shall any such waiver be construed as a waiver of any other indemnification rights such party may have at law or in equity. If the indemnifying party defends the suit or claim, the indemnified party may participate in (but not control) the defense thereof at its sole cost and expense.

Neither party may settle a claim or action related to any Losses without the consent of the other party, if such settlement would impose

any monetary obligation on the other party or require the other party to submit to an injunction or otherwise limit the other party's rights under this Agreement. Any payment made by a party to settle any such claim or action shall be at its own cost and expense.

With respect to any claim by one party against the other arising out of the performance or failure of performance of the other party under this Agreement, the parties expressly agree that the liability of such party to the other party for such breach shall be limited under this Agreement or otherwise at law or equity to direct damages only and in no event shall a party be liable for punitive, exemplary or consequential damages.

10.4 Insurance. During the period of time beginning with the first Commercial Sale and continuing for five (5) years after the expiration or termination of this Agreement, Centocor and Schering-Plough will maintain in force product liability insurance coverage, with commercially reasonable limits adequate to cover their obligations under this Agreement. The insurance obtained by Centocor shall include coverage for products with limits not less than [***] for each claim and in the aggregate. A certificate of insurance shall be provided by Centocor to Schering-Plough promptly after the Effective Date and at each anniversary or renewal date of such insurance. Schering-Plough, as with most major pharmaceutical companies, is largely self-insured for its liability exposures. Schering-Plough's assets are sufficient to cover any contemplated self-insured liability assumed by Schering-Plough under this Agreement.

10.5 Survival. The provisions of this Article X (other than Section 10.3) will survive the termination or expiration of this Agreement.

ARTICLE XI

CONFIDENTIALITY

11.1 Centocor Information. Schering-Plough will maintain in confidence, and will ensure that its Affiliates and its and their consultants, employees, agents and representatives maintain in confidence, all proprietary and confidential information which has been or is provided by Centocor to Schering-Plough, including but not limited to, Centocor's inventions, discoveries, improvements and methods, business plans, marketing techniques or plans, manufacturing and other plant designs, location of operations, and any other information affecting the business operations of Centocor ("Centocor Information"), and will not use for any purpose other than the performance of this Agreement, and will not publish, disseminate, or disclose, in any manner, to any person any Centocor Information unless: (i) Schering-Plough is legally required to do so or is required under rules or regulations of any governmental agency or authority or any stock exchange to be disclosed, provided that Schering-Plough shall, prior to making any such disclosure, give Centocor sufficient advance written notice to permit it to seek a protective order or other similar order with respect to such information and thereafter shall disclose only the minimum information required to be disclosed in order to comply with such law, rule or regulation, whether or not a protective order or other similar order is obtained; (ii) the Centocor Information has entered or enters the public domain through no fault of Schering-Plough; (iii) the Centocor Information was already known by Schering-Plough before receipt from Centocor, or is developed independently by Schering-Plough without breach of this Agreement, in either case as shown by contemporaneous written records; or (iv) the Centocor Information is received by Schering-Plough from a third party under no confidentiality obligation to Centocor.

11.2 Schering-Plough Information. Centocor will maintain in confidence, and will ensure that its Affiliates and its and their consultants, employees, agents and representatives maintain in confidence, all proprietary

and confidential information which has been or is provided by Schering-Plough to Centocor, including but not limited to, Schering-Plough's inventions, discoveries, improvements and methods, business plans, marketing techniques or plans, manufacturing and other plant designs, location of operations, and any other information affecting the business operations of Schering-Plough ("Schering-Plough Information"), and will not use for any purpose other than the performance of this Agreement, and will not publish, disseminate, or disclose in any manner, to any person, any Schering-Plough Information unless: (i) Centocor is legally required to do so or is required under rules or regulations of any governmental agency or authority or any stock exchange to be disclosed, provided that Centocor shall, prior to making any such disclosure, give Schering-Plough sufficient advance written notice to permit it to seek a protective order or other similar order with respect to such information and thereafter shall disclose only the minimum information required to be disclosed in order to comply with such law, rule or regulation, whether or not a protective order or other similar order is obtained; (ii) the Schering-Plough Information has entered or enters the public domain though no fault of Centocor; (iii) the Schering-Plough Information was already known by Centocor before receipt from Schering-Plough, or is developed independently by Centocor without breach of this Agreement, in either case as shown by contemporaneous written records; or (iv) the Schering-Plough Information is received by Centocor from a third party under no confidentiality obligation to Schering-Plough.

11.3 Survival; Specific Performance. The provisions of this Article XI will survive the termination or expiration of this Agreement for a period of ten (10) years. Each party agrees that money damages through arbitration would not be a sufficient remedy for any breach by it of the provisions of this Article XI and that, in addition to any remedy which may be available through arbitration, the non-breaching party will be entitled to apply for and obtain orders for specific performance and injunctive or other equitable relief as a remedy for any such breach from a Court of general jurisdiction in the state, federal judicial district, county or canton (as the case may be) in which the principal place of business of the party in breach is located.

ARTICLE XII

GENERAL PROVISIONS

12.1 Human Anti-TNF Antibodies. In the event Centocor develops a fully human anti-TNF monoclonal antibody through use of transgenic animals or plants or other technology, Centocor shall notify Schering-Plough of such development efforts through the Product Committee. Schering-Plough will have the exclusive right, until such time as Centocor successfully completes a Phase IIb clinical trial establishing proof of efficacy for the new antibody but no earlier than the time at which Centocor makes a milestone or equity payment to a third party licensor due upon initiation of the clinical development of such new antibody, to participate with Centocor in the ongoing clinical development and commercialization of such new antibody. If Schering-Plough elects to participate, it shall reimburse Centocor for [***] of the fully allocated costs (i.e., personnel costs plus out-of-pocket expenses, except that Schering-Plough shall only reimburse Centocor for [***] of any milestones Centocor has paid) incurred to date in the development of such new antibody. If Schering-Plough elects to participate, the new antibody shall be treated as an Improvement to the Product under the terms of this Agreement with respect to the Territory. In the event Schering-Plough elects not to participate, Centocor will be free to market and sell such new antibody product in the United States and the Territory for any and all indications or agree to sell it to one or more other parties for resale in the United States and the Territory for one or more indications. Centocor acknowledges that it is attempting to generate fully human anti-TNF monoclonal antibodies from transgenic mice licensed from [***]. Centocor shall keep Schering-Plough informed through the Product Committee of the progress of that project.

12.2 Force Majeure. Neither party will be liable to the other for failure or delay in the performance of its obligations hereunder, if and to the extent that such failure or delay is attributable to any circumstance beyond its control which it could not have avoided by the exercise of reasonable diligence (hereinafter referred to as "Force Majeure"). The party affected by Force Majeure will provide the other party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities), and will use diligent efforts to overcome the difficulties created thereby and to resume performance of its obligations as soon as practicable. If Force Majeure prevails, or is expected to prevail, for a period of three (3) months or more, the parties will meet to discuss means for overcoming any difficulties, including an amendment to this Agreement to meet the new situation.

12.3 No Agency or Partnership. The parties intend and agree that nothing in this Agreement itself renders either party an agent of the other for any purpose whatsoever and that nothing in this Agreement will be construed as establishing a joint venture or partnership between the parties. Except as otherwise provided herein, without the specific prior written approval of the other party, neither party has authority to, and will not, enter into any contract, make any representation, give any warranty, incur any liability or otherwise act on behalf of the other.

12.4 No Implied Licenses. Nothing in this Agreement is intended to or will be construed to create, confer, give effect to or otherwise imply in Schering-Plough any license, right or property interest in the Product, any Centocor patent, patent application or patent rights, any Centocor trademark or trade name, or any other Centocor property, except as expressly set forth herein. Schering-Plough will not, through any action or inaction, cause any prejudice to or dilution of Centocor's trademark or patent rights (including patent applications). Nothing in this Agreement is intended to or will be construed to create, confer, give effect to or otherwise imply in Centocor any license, right or property interest in any Schering-Plough trademark or trade name except as provided in Section 4.3(b). Centocor will not, through any action or inaction, cause any prejudice to or dilution of Schering-Plough's trademarks.

12.5 Third Party Infringement.

(a) Notice. If either party becomes aware of any infringement or threatened infringement of any patent, trademark or other property right relating to the Product, then the party having such knowledge will give written notice to the other within twenty (20) days of becoming aware of such infringement or threatened infringement. Any such notice shall include evidence to support an allegation of infringement by such third party.

(b) Centocor's Prosecution Rights. Centocor, in consultation with Schering-Plough, will have the right, but not the obligation, to institute, prosecute, and control any action or proceeding with respect to the infringement of patents, trademarks (where Centocor is the holder of the Trademark or a trademark for the Product) or other property right relating to the Product. Centocor shall bear all the expenses of any suit brought by it. Schering-Plough shall have the right, prior to commencement of the trial, suit or action brought by Centocor, to join any such suit or action, and in such event shall pay one-half of the costs of such suit or action. In the event that Schering-Plough has joined in the action and shared in the costs thereof as set forth above, no settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the consent of Schering-Plough. In the event that Schering-Plough has not joined the suit or action, Schering-Plough will reasonably cooperate with Centocor in any such suit or action and shall have the right to consult with Centocor and be represented by its own counsel at its own expense, provided that Centocor shall periodically reimburse Schering-Plough for

its out-of-pocket costs (excluding the costs of retaining its own outside counsel) incurred in cooperating with Centocor. Any recovery or damages derived from a suit which Schering-Plough has joined and shared costs shall be used first to reimburse each of Centocor and Schering-Plough for its documented expenses with respect thereto, with any remaining amounts to be shared equally by the parties. Any recovery or damages derived from a suit which Schering-Plough has not joined shall be retained by Centocor.

(c) Schering-Plough's Prosecution Rights. Where Schering-Plough is the holder of the Trademark or a trademark for the Product, Schering-Plough, in consultation with Centocor, will have the right, but not the obligation, to institute, prosecute, and control any action or proceeding with respect to the infringement of the Trademark or of such trademark for the Product. Schering-Plough shall bear all the expenses of any suit brought by it. Centocor shall have the right, prior to commencement of the trial, suit or action brought by Schering-Plough, to join any such suit or action, and in such event shall pay one-half of the costs of such suit or action. In the event that Centocor has joined in the action and shared in the costs thereof as set forth above, no settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the consent of Centocor. In the event that Centocor has not joined the suit or action, Centocor will reasonably cooperate with Schering-Plough in any such suit or action and shall have the right to consult with Schering-Plough and be represented by its own counsel at its own expense, provided that Schering-Plough shall periodically reimburse Centocor for its out-of-pocket costs (excluding the costs of retaining its own outside counsel) incurred in cooperating with Schering-Plough. Any recovery or damages derived from a suit which Centocor has joined and shared costs shall be used first to reimburse each of Centocor and Schering-Plough for its documented expenses with respect thereto, with any remaining amounts to be shared equally by the parties. Any recovery or damages derived from a suit which Centocor has not joined shall be retained by Schering-Plough.

(d) Assignment of Prosecution Rights. In the event one party (the "Owning Party") does not exercise its prosecution right according to Sections 12.5(b) or (c), as the case may be, to prevent or eliminate the infringement within sixty (60) days of receipt of notice of the infringement or threatened infringement thereof, the other party (the "Other Party") may, at its option, give notice to the Owning Party that unless the Owning Party undertakes such action the Other Party will commence an action to terminate such infringement. If the Owning Party fails to take such action within thirty (30) days of such notice then the Other Party will have the right, but not the obligation, to take such action as it deems appropriate against any infringer at its own cost. The Owning Party shall provide reasonable assistance to the Other Party in any suit for infringement brought by such Other Party against a third party, and shall have the right to consult with the such Other Party and to participate in and be represented by outside counsel in such litigation at its own expense. For purposes of this Section 12.5(d), reasonable assistance shall mean the Owning Party providing the Other Party reasonable access to information, materials and personnel which such Other Party reasonably determines is necessary to enable the Other Party's conduct of the suit. The Other Party shall periodically reimburse the Owning Party for its out-of-pocket costs (excluding Owning Party's costs of retaining outside counsel) incurred in cooperating with the Other Party. The Other Party shall incur no liability to the Owning Party as a consequence of such litigation or any unfavorable decision resulting therefrom, including any decision holding any of the patent rights or trademarks invalid or unenforceable. In the event that the Other Party recovers any sums in such litigation by way of damages or in settlement thereof, the Other Party shall have the right to retain all such sums to offset its costs, losses and expenses.

 $12.6\ \mathrm{Third}\ \mathrm{Party}\ \mathrm{Claims}.$ If either party becomes aware of any action or suit, or threat of action or suit, by a third party alleging that the manufacture, use or sale of the Product in the Territory infringes a patent,

trademark or any other proprietary right of any third party, the party aware will promptly notify the other party of the same and fully disclose the basis therefor. Subject to Sections 10.1 and 10.2, (i) either party agrees to cooperate and consult with the other party during the course of the defense of such action or suit or threat of action or suit and to keep the other party informed in respect of all significant aspects of such defense, and (ii) neither party will settle any such action or suit or threat of action or suit without the express written consent of the other party, which consent will not be unreasonably withheld.

12.7 Arbitration and Limitation of Damages. Any unresolved dispute between the parties or any claim of one party against the other arising under or in connection with this Agreement will be resolved through binding arbitration pursuant to the mechanism set forth in Appendix K; provided, however, that no party will refer a dispute to arbitration under this Section without giving at least twenty (20) days' notice to the Oversight Committee of its intention to do so.

12.8 Modification; Assignment. This Agreement may be modified or amended only in writing signed by duly authorized representatives of Centocor and Schering-Plough. Neither party shall assign this Agreement or any of its rights or obligations under this Agreement without the prior written consent of the other party hereto and any attempted assignments without that written consent will be void; provided, however, that such consent will not be unreasonably withheld. Notwithstanding the previous sentence, this Agreement may be assigned by either party to an Affiliate of that party.

12.9 Notices. All notices required or provided under this Agreement will be given in writing and will be deemed to have been properly served if delivered by hand (including delivery by courier), or sent by registered or certified mail or sent by telefax confirmed by registered or certified mail in each case to the following addresses:

To Centocor:

Centocor, Inc. 200 Great Valley Parkway Malvern, Pennsylvania 19355 Attention: Secretary Fax: 610-651-6331 To Schering-Plough:

Schering-Plough Ltd.
Toepferstrasse 5
CH-6004 Lucerne
Switzerland
Attention: President
Fax: 41-41-4181626
with copies to:

Schering Corporation 2000 Galloping Hill Road Kenilworth, New Jersey 07033 Attention: Vice President, Business Development

Fax: (908) 298-5379

and

Schering Corporation
2000 Galloping Hill Road
Kenilworth, New Jersey 07033
Attention: Senior Legal
Director, Licensing
Fax: (908) 298-2739

or such other address as may be specified in a written notice by the party to whom notice is to be given. Notices will be deemed to have been delivered as follows: if sent by mail, seven (7) days after the date of posting; if delivered

by hand, on the date of delivery; if sent by telefax, on the date of transmission at the place of business of the recipient.

12.10 Entire Agreement. This Agreement supersedes all prior agreements and understandings between Centocor and Schering-Plough with respect to the subject matter hereof. This Agreement contains the entire understanding and agreement between Centocor and Schering-Plough with respect to the subject matter hereof and the terms of this Agreement will govern over conflicting terms of any purchase order or invoice delivered under this Agreement. The Article and Section headings contained in this Agreement are for convenience of reference only and will not be considered when interpreting this Agreement.

12.11 Public Statements. Neither party, nor its representatives and employees, will make any oral or written disclosure, including any news release or other public statement, whether to the press, stockholders, or otherwise, disclosing the existence or terms of this Agreement or of any amendment hereto, without the prior written approval of the other party, which approval will not be unreasonably withheld or delayed; provided that nothing in this Section will be deemed to prevent either party from making such disclosures or statements which, in the opinion of counsel, are legally required. In the event such disclosure or statement is required, the disclosing party will give prior notice to the other party of the proposed disclosure or statement and the reason therefor. The parties anticipate that on or after the Effective Date they will issue a press release in a form to be mutually agreed upon by the parties, and thereafter may from time to time issue additional press releases as mutually agreed upon by the parties. Following any such press release, either party shall have the right to issue subsequent public disclosures containing the same information as that contained in the previously agreed upon press releases.

12.12 Governing Law; Disputes. This Agreement will be governed by and construed in accordance with the internal laws of the Commonwealth of Pennsylvania without regard to conflicts of laws provisions. The parties expressly exclude application of the United Nations Convention for the International Sale of Goods.

12.13 No Waiver. Except as specifically set forth in this Agreement, no failure or delay on the part of a party in exercising any right hereunder will operate as a waiver of, or impair, any such right. No single or partial exercise of any such right will preclude any other or further exercise thereof or the exercise of any other right. No waiver of any such right will be deemed a waiver of any other right hereunder.

12.14 Counterparts. This Agreement may be executed in counterparts, each of which will be an original and all of which will constitute together but one and the same document.

12.15 Filings and Notification. As soon as practicable after the execution of this Agreement, and if deemed necessary, the parties will ensure that this Agreement is jointly notified to the Commission of the European Communities in accordance with Regulation 17 of 1962 of the Council of the European Communities seeking negative clearance or exemption under Article 85(3) of the EC Treaty or both.

12.16 Related Agreements. Concurrently herewith the parties have entered into a License Agreement and a Security Agreement, which are attached hereto as Appendices L and M, respectively, granting to Schering-Plough rights under certain patents and patent applications relating to the Product, and a security interest in the Trademark or trademarks and the good will connected with and symbolized by the Trademark or trademarks, in each country in the Territory. Centocor agrees to execute, acknowledge and deliver such further instruments and to do all such other acts, at Schering-Plough's expense, as may

be reasonably required to perfect Schering-Plough's rights under those agreements.

IN WITNESS WHEREOF, Centocor and Schering-Plough have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

CENTOCOR, INC. SCHERING-PLOUGH LTD.

By: /s/ Joseph C. Scodari By: /s/ Thomas C. Lauda

Title: President and Chief Title: Manager (Direktor)

Operating Officer

Date: April 3, 1998 April 3, 1998

CERTIFICATION

- I, Fred Hassan, Chairman of the Board, Chief Executive Officer and President, certify that:
- 1. I have reviewed the annual report on Form 10-K of Schering-Plough Corporation (the "registrant") filed with the Securities and Exchange Commission on February 26, 2004 and this amended annual report of the registrant on Form 10-K/A;
- 2. Based on my knowledge, the annual report on Form 10-K, as amended by this report on Form 10-K/A, 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 report;
- 3. [omitted]
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, 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 report is being prepared;
 - b) [paragraph omitted pursuant to SEC Release Nos. 33-8238 and 34-47986];
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in the annual report on Form 10-K, as amended by this report on Form 10-K/A, our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report, based on such evaluation; and
 - d) Disclosed in the annual report on Form 10-K, as amended by this report on Form 10-K/A, any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; 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 over financial reporting.

Date: April 29, 2004

/s/Fred Hassan

Fred Hassan

Chairman of the Board, Chief Executive Officer and President

- 7 -

Source: SCHERING PLOUGH CORP, 10-K/A, May 03, 2004

CERTIFICATION

- I, Robert J. Bertolini, Executive Vice President and Chief Financial Officer, certify that:
- 1. I have reviewed the annual report on Form 10-K of Schering-Plough Corporation (the "registrant") filed with the Securities and Exchange Commission on February 26, 2004 and this amended annual report of the registrant on Form 10-K/A;
- 2. Based on my knowledge, the annual report on Form 10-K, as amended by this report on Form 10-K/A, 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 report;
- 3. [omitted]
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, 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 report is being prepared;
 - b) [paragraph omitted pursuant to SEC Release Nos. 33-8238 and 34-47986];
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in the annual report on Form 10-K, as amended by this report on Form 10-K/A, our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report, based on such evaluation; and
 - d) Disclosed in the annual report on Form 10-K, as amended by this report on Form 10-K/A, any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; 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 over financial reporting.

Date: April 29, 2004
/s/Robert J. Bertolini
Robert J. Bertolini Executive Vice President and Chief Financial Officer

- 9 -

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Source: SCHERING PLOUGH CORP, 10-K/A, May 03, 2004