UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of **Ciba-Geigy Limited,** a corporation, **Ciba-Geigy Corporation,** a corporation, **Chiron Corporation,** a corporation, **Sandoz Ltd.,** a corporation, **Sandoz Corporation,** a corporation, and **Novartis AG,** a corporation.	File No. 961-0055

AGREEMENT CONTAINING CONSENT ORDER

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed merger ("Merger") between Ciba-Geigy Limited, including its wholly-owned subsidiary Ciba-Geigy Corporation (collectively, "Ciba"), and Sandoz Ltd., including its wholly-owned subsidiary, Sandoz Corporation (collectively, "Sandoz"), into Novartis AG ("Novartis"), and it now appearing that Ciba, Sandoz, Novartis, and Chiron Corporation ("Chiron") in whom Ciba-Geigy Limited, together with its subsidiaries, is the largest shareholder, holding as of September 30, 1996, not solely as an investment, approximately 46.5% of the Chiron capital stock, hereinafter sometimes collectively referred to as "Proposed Respondents," are willing to enter into an agreement containing an Order to divest certain assets and businesses and to provide for other relief:

IT IS HEREBY AGREED by and between Proposed Respondents, by their duly authorized officers and attorneys, and counsel for the Commission that:

1. Proposed Respondent Ciba-Geigy Limited is a corporation organized, existing and doing business under and by virtue of the laws of Switzerland with its office and principal place of business located at Klybeckstrasse 141, CH-4002 Basel, Switzerland.

2. Proposed Respondent Ciba-Geigy Corporation, a wholly-owned subsidiary of Ciba-Geigy Limited, is a corporation organized, existing, and doing business under and by virtue of the laws of New York with its office and principal place of business located at 520 White Plains Road, Tarrytown, New York 10591.

3. Proposed Respondent Chiron Corporation, in whom Ciba-Geigy Limited, together with its subsidiaries, is the largest shareholder, holding as of September 30, 1996, not solely as an investment, approximately 46.5% of the Chiron capital stock, is a corporation organized, existing, and doing business under and by virtue of the laws of Delaware with its office and principal place of business located at 4560 Horton Street, Emeryville, California 94608.

4. Proposed Respondent Sandoz Ltd. is a corporation organized, existing and doing business under and by virtue of the laws of Switzerland with its office and principal place of business located at Lichtstrasse 35, CH-4002 Basel, Switzerland.

5. Proposed Respondent Sandoz Corporation, a wholly-owned subsidiary of Sandoz Ltd., is a corporation organized, existing, and doing business under and by virtue of the laws of New York with its office and principal place of business located at 608 Fifth Avenue, New York, New York 10020.

6. Proposed Respondent Novartis AG, is a corporation organized, existing, and doing business under and by virtue of the laws of Switzerland with its office and principal place of business located at Centralbahnstrasse 7, CH-4010 Basel, Switzerland.

7. Proposed Respondents admit all the jurisdictional facts set forth in the draft of complaint here attached.

8. Proposed Respondents waive:

a. any further procedural steps;

b. the requirement that the Commission's decision contain a statement of findings of fact and conclusions of law;

c. all rights to seek judicial review or otherwise to challenge or contest the validity of the Order entered pursuant to this agreement; and

d. any claim under the Equal Access to Justice Act.

9. Each Proposed Respondent shall submit within thirty (30) days of the date this agreement is signed by Proposed Respondents, a verified written report, pursuant to Section 2.33 of the Commission's Rules, signed by the Proposed Respondents setting forth in detail the manner in which the Proposed Respondents will comply with Paragraphs II through XII of this Order when entered. Such report will not become part of the public record unless and until the accompanying agreement and Order are accepted by the Commission for public comment.

10. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission it, together with the draft of complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify the Proposed Respondents, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision, in disposition of the proceeding.

11. This agreement is for settlement purposes only and does not constitute an admission by Proposed Respondents that the law has been violated as alleged in the draft of complaint here attached, or that the facts as alleged in the draft complaint, other than jurisdictional facts, are true.

12. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of § 2.34 of the Commission's Rules, the Commission may, without further notice to the Proposed Respondents, (1) issue its complaint corresponding in form and substance with the draft of complaint here attached and its decision containing the following Order to divest and providing for other relief in disposition of the proceeding and (2) make information public with respect thereto. When so entered, the Order shall have the same force and effect and may be altered, modified or set aside in the same manner and within the same time provided by statute for other orders. The Order shall become final upon service. Delivery by personal service, by courier, or by the U.S. Postal Service of the complaint and decision containing the agreed-to Order to Proposed Respondent Novartis' attorney of record, Michael Malina, Esq., Kaye, Scholer, Fierman, Hays & Handler, 425 Park Avenue, New York, NY 10022, and to Proposed Respondent Chiron's attorney of record, William G. Green, Esq., Chiron Corporation, 4560 Horton Street, Emeryville, CA, 94608, shall constitute service. Proposed Respondents waive any right they may have to any other manner of service. The complaint may be used in construing the terms of the Order, and no agreement, understanding, representation, or interpretation not contained in the Order or the agreement may be used to vary or contradict the terms of the Order.

13. Proposed Respondents have read the proposed complaint and Order contemplated hereby. Proposed Respondents understand that once the Order has been issued, they will be

required to file one or more compliance reports showing how they are complying or that they have fully complied with the Order. Proposed Respondents further understand that they may be liable for civil penalties in the amount provided by law for each violation of the Order after it becomes final.

ORDER

I.

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

A. "Ciba" means Ciba-Geigy Limited, its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; its subsidiaries, divisions, groups and affiliates controlled, directly or indirectly, by Ciba-Geigy Limited, including, but not limited to, Ciba-Geigy Corporation, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

B. "Chiron" means Chiron Corporation, its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; its subsidiaries, divisions, groups and affiliates controlled, directly or indirectly, by Chiron, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

C. "Sandoz" means Sandoz Ltd., its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; its subsidiaries, divisions, groups and affiliates controlled, directly or indirectly, by Sandoz Ltd., including, but not limited to, Genetic Therapy, Inc. and Sandoz Corporation, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

D. "Novartis" means Novartis AG, a company jointly formed by Ciba and Sandoz to effectuate the merger of Ciba and Sandoz through the acquisition of Ciba and Sandoz by Novartis. Novartis includes Ciba and Sandoz; all of Novartis's directors, officers, employees, agents and representatives, predecessors, successors and assigns; its subsidiaries, divisions, groups and affiliates controlled, directly or indirectly, by Novartis AG; and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

E. "BASF" means BASF Aktiengesellschaft, a company organized under the laws of Germany with its principal office and principal place of business located at Ludwigshafen, Germany.

F. "Commission" means the Federal Trade Commission.

G. "EPA" means the United States Environmental Protection Agency.

H. "FDA" means the Food and Drug Administration of the United States Department of Health and Human Services.

I. "Respondents" means Ciba, Sandoz, or Novartis, respectively, and in Paragraphs IX.A., IX.B., IX.F., IX.G., X, XIV, XV, XVI, and XVII, Chiron, or any combination thereof.

J. "Agricultural Chemical Active Ingredient" means a chemical that alone or in combination with other chemicals imparts or demonstrates herbicidal, insecticidal, fungicidal, or other pesticidal properties.

K. "Agricultural Chemical Formulation" means a formulation or pre-mix containing one or more Agricultural Chemical Active Ingredients.

L. "Agricultural Chemical Acquirer" means the entity or entities to whom Respondents shall divest either the Sandoz Corn Herbicide Business or the Sandoz Agricultural Chemical Business required to be divested pursuant to this Order.

M. "Agricultural Chemical" means any corn herbicides and other herbicides, insecticides, fungicides, and other pesticides developed, manufactured or sold by Sandoz in the United States or Canada or developed by Sandoz outside the United States and Canada for production or sale in the United States or Canada, other than products manufactured and sold by the Sandoz Animal Health Business.

N. "Base Active Flea Ingredient" means any final or intermediate form of any chemical, that alone or in combination with other chemicals is registered or under development as a Flea Control Product, including, but not limited to, Methoprene.

O. "Core Data Package" means data and information required by regulatory authorities in the United States and Canada to register Flea Control Products, Other Dallas Products, and ingredients for both.

P. "Corn Herbicides" means all Agricultural Chemical Active Ingredients and Agricultural Chemical Formulations used, or suitable for use, on corn crops to control weeds, including, but not limited to, Dimethenamid, Dicamba, and Pyridate.

Q. "Cost" means the manufacturer's average direct per unit cost of manufacturing exclusive of any overhead expenses.

R. "Dicamba" means technical concentrate of dicamba, chemical name 3,6-dichloro-o-anisic acid, and salts of dicamba, e.g., dimethylamine, diglycolamine, potassium, sodium, isopropylamine, DPL, and APM salts of dicamba, and any Agricultural Chemical Formulation containing dicamba.

S. "Dimethenamid" means technical concentrate of dimethenamid, chemical name 2-chloro-N-[(1-methyl-2-methoxy)ethyl]-N-(2,4-dimethyl-thien-3-yl)-acetamide or (1RS, aRS)-2-chloro-N-(2,4-dimethyl-3-thienyl)-N-(2-methoxy-1-methylethyl)-acetamide, and any Agricultural Chemical Formulation containing dimethenamid.

T. "FIFRA" means the Federal Insecticide, Fungicide, and Rodenticide Act and all statutory amendments, modifications or replacements thereof.

U. "Flea Control Products" means all products used or intended to be used to treat or prevent ectoparasitic (flea) infestation in connection with canines or felines and all research and development projects to develop products to be used to treat or control ectoparasitic infestation in connection with canines and felines.

V. "Merger" means the Merger of Ciba and Sandoz into Novartis.

W. "Methoprene" means (S)-Methoprene, chemical name Isopropyl (2E, 4E, 7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate, and (RS)-Methoprene, chemical name Isopropyl (E,E)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate.

X. "Other Dallas Products" means products, other than Flea Control Products, that are manufactured or produced at the Sandoz facility located in Dallas, Texas and are sold in the United States or Canada.

Y. "Pyridate" means technical concentrate of pyridate, chemical name O-(6-chloro-3-phenyl-4-pyridazinyl)-S-octyl-carbonothioate, and includes any Agricultural Chemical Formulation containing pyridate.

Z. "Registration Data" means all data relating to the applicable Agricultural Chemical Active Ingredient or Agricultural Chemical Formulation that has been, or will be, submitted to the EPA, under FIFRA, or to any state or foreign regulatory agency for purposes of obtaining or maintaining any registration or authorizations for any product containing such Agricultural Chemical Active Ingredient or Agricultural Chemical Formulation.

AA. "Sandoz Corn Herbicide Business" means all physical assets, properties and business located in the United States or Canada and all goodwill, tangible and intangible assets,

used by Sandoz in the research, development, manufacture, formulation, registration, distribution or sale of Corn Herbicides (other than Pyridate) in the United States or Canada, all as specified in the Asset Purchase Agreement dated as of September 26, 1996, between Sandoz and BASF.

BB. "Sandoz Agricultural Chemical Business" means all physical assets, properties and business located in the United States or Canada and all goodwill, tangible and intangible assets, used by Sandoz in the research, development, manufacture, formulation, registration, distribution or sale of Agricultural Chemicals in the United States or Canada, or for production or sale in the United States or Canada, excluding the Sandoz Animal Health Business, including, without limitation, the following:

1. all owned or leased production facilities used in the manufacture of Agricultural Chemical Active Ingredients or Agricultural Chemical Formulations, including, but not limited to, the following:

    a. the Dimethenamid plant and assets at Beaumont, Texas; and

    b. the Dicamba plant and assets at Beaumont, Texas;

2. all EPA, state and foreign registrations and approvals relating to the manufacture or sale of Agricultural Chemical Active Ingredients and Agricultural Chemical Formulations in North America, including, but not limited to, EPA registrations 55947-1 (Banvel), 55947-24 (Weedmaster), 55947-28 (Banvel SGF), 55947-39 (Marksman), 55947-46 (Clarity), 55947-47 (dicamba, isopropylamine salt), 55947-140 (Frontier), 55947-141 (dimethenamid 96% technical), 55947-149 (dicamba, potassium salt), 55947-150 (Guardsman), 55947-155 (dicamba WG/70.0% wettable granule), 55947-159 (Frontier 6.0), 55947-160 (sodium dicambate technical 85% wettable granule), 55947-161 (Tough 3.75 EC), Tough 5 EC (56% EC), 55947-162 (Tough 45% WP), 55947-164 (Banvel 10G), 55947-165 (dicamba, diglycolamine salt), and 55947-166 (66% sodium salt of dicamba + 10% metribuzin);

3. all Registration Data, submissions and supporting data and documents, including, without limitation, all labels, label extensions, or planned or pending label extensions for any application;

4. all intellectual property located, generated, obtained, or used in the United States and Canada, including, but not limited to, trade secrets, test data, technology and know-how, and all United States and Canadian patents, patent applications, patent rights and licenses;

5. a paid-up, non-exclusive right to develop, manufacture and sell any Agricultural Chemical Active Ingredient or Agricultural Chemical Formulation anywhere in the world under all foreign patents, patent applications, licenses, registrations, submissions and approvals and to use all other intellectual property located, generated, obtained, or used outside the United States and Canada, including a copy of all trade secrets, test data, technology and know-how;

6. all trademarks and trade names for Agricultural Chemical Active Ingredients and Agricultural Chemical Formulations, including, without limitation, exclusive world rights to the trademarks or trade names Frontier, Guardsman, Century, Banvel, Clarity, Marksman, Dycleer, Vanquish, Weedmaster, Tough, Lentagran and Phoenix;

7. all contracts and agreements relating to formulating and packaging, including, without limitation, all toll supply agreements;

8. all owned or leased facilities, equipment, real property and other assets used in research, development, technical support, testing, or product registration in the United States and Canada, including, but not limited to, the Gilroy Research Center, the Palo Alto Research Center, the Greenville Field Station, and facilities at Des Plaines, Illinois;

9. all tangible and intangible assets associated with research and development projects, process improvement projects, production projects, and label extension projects; and all registrations, submissions and approvals, Registration Data, supporting data and documents, patents, patent applications, and other intellectual property relating to each such project;

10. all owned or leased offices, distribution facilities, real property and other assets used in sales or technical service of Sandoz Agricultural Chemicals, including, but not limited to, offices and facilities located in Englewood, Colorado, Des Plaines, Illinois and Palo Alto, California;

11. all books, records and files, customer lists, customer records and files, vendor lists, catalogs, sales promotion literature, advertising materials, research materials, technical information, management information systems, software, inventions, specifications, designs, drawings, processes and quality control data;

12. all interest in and to contracts and agreements with customers, joint venturers, suppliers, sales representatives, distributors, agents, personal property lessors,

personal property lessees, licensors, licensees, consignors and consignees, and rights under warranties and guarantees, express or implied; and

13. rights to make or sell Pyridate in the United States and Canada and to make or sell, or license others to make or sell, in the United States and Canada, Agricultural Chemical Formulations containing Pyridate.

CC0 "Sandoz Animal Health Business" means the business units of Sandoz that are engaged in the research, development, manufacture and production of Flea Control Products and Other Dallas Products at the Sandoz facility in Dallas, Texas which products are distributed and sold in the United States and Canada, excluding the Sandoz Agricultural Chemical Business, and all assets, properties, business and goodwill, tangible and intangible, trademarks and trade names used, in whole or in part, in the research, development, manufacture, and production of Flea Control Products and Other Dallas Products at the Sandoz facility located in Dallas, Texas which products are distributed and sold in the United States and Canada, including, but not limited to, the following:

1. all machinery, fixtures, equipment, vehicles, transportation facilities, furniture, tools and other tangible personal property;

2. all customer lists, vendor lists, catalogs, sales promotion literature, advertising materials, research materials, technical information, management information systems, software, inventions, trade secrets, intellectual property, patents, technology, know-how, specifications, designs, drawings, processes and quality control data;

3. inventory and storage capacity;

4. all rights, titles and interests in and to owned or leased real property at the Sandoz facility located at 12200 Denton Drive, Dallas, Texas, together with appurtenances, licenses and permits;

5. all rights, titles and interests in and to the contracts entered into in the ordinary course of business with customers (together with associated bid and performance bonds), suppliers, sales representatives, distributors, agents, personal property lessors, personal property lessees, licensors, licensees, consignors and consignees;

6. all rights, titles and interests in and to development projects;

7. all rights under warranties and guarantees, express or implied;

8. all books, records, and files;

9. all rights, titles and interests in registrations or other governmental approvals for manufacture and sale of any Flea Control Products and Other Dallas Products or research and development efforts for Flea Control Products and Other Dallas Products; provided, however, Respondents shall retain rights of referral to the Core Data Package for uses outside the United States and Canada;

10. a non-exclusive license to develop, manufacture and sell any Flea Control Products and Other Dallas Products, including research and development efforts for Flea Control Products and Other Dallas Products, anywhere in the world under all foreign patents, patent applications, and licenses, and to use all other intellectual property (exclusive of any trademarks and trade names) located, generated, obtained, or used anywhere in the world, including all trade secrets, test data, technology and know-how; and

11. all items of prepaid expense.

Notwithstanding the foregoing, Sandoz Animal Health Business shall exclude the production facility located at Muttenz, Switzerland, operated by Sandoz to produce Methoprene and other materials, Flea Control Products and Other Dallas Products that are sold outside of the United States and Canada, and assets that were part of Ciba prior to the Merger.

DD0 "Sandoz Animal Health Business Acquirer" means the entity or entities to whom Respondents shall divest the Sandoz Animal Health Business required to be divested pursuant to this Order.

EE0 "Sandoz Flea Control Products" means all Flea Control Products that as of November 22, 1996, are: (1) being manufactured, distributed and sold by Sandoz in the United States and Canada; and (2) all projects in research and development by Sandoz in the United States and Canada that relate to improving existing, or developing new, Flea Control Products or Base Active Flea Ingredients therefor.

FF0 "Strategic Plan" means a detailed plan that sets forth *inter alia* the means by which the Sandoz Animal Health Business Acquirer will begin the manufacture and sale of Methoprene, including dates by which the Sandoz Animal Health Business Acquirer plans to have received necessary governmental approvals to manufacture and sell Methoprene in the United States and Canada.

GG0 "Anderson Patent" means US Patent Number 5,399,346 issued March 21, 1995, and any pending divisionals, continuations, continuations in part, extensions or reissues of said original US patent application number 07/365,567.

HH0 "Anderson Patent License" means a non-exclusive license obtained by any Person under the Anderson Patent for any gene therapy product or process.

II0 "Anderson Patent Licensee" means a Person that obtains an Anderson Patent License.

JJ0 "Cytokine License" means, as to each Respondent, a non-exclusive license or sublicense under such Respondent's Cytokine Patent Rights for use in any Cytokine Licensed Product as follows: (a) as to Respondent Chiron, with respect to IL-2, the right to use IL-2 sold by Respondent Chiron in a Cytokine Licensed Product, or if Respondent Chiron ceases offering IL-2 for sale, then the right to manufacture and use IL-2 in a Cytokine Licensed Product; and (b) as to Respondent Novartis with respect to IL-3 and IL-6, the right to manufacture and use IL-3 and/or IL-6 in a Cytokine Licensed Product.

KK0 "Cytokine Licensed Product" means any research protocol or commercial product and/or service incorporating or to be used with cells that have been expanded, mobilized or cultured *ex vivo* with IL-2, IL-3 and/or IL-6 proteins.

LL0 "Cytokine Licensee" means each and every Person that requests and obtains a Cytokine License.

MM0 "Cytokine Patent Rights" means with respect to each Respondent, all worldwide patents and patent applications, issued or pending, which, as of the date this Order becomes final, are owned or controlled by such Respondent or licensed by a third party to such Respondent with the right to sublicense, which, in the case of Respondent Chiron, are directed to the manufacture, use, or sale of IL-2 in Cytokine Licensed Products, and, in the case of Respondent Novartis, are directed to the manufacture, use, or sale of IL-3 and/or IL-6 in Cytokine Licensed Products. Additionally, at the option of the Cytokine Licensee, the Cytokine Patent Rights shall also include a cross-reference right to the licensing Respondent's respective drug regulatory files at the FDA with respect to IL-2 in the case of Respondent Chiron, and with respect to IL-3 and/or IL-6 in the case of Respondent Novartis.

NN0 "Gene Therapy" means a therapeutic intervention in humans based on modification of the genetic material of autologous, allogeneic, or xenogeneic living cells. Cells may be modified *ex vivo* for subsequent administration or altered *in vivo* by gene therapy products given directly to the patient.

OO0 "Gene Therapy License" means any and all of the HSV-tk License, Cytokine License, Anderson Patent License, and Hemophilia License.

PP0 "Hemophilia License" means one (1) non-exclusive license under patents and/or patent applications to which Sandoz held rights, as of October 1, 1996, to develop a gene therapy product using the beta-domain deleted Factor VIII gene for the treatment of hemophilia, including, at the option of RPR or the Subsequent Hemophilia Licensee, all technical information, know-how or materials owned or controlled by Sandoz, as of the date on which this Order becomes final, necessary for the development and manufacture of such product, including, but not limited to, hemophilia gene therapy vectors.

QQ0 "HSV-tk Gene Therapy" means the introduction of the HSV-tk gene into a patient by *in vivo* and/or *ex vivo* transduction for the treatment of human disease.

RR0 "HSV-tk License" means, as to each Respondent, the license or sublicense granted to RPR or the HSV-tk Licensee under such Respondent's HSV-tk Patent Rights, to make, use, or sell an HSV-tk Licensed Product, including, at the option of RPR or the HSV-tk Licensee, the right to sublicense in fields that are not being developed by RPR or the HSV-tk Licensee.

SS0 "HSV-tk Licensee" means a pharmaceutical company, other than RPR, with the demonstrated plan and ability to commercialize the HSV-tk Licensed Product, including vector production facilities and clinical gene therapy experience.

TT0 "HSV-tk Licensed Product" means an HSV-tk Gene Therapy product in development or to be developed by RPR or the HSV-tk Licensee.

UU0 "HSV-tk Patent Rights" means the following:

1. With respect to Respondent Novartis, all claims in issued U.S. and foreign patents and all claims in the pending patent applications, respectively, to make, have made, use and sell HSV-tk Licensed Products, owned by or under the control of Respondent Novartis as of the date this Order becomes final, including divisionals, continuations, extensions and reissues of such patents or pending patent applications, and including those which Respondent Novartis has licensed from a third party as of said date and has a right to sublicense, all to the extent that such patents or patent applications are directed to the use of the HSV-tk gene in the development of any and all HSV-tk Licensed Products. The HSV-tk Patent Rights owned by or under the control of Respondent Novartis are referenced in Part 1 of non-public Appendix A. Respondent Novartis HSV-tk Patent Rights shall include any and all rights obtained in the future to the patents and patent applications listed in Part 3 of non-public Appendix A under exclusive license with the right to sublicense. Respondent Novartis' HSV-tk Patent Rights may also include, at the option of RPR or the HSV-tk Licensee, all technical information, know-how or materials, owned or controlled by Respondent Novartis as of the date on which this Order becomes

final, necessary to enable RPR or the HSV-tk Licensee to adequately and fully research and develop any and all HSV-tk Licensed Products; and

2. With respect to Respondent Chiron, all claims in the issued U.S. and foreign patents which are issued from patent applications corresponding to, derived from or equivalent to those United States patent applications listed in Part 2 of non-public Appendix A, and divisionals, continuations, extensions and reissues thereof, which claims are directed specifically to the use of the HSV-tk gene in HSV-tk Gene Therapy, or would otherwise dominate such use of the HSV-tk gene. Respondent Chiron's HSV-tk Patent Rights do not include claims to proprietary manufacturing methods, methods of administration, vector constructs, packaging or producer cells lines, genes, or other compositions, methods or processes that may be useful in making, using, or selling HSV-tk Licensed Products, but which do not dominate the use of the HSV-tk gene in HSV-tk Gene Therapy. Respondent Chiron's HSV-tk Patent Rights also do not include technical information, know-how or materials. Respondent Chiron's HSV-tk Patent Rights shall include any and all rights obtained in the future to the claims in patents and patent applications listed in Part 3 of non-public Appendix A under exclusive license with the right to sublicense, which claims are directed specifically to the use of the HSV-tk gene in HSV-tk Gene Therapy, or would otherwise dominate such use of the HSV-tk gene.

VV0 "HSV-tk Business" means all the assets utilized by Respondent Sandoz in the research and development of HSV-tk Gene Therapy products, or at the option of all Respondents in the event that the requirements of Paragraph IX.A. have not been satisfied, all the assets utilized by Respondent Chiron in the research and development of HSV-tk Gene Therapy products.

WW0 "HSV-tk Sublicensee" means any Person that receives a sublicense under the HSV-tk Patent Rights from RPR or the HSV-tk Licensee in fields not being developed by RPR or the HSV-tk Licensee.

XX0 "MDR-1" means the multiple drug resistance-1 gene.

YY0 "MRP" means the multiple resistance protein gene.

ZZ0 "Net Sales Price" means the total amount received from the sale of royalty bearing products and/or services, less transportation charges and insurance, sales taxes, use taxes, excise taxes, value added taxes, customs duties or other imposts, normal and customary quantity and cash discounts, rebates (to the extent actually made) and disallowed reimbursements and allowances and credit on account of rejection or return of royalty bearing products or services. Royalty bearing products or services shall be considered "sold" when billed out or invoiced. The total amount received by Cytokine Licensee from the sale of Cytokine Licensed Products and/or

by Anderson Patent Licensee from the sale of gene therapy products covered by the Anderson Patent Rights may or may not incorporate hospital and/or physician costs relating to the *ex vivo* gene therapy treatment (e.g., physician charges related to the removal and readministration of cells).

AAA0 "Other Cytokines" means all cytokines, other than IL-2, IL-3, and IL-6, including but not limited to, stem cell factors, interferons, colony stimulating factors, tumor necrosis factors and erythropoetins.

BBB0 "Person" means any natural person, corporate entity, partnership, association, joint venture, non-profit organization, university, government entity, or trust.

CCC0 "RPR" means Rhone Poulenc Rorer, Inc., 500 Arcola Road, Collegeville, PA 19426-0107.

DDD0 "Subsequent Hemophilia Licensee" means any Person, other than RPR, that may obtain a Hemophilia License from Novartis, or from Genetics Institute, Inc. if Novartis converts its exclusive license from Genetics Institute, Inc. to a non-exclusive license.

II.

IT IS FURTHER ORDERED that:

A. Respondents shall divest, absolutely and in good faith, as an ongoing business, the Sandoz Corn Herbicide Business to BASF pursuant to the agreement between Sandoz and BASF dated as of September 26, 1996, no later than ten (10) days after the date on which this Order becomes final; or, in the event that BASF breaches that agreement, Respondents shall divest, absolutely and in good faith, as an ongoing business, the Sandoz Corn Herbicide Business, at no minimum price, within sixty (60) days of the date on which this Order becomes final, to an Agricultural Chemical Acquirer that receives the prior approval of the Commission and in a manner that receives the prior approval of the Commission, and shall also divest such additional ancillary assets and businesses and effect such arrangements as are necessary to assure the marketability and the independence, viability and competitiveness of the Sandoz Corn Herbicide Business.

B. The purpose of the divestiture of the Sandoz Corn Herbicide Business is to ensure the continuation of the Sandoz Corn Herbicide Business as an ongoing, viable enterprise engaged in the research, development, manufacture, distribution and sale of Corn Herbicides independent of Ciba, Sandoz, and Novartis and able to compete with Ciba, Sandoz and Novartis and to remedy the lessening of competition alleged in the Commission's complaint.

C. Pending divestiture of the Sandoz Corn Herbicide Business, Respondents shall take such actions as are necessary to maintain the viability and marketability of the Sandoz Corn Herbicide Business and the Sandoz Agricultural Chemical Business and shall not cause or permit the destruction, removal, wasting, deterioration, or impairment of the Sandoz Corn Herbicide Business or of the Sandoz Agricultural Chemical Business, except in the ordinary course of business and except for ordinary wear and tear.

III.

IT IS FURTHER ORDERED that:

A. Respondents shall divest, absolutely and in good faith, as an ongoing business, within the time periods specified in Paragraph III.B. below, the Sandoz Animal Health Business. Respondents shall also enter into, and fulfill the terms of, a Contract Manufacturing Agreement ("CMA"), as specified in Paragraph V below, and effect such arrangements as are necessary to assure the marketability, independence, viability and competitiveness of the Sandoz Animal Health Business.

B. Respondents shall divest the Sandoz Animal Health Business to Central Garden and Pet Company and/or its affiliates pursuant to the Asset Purchase Agreement dated as of October 11, 1996, among Sandoz Ltd., Central Garden and Pet Company, and Centic Acquisition Corp., as amended to conform to the terms of this Order in a manner that receives the prior approval of the Commission, within thirty (30) days of the date on which this Order becomes final; or, Respondents shall divest the Sandoz Animal Health Business, at no minimum price, within ninety (90) days of the date on which this Order becomes final, to a Sandoz Animal Health Business Acquirer that receives the prior approval of the Commission and in a manner that receives the prior approval of the Commission. The purpose of the divestiture of the Sandoz Animal Health Business is to ensure the continued use of the assets of the Sandoz Animal Health Business in the same business in which the assets of the Sandoz Animal Health Business are engaged at the time of the proposed divestiture and to remedy the lessening of competition from the proposed merger of Ciba and Sandoz as alleged in the Commission's complaint.

C. Pending divestiture of the Sandoz Animal Health Business, Respondents shall take such actions as are necessary to maintain the viability and marketability of the Sandoz Animal Health Business and shall not cause or permit the destruction, removal, wasting, deterioration or impairment of the Sandoz Animal Health Business, except in the ordinary course of business and except for ordinary wear and tear. Respondents shall maintain research and development of all current research and development projects at the levels planned by Sandoz for such projects as of June 4, 1996.

D. The contract of divestiture shall provide that, at the option of Respondent Novartis, the Sandoz Animal Health Business Acquirer shall enter into a transitional toll manufacturing agreement of up to two year's duration to produce for Respondents products currently produced at Dallas, but not subject to the divestiture pursuant to this Paragraph, for sale by Respondents outside the United States and Canada, all at a price equal to the Sandoz Animal Health Business Acquirer's Cost plus twenty percent (20%) mark-up.

IV.

IT IS FURTHER ORDERED that:

Upon reasonable notice and request to Respondents from the Sandoz Animal Health Business Acquirer, Respondents shall provide information, assistance and advice with respect to the Sandoz Animal Health Business divested pursuant to this Order such that the Sandoz Animal Health Business Acquirer or its designee will be capable of:

(1) manufacturing all products currently produced by the Sandoz Animal Health Business divested pursuant to this Order; and

(2) manufacturing and/or obtaining all necessary ingredients, other than Methoprene, for products of the Sandoz Animal Health Business divested pursuant to this Order,

in substantially the same manner and quality employed, achieved or planned by the Respondents prior to divestiture. Such information, assistance and advice shall include reasonable consultation with knowledgeable employees of Respondents for a period of time sufficient to satisfy the Sandoz Animal Health Business Acquirer's management that its personnel are appropriately trained in the research, development, manufacture, distribution and sale of the products and research and development projects of the Sandoz Animal Health Business divested pursuant to this Order. Respondents shall convey all know-how necessary to manufacture or have manufactured, distribute, sell and obtain all necessary governmental approvals, including EPA approvals, and licenses to research, develop, manufacture or have manufactured, distribute and sell in the United States and Canada the products of the Sandoz Animal Health Business divested pursuant to this Order. Respondents shall provide such information, assistance and advice for one (1) year from the date Respondents divest the Sandoz Animal Health Business divested pursuant to this Order. Respondents may charge the Sandoz Animal Health Business Acquirer at a rate no greater than Respondents' Cost for providing such technical assistance.

V.

IT IS FURTHER ORDERED that:

Respondents shall enter into a Contract Manufacturing Agreement ("CMA") with the Sandoz Animal Health Business Acquirer to contract manufacture and deliver to the Sandoz Animal Health Business Acquirer, in a timely manner, Methoprene in the volumes requested by the Sandoz Animal Health Business Acquirer. The CMA shall be effective for the shorter of six (6) years from the date Respondents divest the Sandoz Animal Health Business or three (3) months after the Sandoz Animal Health Business Acquirer or its designee obtains all EPA or FDA approvals necessary to manufacture all Methoprene required for products of the Sandoz Animal Health Business. The CMA shall contain the following provisions:

A. Respondents shall make representations and warranties to the Sandoz Animal Health Business Acquirer that the Methoprene manufactured pursuant to the CMA meets all applicable EPA, FDA and other governmental requirements for the United States and Canada, and Respondents shall agree to indemnify, defend and hold the Sandoz Animal Health Business Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of Methoprene manufactured pursuant to the CMA to meet such governmental specifications. This obligation shall be contingent upon the Sandoz Animal Health Business Acquirer giving Respondents prompt, adequate notice of such claim, cooperating fully in the defense of such claim, and permitting Respondents to assume the sole control of all phases of the defense and/or settlement of such claim, including the selection of counsel. This obligation shall not require Respondents to be liable for any negligent act or omission of the Sandoz Animal Health Business Acquirer or for any representations and warranties, express or implied, made by the Sandoz Animal Health Business Acquirer that exceed the representations and warranties made by Respondents to the Sandoz Animal Health Business Acquirer.

B. Respondents shall agree to package and deliver the Methoprene manufactured pursuant to the CMA in a manner and form and according to a schedule reasonably requested by the Sandoz Animal Health Business Acquirer.

C. The CMA shall require that, for the first three years during which the CMA is effective, the Sandoz Animal Health Business Acquirer shall compensate Respondents for all Methoprene supplied pursuant to the CMA at a rate not to exceed Respondents' Cost of producing such Methoprene during the period from July 1, 1995, through June 30, 1996, which Cost may be adjusted for demonstrated input expenditure increases as determined by the trustee appointed pursuant to Paragraph VIII of this Order.

D. The contract of divestiture shall be submitted to and approved by the Commission prior to the divestiture of the Sandoz Animal Health Business required by this Order. Respondents' application for approval of the divestiture pursuant to this Order shall include: (1) a certification attesting to the good faith intention of the Sandoz Animal Health Business Acquirer

to obtain, or to cause its designee to obtain, in an expeditious manner all FDA, EPA and other governmental approvals required in the United States and Canada to manufacture and sell Methoprene; (2) a Strategic Plan to obtain all FDA, EPA and other governmental approvals required in the United States and Canada to manufacture or have manufactured, and sell Methoprene; and (3) a CMA pursuant to this Paragraph.

E. Respondents shall provide information, assistance, and advice to the Sandoz Animal Health Business Acquirer, or its designee, to enable the Sandoz Animal Health Business Acquirer, or its designee, to manufacture and sell Methoprene in the United States or Canada. Respondents shall convey all know-how required to manufacture, sell and obtain all necessary EPA, FDA and other government approvals to manufacture and sell Methoprene in the United States or Canada. Such information, assistance and advice shall include reasonable consultation with knowledgeable employees of Respondents and training at either or both the Sandoz Animal Health Business Acquirer's facilities, or those of its designee, and the Respondents' facilities for a period of time sufficient to satisfy the Sandoz Animal Health Business Acquirer's management that its personnel, or those of its designee, are appropriately trained in the manufacture of Methoprene. Respondents shall continue to provide such information, assistance and advice until the ninetieth (90th) day following the date on which the Sandoz Animal Health Business Acquirer, or its designee, obtains EPA approval to manufacture and sell Methoprene. Respondents may charge the Sandoz Animal Health Business Acquirer at a rate no greater than Respondents' direct cost for providing such technical assistance.

F. Respondents shall use best efforts to facilitate the Sandoz Animal Health Business Acquirer's ability to obtain adequate supplies of Methoprene starter material, chemical name S-(3,7-Dimethyl-7-methoxy-1-octanal) from Takasago Iwata.

VI.

IT IS FURTHER ORDERED that for a period of six (6) years from the date on which the Sandoz Animal Health Business is divested, Respondents shall not: (1) manufacture and sell, or cause to be manufactured for sale, in the United States and Canada, Methoprene to any entity other than the Sandoz Animal Health Business Acquirer, or its designee; and (2) sell any products that contain Methoprene in the United States and Canada.

VII.

IT IS FURTHER ORDERED that for a period of six (6) years from the date this Order is placed on the public record for comment, except as required to comply with the terms of this Order, Respondents shall not provide, disclose or otherwise make available to any other Person or

to any employee of Novartis, any non-public information relating to any research and development project ongoing as of March 1, 1996, at Sandoz to develop or improve any Base Active Flea Ingredient or any Sandoz Flea Control Product, if said Person or employee did not have knowledge of such non-public information as of March 1, 1996.

VIII.

IT IS FURTHER ORDERED that:

A. The Commission may appoint a trustee to ensure that Respondents and the Sandoz Animal Health Business Acquirer expeditiously perform their responsibilities required under this Order with respect to the Sandoz Animal Health Business. The trustee shall also ensure that the provisions of the Agreement to Hold Separate between Respondents and the Commission, dated November 26, 1996, are carried out in good faith. Respondents shall consent to the following terms and conditions regarding the trustee's powers, duties, authority, and responsibilities:

1 The Commission shall select the trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed trustee within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed trustee, Respondents shall be deemed to have consented to the selection of the proposed trustee.

2 The trustee shall have the power and authority to assure Respondents' compliance with the terms of this Order.

3 Within ten (10) days after appointment of the trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the trustee all rights and powers necessary to permit the trustee to assure Respondents' compliance with the terms of this Order relating to the Sandoz Animal Health Business. As part of the trust agreement, the trustee shall execute confidentiality agreement(s) with Respondents.

4 The trustee shall serve until the ninetieth (90th) day following the date on which the Sandoz Animal Health Business Acquirer or its designee obtains EPA approval to manufacture and sell Methoprene. If the responsibilities of the trustee are extended pursuant to the provisions of Paragraph X, the trustee shall serve until such date as required by that Paragraph.

5 The trustee shall have full and complete access to the personnel, books, records and facilities related to the Sandoz Animal Health Business or to any other relevant information, as the trustee may request. Respondents shall develop such financial or other information as such trustee may request and shall cooperate with the trustee. Respondents shall take no action to interfere with or impede the trustee's accomplishment of his or her responsibilities pursuant to this Order.

6 The trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as set forth in the trust agreement. The trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the trustee's duties and responsibilities. The trustee shall account for all expenses incurred. The Commission shall approve the account of the trustee, including fees for his or her services.

7 Respondents shall indemnify the trustee and hold the trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of any claim, whether or not resulting in any liability, except to the extent that such liabilities, losses, damages, claims, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the trustee.

8 If the trustee ceases to act or fails to act diligently, a substitute trustee shall be appointed in the same manner as provided in Subparagraph A. of this Paragraph.

9 The Commission may on its own initiative or at the request of the trustee issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order.

B. The agreement pursuant to which Respondents divest the Sandoz Animal Health Business shall require the Sandoz Animal Health Business Acquirer to submit to the trustee appointed pursuant to this Paragraph, periodic written reports setting forth in detail the efforts of the Sandoz Animal Health Business Acquirer to obtain all FDA, EPA and other governmental approvals required in the United States and Canada to continue the research, development, manufacture and sale of the products and projects of the Sandoz Animal Health Business. The first report shall be submitted within sixty (60) days after the date on which the Commission approves the Sandoz Animal Health Business Acquirer and every ninety (90) days thereafter until the Sandoz Animal Health Business Acquirer has obtained all FDA, EPA and other governmental

approvals required in the United States and Canada to continue the research, development, manufacture and sale of the products and projects of the Sandoz Animal Health Business.

C. Respondents shall comply with all reasonable directives of the trustee regarding Respondents' obligations to comply with this Order.

IX.

IT IS FURTHER ORDERED that:

A.

1. On or before September 1, 1997, each Respondent shall (i) grant a non-exclusive license to RPR to make, use and sell HSV-tk Licensed Products under such Respondent's HSV-tk Patent Rights, in a manner that has received prior Commission approval and, except as provided in this Order, is consistent with the Letter of Intent dated November 20, 1996 between RPR and Sandoz Ltd., which contains licensing terms concerning Sandoz and Chiron HSV-tk Patent Rights, hemophilia gene rights, and the Anderson Patent; or (ii) grant a non-exclusive license to make, use and sell HSV-tk Licensed Products under such Respondent's HSV-tk Patent Rights to an HSV-tk Licensee that receives the prior approval of the Commission and in a manner that receives the prior approval of the Commission, in perpetuity and in good faith, at no minimum price. In consideration for the HSV-tk License, each Respondent may request from the HSV-tk Licensee compensation in the form of royalties and/or an equivalent cross-license.

2. At the option of RPR or the HSV-tk Licensee, Novartis shall, in good faith, within one (1) year of execution of said HSV-tk License, or within one (1) year of the execution of any sublicense to the HSV-tk Patent Rights by RPR or the HSV-tk Licensee, provide to RPR or the HSV-tk Licensee, or the HSV-tk Sublicensee(s), technical information, know-how or material owned or controlled by Novartis as of the date on which this Order become final, as is necessary to develop the HSV-tk Licensed Products. Such technical assistance may include reasonable consultation with knowledgeable employees of Novartis and training at RPR or the HSV-tk Licensee's facilities, or the HSV-tk Sublicensee's facilities, or at such other place as is mutually satisfactory to Novartis and RPR or the HSV-tk Licensee or the HSV-tk Sublicensee(s), such consultation to be for a period of time within the one-year period reasonably sufficient to satisfy RPR or the HSV-tk Licensee or the HSV-tk Sublicensee(s).

3. RPR or the HSV-tk Licensee may sublicense, to any HSV-tk Sublicensee, fields that are not being developed by RPR or said HSV-tk Licensee.

4. The purpose for the HSV-tk License is to ensure the continuation of HSV-tk gene therapy research and development for an HSV-tk Gene Therapy product to be approved by the FDA for sale in the United States and to remedy the lessening of competition resulting from the Merger as alleged in the Commission's complaint.

5. Pending licensing of the HSV-tk Patent Rights, each Respondent shall take such action as is necessary to maintain the viability and marketability of the HSV-tk Patent

Rights and the HSV-tk Licensed Products, including, but not limited to, maintaining in the ordinary course the research and development of HSV-tk products.

B. For the purpose of ensuring continuation of *ex vivo* gene therapy research and development, and to ensure the availability of cytokines for Gene Therapy, and to remedy the lessening of competition and research and development of Gene Therapy resulting from the Merger as alleged in the Commission's complaint, commencing within thirty (30) days of the date this Order becomes final, Respondents shall perform the following obligations:

1. Respondent Novartis shall grant to each Person who so requests a Cytokine License, in perpetuity and in good faith. In payment for such license, Respondent Novartis shall receive a royalty, or its equivalent, of no greater than three percent (3%) of the Net Sales Price of Cytokine Licensed Products, paid from the date of first commercial sale of royalty bearing products or services until a time no later than the expiration of the last to expire patent. Respondent Novartis may also request certain non-exclusive rights to obtain and use safety and efficacy data generated by said Cytokine Licensee to support its own regulatory filings.

2. Respondent Chiron shall grant to each Person who so requests a Cytokine License, in perpetuity and in good faith. In payment for such license, Respondent Chiron shall receive a royalty, or its equivalent, of no greater than three percent (3%) of the Net Sales Price of Cytokine Licensed Products, paid from the date of first commercial sale of royalty bearing products or services until a time no later than the expiration of the last to expire patent; provided, however, that if Respondent Chiron's grant of a Cytokine License includes the right to manufacture, then Respondent Chiron shall receive a royalty of no greater than one percent (1%) above the royalty due from Respondent Chiron to all third party IL-2 licensors of Respondent Chiron. Respondent Chiron may also request certain non-exclusive rights to obtain and use safety and efficacy data generated by said Cytokine Licensee to support its own regulatory filings.

3. In the event that royalties are to be paid by any such Cytokine Licensee under a Cytokine License described in Subparagraphs 1 or 2 to a party who is not an affiliate of such Cytokine Licensee for royalty bearing products or services, then the royalties to be paid to Respondents shall be reduced by up to one-half of the negotiated royalty rate of said Cytokine License, but in no event shall any royalties under Subparagraphs 1 and/or 2 be reduced by more than fifty percent (50%). These stacking provisions shall also apply if at any time in the future it becomes scientifically advantageous to combine IL-2, IL-3, and IL-6, or any combination thereof, into a single Cytokine Licensed Product so that the royalty payable to all Respondents shall be no more than three percent (3%). However, if Respondent Chiron's grant of a Cytokine License includes the right to manufacture, this Subparagraph IX.B.3. shall not apply to reduce the

Cytokine Licensee's obligations to pay royalties owed to third party IL-2 licensors of Chiron.

4. If a Person seeking a Cytokine License has patent rights and/or drug regulatory files on Other Cytokines for use in *ex vivo* cell expansion, the licensing Respondent may require equivalent cross licenses for such Other Cytokines from such Person.

C. For the purpose of ensuring continuation of *ex vivo* gene therapy research and development, and to ensure the availability of Anderson Patent Licenses, and to remedy the lessening of competition in research and development of Gene Therapy resulting from the Merger as alleged in the Commission's complaint, commencing within thirty (30) days of the date this Order becomes final, Respondent Novartis shall grant to each Person who requests an Anderson Patent License a non-exclusive license or sub-license under any and all Anderson Patent Rights, in perpetuity and in good faith, in the United States. In payment for such license, Respondent Novartis shall be entitled to receive: (i) a one-time payment of Ten Thousand Dollars ($10,000) and (ii) a royalty based on the Net Sales Price of any gene therapy product covered by the Anderson Patent Rights of no greater than one percent (1%) above the royalty due from Respondent Novartis to the United States National Institutes of Health. Such royalty shall be paid from the date of first commercial sale of royalty bearing products or services in the United States, provided that the Anderson Patent is valid and enforceable, until the expiration of the last to expire patent.

D. Respondent Novartis shall by no later than September 1, 1997, either (i) convert its exclusive rights to the beta-domain deleted Factor VIII hemophilia gene from Genetics Institute to a non-exclusive license; or (ii) grant a Hemophilia License to RPR in a manner that has received prior Commission approval and in a manner consistent with the Letter of Intent dated November 20, 1996 between RPR and Sandoz Ltd.; or (iii) grant a Hemophilia License to a Subsequent Hemophilia Licensee that receives the prior approval of the Commission and in a manner that receives the prior approval of the Commission, at no minimum amount. In consideration for the Hemophilia License, Respondent Novartis may request from RPR or the Subsequent Hemophilia Licensee compensation in the form of royalties and/or an equivalent cross-license. At the option of RPR or the Subsequent Hemophilia Licensee, Respondent Novartis shall, in good faith, within one (1) year of the execution of the Hemophilia License provide to RPR or the Subsequent Hemophilia Licensee, such technical information, know-how or materials, owned or controlled by Genetic Therapy, Inc. as of the date on which this Order become final, necessary for the development of a gene therapy product using the beta-domain deleted Factor VIII gene for the treatment of hemophilia.

E. Respondent Novartis shall not acquire from Ingenex, Inc. or the United States National Institutes of Health exclusive rights in intellectual property related to the gene sequence for MDR-1 or MRP.

F. Respondents shall include in each license granted pursuant to this Paragraph a provision that ensures Respondents have no access to any Licensee's Net Sales Price information. Respondents shall, in each license granted pursuant to this Paragraph, provide for:

1. The appointment of an independent auditor agreed upon among the respective parties who shall: (a) enter into appropriate confidentiality agreements; (b) have full and complete access to the pertinent personnel, books, records, technological information, or any other information as to which the auditor may reasonably require; and (c) be authorized to collect, audit, aggregate and distribute the respective aggregated royalties on an annual basis. Respondents shall notify the Commission of the appointment of any independent auditor.

2. A binding arbitration clause to resolve any and all disputes regarding the royalties or any other License terms. Respondents shall notify the Commission of the institution of any arbitration.

G. There will be no limitations upon the rights of any Respondent or any licensee or sublicensee hereunder to license or sublicense its own patents or patent applications to other third parties. Nothing in this Order requires any Respondent to guarantee freedom of operation under any third party patents not included within such Respondent's HSV-tk Patent Rights, Cytokine Patent Rights, Anderson Patent Rights or the patent rights subject to the Hemophilia License.

X.

IT IS FURTHER ORDERED that:

A. If Respondent Novartis has not divested, absolutely and in good faith and with the Commission's prior approval, the Sandoz Corn Herbicide Business within the time required by Paragraph II of this Order, the Commission may appoint a trustee, or direct the trustee appointed pursuant to Paragraph VIII of this Order, to divest the Sandoz Agricultural Chemical Business.

B. If Respondent Novartis has not divested, absolutely and in good faith and with the Commission's prior approval, the Sandoz Animal Health Business within the time required by Paragraph III of this Order, the Commission may appoint a trustee, or direct the trustee appointed pursuant to Paragraph VIII of this Order, to divest the Sandoz Animal Health Business.

C. If Respondents have not complied with the requirements of Paragraph IX.A. of this Order within the time required by Paragraph IX.A. of this Order, the Commission may appoint a trustee or direct the trustee appointed pursuant to Paragraph VIII of this Order to divest the HSV-tk Business to a buyer that receives the prior approval of the Commission, and in a manner that receives the prior approval of the Commission, at no minimum price. If Respondent Novartis has not complied with the requirements of Paragraph IX.D. of this Order within the time required by Paragraph IX.D. of this Order, the Commission may appoint a trustee or direct the trustee appointed pursuant to Paragraph VIII of this Order to convert Respondent Novartis exclusive rights to the beta-domain deleted Factor VIII gene from Genetics Institute to a non-exclusive license.

D. In the event that the Commission or the Attorney General brings an action pursuant to §5(*l*) of the Federal Trade Commission Act, 15 U.S.C§45(*l*), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a trustee in such action. Neither the appointment or extension of responsibilities of a trustee nor a decision not to appoint or extend the responsibilities of a trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed trustee, pursuant to§ 5(*l*) of the Federal Trade Commission Act, 15 U.S.C. §45(*l*), or any other statute enforced by the Commission, for any failure by the Respondents to comply with this Order.

E. If a trustee is appointed or directed by the Commission or a court pursuant to Subparagraph A. of this Paragraph to divest the Sandoz Agricultural Chemical Business, or pursuant to Subparagraph B. of this Paragraph to divest the Sandoz Animal Health Business, or pursuant to Subparagraph C. of this Paragraph to divest the HSV-tk Business, Respondents shall consent to the following terms and conditions regarding the trustee's powers, duties, authority, and responsibilities:

1. The Commission shall select the trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing the selection of any proposed trustee within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed trustee, Respondents shall be deemed to have consented to the selection of the proposed trustee.

2. If a trustee is directed under Subparagraph A. of this Paragraph to divest the Sandoz Agricultural Chemical Business, the Commission may extend the authority and responsibilities of the trustee appointed under Paragraph VIII of this Order to include divesting the Sandoz Agricultural Chemical Business.

3. If a trustee is directed under Subparagraph B. of this Paragraph to divest the Sandoz Animal Health Business, the Commission may extend the authority and responsibilities of the trustee appointed under Paragraph VIII of this Order to include divesting the Sandoz Animal Health Business.

4. If a trustee is directed under Subparagraph C. of this Paragraph to divest the HSV-tk Business, the Commission may extend the authority and responsibilities of the trustee appointed under Paragraph VIII of this Order to include divesting the HSV-tk Business. If a trustee is directed under Subparagraph C. of this Paragraph to convert Respondent Novartis' exclusive rights to the beta-domain deleted Factor VIII gene from Genetics Institute to a non-exclusive license, the Commission may extend the authority and responsibilities of the trustee appointed under Paragraph VIII of this Order to include converting Respondent Novartis' exclusive rights to the beta-domain deleted Factor VIII gene from Genetics Institute to a non-exclusive license.

5. Subject to the prior approval of the Commission and consistent with Paragraphs II through IX, the trustee shall have the exclusive power and authority to divest the assets identified in the Commission's appointment or extension of the trustee's authority and responsibilities.

6. Within ten (10) days after the appointment of the trustee or the extension of the trustee's authority and responsibilities, Respondents shall execute a trust agreement, or shall amend the existing trust agreement in a manner that, subject to the prior approval of the Commission and, in the case of a court-appointed trustee, of the court, transfers to the trustee all rights and powers necessary to permit the trustee to effect the divestiture required by this Order.

7. The trustee shall have twelve (12) months from the date the Commission approves the trust agreement or the amended trust agreement, described in Subparagraph E. of this Paragraph, to accomplish the divestiture or divestitures, which shall be subject to the prior approval of the Commission. If, however, at the end of the applicable twelve-month period, the trustee has submitted a plan of divestiture or believes that divestiture can be achieved within a reasonable time, such divestiture period may be extended by the Commission, or, in the case of a court-appointed trustee, by the court; provided, however, the Commission may extend each divestiture period only two (2) times.

8. The trustee shall have full and complete access to the personnel, books, records and facilities related to the Sandoz Agricultural Chemical Business, the Sandoz Animal Health Business, the HSV-tk Business, the license to hemophilia patents and/or patent applications granted to Respondent Novartis by Genetics Institute, or to any other relevant information, as the trustee may request. Respondents shall develop such financial or other information as such trustee may request and shall cooperate with the trustee.

Respondents shall take no action to interfere with or impede the trustee's accomplishment of the divestitures. Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed trustee, by the court.

9. The trustee shall make every reasonable effort to negotiate the most favorable price and terms available in each contract submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest at no minimum price. The divestiture shall be made in the manner and to the Agricultural Chemical Acquirer as set out in Paragraph II of this Order, or to the Animal Health Business Acquirer as set out in Paragraph III of this Order, or to the acquirer of the HSV-tk Business as set out in Paragraph X.C. of this Order, as applicable; provided, however, if the trustee receives bona fide offers from more than one acquiring entity for the Sandoz Agricultural Chemicals Business, or for the Sandoz Animal Health Business, or for the HSV-tk Business, and if the Commission determines to approve more than one such acquiring entity, the trustee shall divest to the acquiring entity or entities selected by Respondents from among those approved by the Commission.

10. The trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the trustee's duties and responsibilities. The trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission and, in the case of a court-appointed trustee, by the court, of the account of the trustee, including fees for his or her services, all remaining monies shall be paid at the direction of the Respondents, and the trustee's power shall be terminated. The trustee's compensation shall be based at least in significant part on a commission arrangement contingent on the trustee's divesting the Sandoz Agricultural Chemical Business, the Sandoz Animal Health Business, or the HSV-tk Business, as applicable.

11. Respondents shall indemnify the trustee and hold the trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of any claim, whether or not resulting in any liability, except to the extent that such liabilities, losses, damages, claims, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the trustee.

12. If the trustee ceases to act or fails to act diligently, a substitute trustee shall be appointed in the same manner as provided in Paragraph VIII or this Paragraph of this Order.

13. The Commission or, in the case of a court-appointed trustee, the court, may on its own initiative or at the request of the trustee issue such additional Orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

14. In the event that the trustee determines that he or she is unable to divest the Sandoz Agricultural Chemical Business, if directed to divest pursuant to Subparagraph A. of this Paragraph, in a manner consistent with the Commission's purpose as described in Paragraph II of this Order; or in the event that the trustee determines that he or she is unable to divest the Sandoz Animal Health Business, if directed to divest pursuant to Subparagraph B. of this Paragraph, in a manner consistent with the Commission's purpose as described in Paragraph III of this Order; or in the event that the trustee determines that he or she is unable to divest the HSV-tk Business, if directed to divest pursuant to Subparagraph C. of this Paragraph, in a manner consistent with the Commission's purpose as described in Paragraph IX.A.2. of this Order, the trustee may divest additional assets ancillary to the Sandoz Agricultural Chemical Business, ancillary to the Sandoz Animal Health Business, or as applicable, ancillary to the HSV-tk Business, and effect such arrangements as are necessary to satisfy the requirements of this Order.

15. The trustee shall have no obligation or authority to operate or maintain the Sandoz Agricultural Chemical Business, the Sandoz Animal Health Business, or the HSV-tk Business.

16. The trustee shall report in writing to Respondents and the Commission every sixty (60) days concerning the trustee's efforts to accomplish divestiture.

XI.

IT IS FURTHER ORDERED that, Respondents shall comply with all terms of the Agreement to Hold Separate attached to this Order and made a part hereof as Appendix I. The Agreement to Hold Separate shall continue in effect until (a) with respect to the Sandoz Corn Herbicide Business, such time as Respondents have divested the Sandoz Corn Herbicide Business and (b) with respect to the Sandoz Animal Health Business, such time as Respondents have divested the Sandoz Animal Health Business pursuant to Paragraphs II and III of this Order; or, if a trustee is appointed or the trustee's authorities and responsibilities have been extended pursuant to Paragraph X of this Order, the Agreement to Hold Separate shall continue in effect until such time as Respondents or the trustee have divested all of the Sandoz Animal Health Business and, as applicable, the Sandoz Corn Herbicide Business or the Sandoz Agricultural Chemical Business pursuant to this Order.

XII.

IT IS FURTHER ORDERED that, for a period of ten (10) years after the date the Order becomes final, Respondents shall not, without prior notice to the Commission, directly or indirectly, through subsidiaries, partnerships, or otherwise:

A. Acquire more than 5% of any stock, share capital, equity, or other interest in any concern, corporate or non-corporate, engaged in at the time of such acquisition, or within the two years preceding such acquisition, the research, development, manufacture, distribution or sale of Flea Control Products or other products containing Methoprene in the United States; or

B. Acquire any assetscurrently used, or used in the previous two years (and still suitable for use for) for the research, development, manufacture, distribution or sale of Flea Control Products or other products containing Methoprene in the United States. Provided, however, that this Paragraph XII shall not apply to the acquisition of equipment, machinery, supplies or facilities constructed, manufactured or developed by or for Respondents.

The prior notifications required by this Paragraph shall be given on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations, as amended, (hereinafter referred to as "the Notification"), and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such notification, notification shall be filed with the Secretary of the Commission, notification need not be made to the United States Department of Justice, and Notification is required only of

Respondents and not of any other party to the transaction. Respondents shall provide the Notification to the Commission at least thirty (30) days prior to consummating any such transaction (hereinafter referred to as the "first waiting period"). If, within the first waiting period, representatives of the Commission make a written request for additional information, Respondents shall not consummate the transaction until twenty (20) days after substantially complying with such request for additional information. Early termination of the waiting periods in this Paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition. Notwithstanding, prior notification shall not be required by this Paragraph for a transaction for which notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C.§ 18a.

XIII.

IT IS FURTHER ORDERED that, Respondent Ciba and/or Respondent Novartis shall not, without prior notice to the Commission, directly or indirectly, through subsidiaries, partnerships, or otherwise acquire common stock of Chiron such as to increase by more than one percent (1%) or more the percentage of Chiron stock that Ciba owns as of the date this Order becomes final, until the receipt by the Commission of a certification by RPR, the trustee, or Respondents, that Respondents have complied with the requirements of Paragraphs IX.A. and IX.D. of this Order; provided, however, in no event shall this provision apply later than five (5) years from the date this Order becomes final.

The prior notifications required by this Paragraph XIII shall be given on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations, as amended, (hereinafter referred to as "the Notification"), and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such notification, notification shall be filed with the Secretary of the Commission, notification need not be made to the United States Department of Justice, and Notification is required only of Respondent Novartis and not of any other party to the transaction. Respondents shall provide the Notification to the Commission at least thirty (30) days prior to consummating any such transaction (hereinafter referred to as the "first waiting period"). If, within the first waiting period, representatives of the Commission make a written request for additional information, Respondent Novartis shall not consummate the transaction until twenty (20) days after substantially complying with such request for additional information. Early termination of the waiting periods in this Paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition. Notwithstanding, prior notification shall not be required by this Paragraph for a transaction for which notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C§ 18a.

XIV.

IT IS FURTHER ORDERED that:

A. Within sixty (60) days after the date this Order becomes final and every sixty (60) days thereafter until Respondents have fully complied with the provisions of Paragraphs II, III, and IX.A. and IX.D. of this Order requiring, respectively, divestiture of the Sandoz Corn Herbicide Business, divestiture of the Sandoz Animal Health Business, and granting of the HSV-tk License, Respondent Novartis shall submit to the Commission verified written report(s) ("Compliance Reports") setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with Paragraphs II through IX of this Order. After completing the divestitures required under Paragraphs II, III., the licensing required under Paragraph IX.A, and the requirements of Paragraph IX.D. of this Order, and until the termination of the CMA required under Paragraph V of this Order, Respondent Novartis shall submit such Compliance Reports every one hundred eighty (180) days beginning on the date of the divestiture of the Sandoz Animal Health Business. Following termination of the CMA required under Paragraph V of this Order, Respondent Novartis shall submit to the Commission annual Compliance Reports on the anniversary of the date this Order became final, until and including the tenth anniversary date of this Order. Respondents shall include in their Compliance Reports, among other things that are required from time to time, a full description of the efforts being made to comply with Paragraphs II through IX of the Order, including a description of all substantive contacts or negotiations for the divestiture or relating to the Gene Therapy License obligations. Respondents shall include in their compliance reports copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning divestiture.

B. One year (1) from the date this Order becomes final, annually for the next nine (9) years on the anniversary of the date this Order becomes final, and at other times as the Commission may require, Respondent Novartis shall file a verified written report with the Commission setting forth in detail the manner and form in which they have complied and are complying with Paragraphs XII and XIII of this Order.

XV.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any proposed change in the corporate Respondents such as dissolution, assignment, sale resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries or any other change in the corporation that may affect compliance obligations arising out of this Order.

XVI.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, upon written request, Respondents shall permit any duly authorized representative of the Commission:

A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of Respondents relating to any matters contained in this Order; and

B. Upon five days' notice to Respondents and without restraint or interference from them, to interview officers, directors, or employees of Respondents.

XVII.

IT IS FURTHER ORDERED that this Order shall terminate ten (10) years from the date this Order becomes final.

Signed this _____ day of _____, 1996.

FOR THE BUREAU OF COMPETITION
FEDERAL TRADE COMMISSION

_____
Morris A. Bloom
Attorney

_____
Elizabeth A. Jex
Attorney

_____
Claudia R. Higgins
Attorney

_____
Rhett R. Krulla
Senior Litigator

FOR CIBA-GEIGY LIMITED

_____
A. Krauer

_____
H. Gut

FOR CIBA-GEIGY CORPORATION

_____
Jeff Benjamin

FOR CHIRON CORPORATION

_____
Dr. William J. Rutter
Chairman

FOR SANDOZ LTD.

APPROVED:

Raymond Breu

M. Howard Morse
Assistant Director

H. J. Rudloff

FOR SANDOZ CORPORATION

George S. Cary
Senior Deputy Director

Robert L. Thompson, Jr.

William J. Baer
Director

FOR NOVARTIS AG

Dr. Daniel Vasella

Urs Bärlocher

_____
Michael Malina
Kaye, Scholer, Fierman, Hays & Handler
Counsel for Ciba-Geigy Ltd., Ciba-Geigy Corporation, Sandoz Ltd., Sandoz Corporation and Novartis AG

_____
Kenneth S. Prince
Shearman & Sterling
Counsel for Ciba-Geigy Ltd., Ciba-Geigy Corporation, Sandoz Ltd., Sandoz Corporation and Novartis AG

_____
William G. Green
Counsel for Chiron Corporation

APPENDIX I

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of **Ciba-Geigy Limited,** a corporation, **Ciba-Geigy Corporation,** a corporation, **Chiron Corporation,** a corporation, **Sandoz Ltd.,** a corporation, **Sandoz Corporation,** a corporation, and **Novartis AG,** a corporation.	**File No. 961-0055**

AGREEMENT TO HOLD SEPARATE

This Agreement to Hold Separate ("Hold Separate") is by and between Sandoz Ltd. ("Sandoz"), a corporation organized, existing, and doing business under and by virtue of the laws of Switzerland, with its office and principal place of business at Lichtstrasse 35, Basel, Switzerland, 4002; Ciba-Geigy Limited ("Ciba"), a corporation, organized, existing, and doing business under and by virtue of the laws of Switzerland with its principal place of business located at Klybeckstrasse 141, Basel, Switzerland 4002; and the Federal Trade Commission (the "Commission"), an independent agency of the United States Government, established under the Federal Trade Commission Act of 1914, 15 U.S.C. § 41, *et seq.* (collectively, the "Parties") .

PREMISES

WHEREAS, on March 6, 1996, Ciba and Sandoz entered into an Agreement providing for the merger (hereinafter the "Merger") of Ciba and Sandoz into Novartis AG ("Novartis"); and

WHEREAS, Sandoz, through its subsidiary Sandoz Agro, Inc., operates, *inter alia*, (a) an Agricultural Chemical Business as defined in an Agreement Containing Consent Order attached hereto (the "Consent Order"); and (b) an Animal Health Business as defined in the Consent Order; and

WHEREAS, Ciba, through its subsidiary Ciba-Geigy Corporation, operates *inter alia*, (a) an agricultural chemical business, and (b) an animal health business, and

WHEREAS, the Commission is now investigating the Merger to determine whether it would violate any of the statutes enforced by the Commission; and

WHEREAS, if the Commission accepts the Consent Order, which would require the divestiture of certain assets, the Commission must place the Consent Order on the public record for a period of at least sixty (60) days and may subsequently withdraw such acceptance pursuant to the provisions of Section 2.34 of the Commission's Rules; and

WHEREAS, the Commission is concerned that if an understanding is not reached, preserving the *status quo ante* of the Sandoz Agricultural Chemical Business and the Sandoz Animal Health Business as defined in Paragraph I of the Consent Order during the period prior to the final acceptance and issuance of the Consent Order by the Commission (after the 60-day public comment period), divestiture resulting from any proceeding challenging the legality of the Merger might not be possible, or might be less than an effective remedy; and

WHEREAS, the Commission is concerned that if the Merger is consummated, it will be necessary to preserve the Commission's ability to require the divestiture of the Sandoz Agricultural Chemical Business, as described in Paragraph I.BB. of the Consent Order, and the Sandoz Animal Health Business, as described in Paragraph **CC. of the Consent Order, and the Commission's right to have the Sandoz Agricultural Chemical Business and the Sandoz Animal Health Business** continue as viable competitors independent of Ciba, Sandoz and Novartis; and

WHEREAS, even if the Commission determines to finally accept the consent Order, it is necessary to hold separate the Sandoz Agricultural Chemical Business and the Sandoz Animal Health Business to protect interim competition pending divestiture or other relief; and

WHEREAS, the purpose of the Hold Separate and the Consent Order is:

1. to preserve the Sandoz Agricultural Chemical Business and the Sandoz Animal Health Business as viable and competitive, independent businesses pending the divestitures required by the Consent Order;

2. to remedy any anticompetitive effects of the Merger; and

3. to preserve the Sandoz Agricultural Chemical Business and the Sandoz Animal Health Business as ongoing and competitive entities engaged in the same businesses in which they are presently employed until divestiture is achieved; and

WHEREAS, Sandoz and Ciba's entering into this Hold Separate shall in no way be construed as an admission by Sandoz or Ciba that the Merger is illegal; and

WHEREAS, Sandoz and Ciba understand that no act or transaction contemplated by this Hold Separate shall be deemed immune or exempt from the provisions of the antitrust laws or the Federal Trade Commission Act by reason of anything contained in this Hold Separate.

NOW, THEREFORE, the Respondents, upon understanding that the Commission has not yet determined whether the Merger will be challenged, and in consideration of the Commission's agreement at the time it accepts the Consent Order for public comment that, unless the Commission determines to reject the Consent Order, the Commission will not seek a temporary restraining order, preliminary injunction, or permanent injunction to prevent consummation of the Merger, and will grant early termination of the Hart-Scott-Rodino waiting period, the Parties agree as follows:

1. Ciba and Sandoz agree that from the date this Hold Separate is signed by Sandoz and Ciba until the earliest of the dates listed in Paragraphs 1.a or 1.b, they each will comply with the provisions of this Hold Separate:

   . twenty (20) days after the Commission withdraws its acceptance of the Consent Order pursuant to the provisions of Section 2.34 of the Commission's Rules; or

   . the day after each of the divestitures required by the Consent Order has been completed.

2. Ciba and Sandoz agree to execute and be bound by the attached Consent Order and to comply, from the date this Hold Separate is accepted, with the provisions of the Consent Order as if it were final.

3. The terms capitalized herein shall have the same definitions as in the Consent Order.

4. To ensure the complete independence and viability of The Properties To Be Divested and to ensure that no competitive information is exchanged between The Properties To Be Divested and Sandoz, Ciba or Novartis, Sandoz and Novartis shall hold The Properties To Be Divested as they are presently constituted separate and apart on the following conditions:

   . the held separate businesses shall be held separate and apart and shall be operated independently of Ciba, Sandoz and Novartis (meaning here and hereinafter, Ciba, Sandoz and Novartis excluding The Properties To Be Divested and excluding all personnel connected with The Properties To Be Divested as of the date this Hold Separate was signed) except to the extent that Ciba, Sandoz or Novartis must exercise direction and control over the held separate businesses to assure compliance with this Hold Separate or the Consent Order.

   . The Properties To Be Divested shall be staffed with sufficient employees to maintain the viability and competitiveness of The Properties To Be Divested. Neither Sandoz, Ciba nor Novartis shall employ, or make offers of employment to, any person employed by Sandoz in connection with The Properties To Be Divested or whose principal duties, during the year prior to the date of the signing of this Hold Separate, related to the management, operation, research, development, regulatory registration, sales or marketing activities of The Properties To Be Divested. Sandoz, Ciba and Novartis shall encourage and facilitate employment by The Properties To Be Divested of Sandoz employees who had line responsibility with respect to The Properties To Be Divested in the year prior to the signing of this Hold Separate; shall not

offer any incentive to such employees to decline employment with The Properties To Be Divested or accept other employment in Sandoz, Ciba or Novartis; and shall remove any impediments that may deter such employees from accepting employment with The Properties To Be Divested, including but not limited to, the payment, or transfer for the account of the employee, of all accrued bonuses, pensions and other accrued benefits to which such employees would otherwise have been entitled had they remained in the employment of Sandoz.

. Ciba, Sandoz or Novartis personnel connected with The Properties To Be Divested or providing support services to The Properties To Be Divested as of the date of this Hold Separate was signed may continue, as employees of Sandoz or Novartis, to provide such services as they are currently providing to the held separate businesses. Such Sandoz or Novartis personnel must retain and maintain all material confidential information relating to the held separate businesses on a confidential basis and, except as is permitted by this Hold Separate, such persons shall be prohibited from providing, discussing, exchanging, circulating, or otherwise furnishing any such information to or with any other person whose employment involves any Sandoz or Novartis business.

. Sandoz, Ciba and Novartis shall not exercise direction or control over, or influence directly or indirectly, The Properties To Be Divested, the Management Committee (as defined in subparagraph 4.f.), or any of its operations or businesses; provided, however, that Ciba, Sandoz and Novartis may exercise only such direction and control over The Properties To Be Divested as is necessary to assure compliance with this Hold Separate or with the Consent Order.

. Ciba, Sandoz and Novartis shall maintain the marketability, viability and competitiveness of The Properties To Be Divested and shall not take any action that may cause or permit the destruction, removal, wasting, deterioration or impairment of The Properties To Be Divested, except for ordinary wear and tear, and shall not sell, transfer, encumber (other than in the normal course of business), or otherwise impair the marketability, viability or competitiveness of The Properties To Be Divested. Sandoz shall provide The Properties To Be Divested with sufficient working capital to operate at current rates of operation, including but not limited to, current levels of research and development activities, to perform all necessary routine maintenance to, and replacement of, plant and equipment of The Properties To Be Divested, and to maintain the viability and competitiveness of The Properties To Be Divested.

. Sandoz shall appoint a three-person Management Committee for The Properties To Be Divested (the "Management Committee"), one of whom shall be named Chairman of the Management Committee. The Management Committee shall consist of persons who are, and shall remain, independent of Sandoz, Ciba and Novartis and competent to assure the continued viability and competitiveness of The Properties To Be Divested. Sandoz shall not permit any director, officer, employee or agent of Ciba, Sandoz or Novartis also to be a director, officer, employee or agent of The Properties To Be Divested. Each Management Committee member shall enter into a

confidentiality agreement agreeing to be bound by the terms and conditions of this Hold Separate.

. Except as required by law and except to the extent that necessary information is exchanged in the course of evaluating and consummating the Merger, defending investigations or litigation, obtaining legal advice, or complying with this Hold Separate or the Consent Order (including accomplishing the divestitures), neither Sandoz, Ciba nor Novartis shall receive or have access to, or the use of, any material confidential information of The Properties To Be Divested or the activities of the Management Committee, not in the public domain. Sandoz may receive on a regular basis from The Properties To Be Divested aggregate financial information necessary and essential to allow Sandoz to file financial reports, tax returns and personnel reports. Any such information that is obtained pursuant to this subparagraph shall only be used for the purposes set out in this subparagraph. ("Material confidential information," as used in this Hold Separate, means competitively sensitive or proprietary information not independently known to Ciba, Sandoz or Novartis from sources other than The Properties To Be Divested or the Management Committee, as applicable, and includes but is not limited to customer lists, customers, price lists, prices, individual transactions, marketing methods, patents, technologies, processes, or other trade secrets).

. All material transactions, out of the ordinary course of business and not precluded by Paragraph 4 hereof, shall be subject to a majority vote of the Management Committee (as defined in Paragraph 4.f. hereof).

. Sandoz shall not change the composition of the Management Committee unless it is necessary to do so in order to assure compliance with this Hold Separate or with the Consent Order. The Chairman of the Management Committee shall have the power to remove members of the Management Committee for cause and to appoint replacement members of the Management Committee. Sandoz shall not change the composition of the management of The Properties To Be Divested except that the Management Committee shall have the power to remove management employees for cause. If the Chairman ceases to act or fails to act diligently, a substitute Chairman shall be appointed in the same manner as provided in Paragraph 4.f. The Management Committee shall circulate to the management employees of The Properties To Be Divested and appropriately display a notice of this Hold Separate and the Consent Order at a conspicuous place at all offices and facilities of The Properties To Be Divested.

. All earnings and profits of The Properties To Be Divested shall be retained separately in The Properties To Be Divested.

. Subject to the direction of the Management Committee, Sandoz and Novartis shall cause The Properties To Be Divested to continue to expend funds for the advertising and trade promotion of such businesses at levels not lower than those budgeted for 1995 and 1996, and shall increase such spending as deemed reasonably necessary in light of competitive conditions. If necessary, Sandoz and Novartis shall provide the held separate businesses with funds necessary to accomplish the foregoing. Sandoz and Novartis shall continue to provide to The Properties To Be Divested such support services as is reasonably necessary and was provided prior to the merger by Sandoz.

5. Should the Federal Trade Commission seek in any proceeding to compel dissolution of Novartis, to compel Sandoz or Novartis to divest any assets or businesses of Ciba that they may hold, to compel Ciba or Novartis to divest any assets or businesses of Sandoz that they may hold, or to seek any other injunctive or equitable relief, neither Sandoz nor Ciba shall raise any objection based upon the expiration of the applicable Hart-Scott-Rodino Antitrust Improvements Act waiting period or the fact that the Commission has permitted the Merger. Sandoz and Ciba also waive all rights to contest the validity of this Hold Separate.

6. Within twenty (21) days after the date this Hold Separate is signed by Respondents and every thirty (30) days thereafter, Respondents shall each submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Hold Separate and the Consent Order. Respondents shall include in their compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with the terms of the Consent Order, including a description of all contacts and negotiations for the divestiture and the identity of all parties contacted. Respondents shall include in their compliance reports copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning the divestitures.

7. For the purpose of determining or securing compliance with this Hold Separate, subject to any legally recognized privilege, and upon written request and five day's notice, Sandoz and Ciba shall permit any duly authorized representative(s) of the Commission:

. Access during the office hours of Sandoz or Ciba and in the presence of counsel to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and other records and documents in the possession or under the control of Sandoz, Ciba or Sandoz Agro relating to compliance with this Hold Separate;

. Without restraint or interference from Respondents, to interview Sandoz or Ciba officers, directors or employees, or employees of The Properties To Be Divested, who may have counsel present, regarding any such matters.

8. This Hold Separate shall not be binding until approved by the Commission.

Dated: December 16, 1996

CIBA-GEIGY LIMITED

By: _____

CIBA-GEIGY CORPORATION

By: _____

SANDOZ LTD.

By: _____

SANDOZ CORPORATION

By: _____

FEDERAL TRADE COMMISSION

By: _____
Stephen Calkins
General Counsel

ATTACHMENT A

NOTICE OF DIVESTITURE AND
REQUIREMENT FOR CONFIDENTIALITY

Ciba-Geigy Limited ("Ciba") and Sandoz Ltd. ("Sandoz") have entered into a Agreement Containing Consent Order and Agreement to Hold Separate with the Federal Trade Commission ("Commission") relating to the divestiture of certain Sandoz businesses. Until after the Commission's order becomes final and those businesses are divested, the Sandoz Agricultural Chemical Business and the Sandoz Animal Health Business must be managed and maintained as separate, ongoing businesses, independent of all other Ciba, Sandoz and Novartis businesses. All competitive information relating to the held separate businesses, must be retained and maintained by the persons involved in these businesses on a confidential basis and such persons shall be prohibited from providing, discussing, exchanging, circulating, or otherwise furnishing any such information to or with any other person whose employment involves any other Ciba, Sandoz or Novartis business. Similarly, all such persons involved in the Ciba, Sandoz or Novartis Agricultural Chemical and Animal Health Business shall be prohibited from providing, discussing, exchanging, circulating or otherwise furnishing competitive information about such business to or with any person whose employment involves the held separate businesses.

Any violation of the Consent Order or the Agreement to Hold Separate, incorporated by reference as part of the Consent Order, may subject Ciba, Sandoz and Novartis to civil penalties and other relief as provided by law.

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
Ciba-Geigy Limited, a corporation,	)	
Ciba-Geigy Corporation, a corporation,	)	
Chiron Corporation, a corporation,	)	Docket No. C-
Sandoz Ltd., a corporation,	)	
Sandoz Corporation, a corporation, and	)	
Novartis AG, a corporation.	)	

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act and of the Clayton Act, and by virtue of the authority vested in it by said Acts, the Federal Trade Commission (the "Commission"), having reason to believe that respondents Ciba-Geigy Ltd., a corporation including its wholly-owned subsidiary, Ciba-Geigy Corporation, (collectively, "Ciba"), and Sandoz Ltd., a corporation, including its wholly-owned subsidiary, Sandoz Corporation, (collectively, "Sandoz"), corporations subject to the jurisdiction of the Commission, have agreed to merge into Novartis Ltd. ("Novartis"), a corporation, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENTS

1. Respondent Ciba-Geigy Limited is a corporation organized, existing and doing business under and by virtue of the laws of Switzerland, with its office and principal place of business located at Klybeckstrasse 141, CH-4002 Basel, SwitzerlandCiba operates in the United States through its wholly-owned subsidiary, Ciba-Geigy Corporation, and is engaged in the discovery, development, manufacture and sale of agricultural crop protection chemicals, proprietary and generic pharmaceutical products, and animal health products. Ciba participates in the field of gene therapy in the United States through the Chiron Corporation.

1. Respondent Ciba-Geigy Corporation, a wholly-owned subsidiary of Ciba-Geigy Limited, is a corporation organized, existing, and doing business under and by virtue of the laws of New York with its office and principal place of business located at 520 White Plains Road, Tarrytown, New York 10591.

1. Respondent Sandoz Ltd. is a corporation organized, existing and doing business under and by virtue of the laws of Switzerland, with its office and principal place of business located at Lichtstrasse 35, CH-4002 Basel, Switzerland. Sandoz operates in the United States through its wholly-owned subsidiary, Sandoz Corporation, and is engaged in the discovery, development, manufacture and sale of agricultural crop protection chemicals, proprietary and generic pharmaceutical products, and animal health products. Sandoz participates in the field of gene therapy in the United States through its wholly-owned subsidiary, Sandoz Pharmaceuticals Corporation, headquartered in New Jersey, and through its wholly-owned subsidiary, Genetic Therapy, Inc., headquartered in Maryland.

1. Respondent Sandoz Corporation, a wholly-owned subsidiary of Sandoz Ltd., is a corporation organized, existing, and doing business under and by virtue of the laws of New York with its office and principal place of business located at 608 Fifth Avenue, New York, New York 10020.

1. Respondent Chiron Corporation ("Chiron") is a corporation organized, existing, and doing business under and by virtue of the laws of Delaware with its office and principal place of business located at 4560 Horton Street, Emeryville, California 94608. Ciba-Geigy Limited, together with its subsidiaries, is the largest shareholder of Chiron, holding, not solely for investment, approximately 46.5% of the Chiron capital stock as of September 30, 1996. Chiron is engaged in the discovery, development, manufacture and sale of proprietary and generic pharmaceutical products, including gene therapy products. Ciba has agreed to fund research at Chiron and guarantee its debt, and has the right to appoint members of its board of directors and to veto specified actions of the company.

1. Respondent Novartis AG, is a corporation organized, existing, and doing business under and by virtue of the laws of Switzerland with its office and principal place of business located at Centralbahnstrasse 7, CH-4010 Basel, Switzerland.

II. JURISDICTION

1. Ciba, Sandoz, Chiron, and Novartis are, and at all times relevant herein have been, engaged in commerce as "commerce" is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and are corporations whose businesses are in or affect commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

III. THE PROPOSED MERGER

1. On or about March 6, 1996, Ciba and Sandoz signed a merger agreement providing that both companies will merge with Novartis Ltd., a Swiss company jointly formed by Ciba and Sandoz to effectuate the merger of their businesses. The total value of the stock involved in the transaction is in excess of $63 billion. The merged entity, Novartis, will control worldwide assets valued at approximately $80 billion.

IV. THE RELEVANT MARKETS

1. One relevant line of commerce in which to analyze the effects of the proposed merger is gene therapy technology and research and development of gene therapies, including *ex vivo* and *in vivo* gene therapy. Specific gene therapy product markets, in which the effects of the proposed merger may be analyzed include the research, development, manufacture and sale of :

(a) herpes simplex virus-thymidine kinase ("HSV-tk") gene therapy for the treatment of cancer;

(b) HSV-tk gene therapy for the treatment of graft versus host disease;

(c) gene therapy for the treatment of hemophilia; and

(d) chemoresistance gene therapy.

Gene therapy is a therapeutic intervention in humans based on modification of the genetic material of living cells. Cells may be modified *ex vivo* for subsequent administration or altered *in vivo* by gene therapy products given directly to the patient.

1. While no gene therapy product has yet been approved by the FDA, gene therapy treatments now in clinical trials offer patients the prospect of significant medical improvements or cures for diseases, particularly in oncology, transplantation and central nervous system diseases. The first regulatory approvals for commercial sales of gene therapy products, expected by the year 2000,

will most likely be in the area of oncology. These oncology gene therapy products are anticipated to have sales exceeding $600 million by 2002 and will likely use the HSV-tk gene with viral vectors, the means of delivering the gene. Sales of all gene therapy products are projected to reach $45 billion by 2010, resulting from approvals for additional gene therapies using the HSV-tk gene and other gene therapies. HSV-tk gene therapy is expected to be used, inter alia, to treat graft versus host disease, an acute, chronic and sometimes fatal complication occurring in approximately 70 percent of all bone marrow transplantations. Gene therapy treatments for hemophilia are likely to be used prophylactically, other than in cases of trauma in which instance gene therapy products would likely be used in combination with recombinant and purified Factor VIII proteins. Cancer patients could benefit significantly from gene therapy for chemoresistance that could provide protection to patients' blood systems and allow higher, more effective doses of cancer chemotherapy to be administered. If chemoresistance gene therapy research is successful, sales are projected to exceed $1 billion by 2004. There are no economic substitutes for gene therapy products.

1. Another relevant line of commerce in which to analyze the effects of the proposed merger is the research, development, manufacture and sale of corn herbicide. Corn herbicides are chemical products designed to kill or control weeds that interfere with corn production. Separate markets for corn herbicides are distinguished by the types of weeds, *i.e.*, broadleaf or grass, against which the herbicide is economically effective and the stage of growth of the corn crop or weeds, *i.e.*, pre-emergent or post emergent, at which the herbicide is both safe for use on the corn crop and economically effective against the weeds to be controlled. Corn herbicides are essential to economic production of corn. There are no economic substitutes for corn herbicide for pre-emergent control of grasses or for corn herbicides for post emergent control of broadleaf weeds.

1. Another relevant line of commerce in which to analyze the effects of the proposed merger is the research, development, manufacture and sale of flea control products. Flea control products are chemical products designed to treat and prevent flea infestation in cats and dogs. Flea control products are sold in various forms including pills, collars, shampoos, sprays, and foggers, and are sold through various channels of distribution including veterinarians, pet specialty stores, lawn and garden centers, mass merchandisers, and grocery stores. There are no economic substitutes for flea control products for the treatment and prevention of flea infestation in cats and dogs.

1. The United States is a relevant geographic area in which to analyze the effects of the merger. U.S. Environmental Protection Agency ("EPA") and Food and Drug Administration ("FDA") regulations impose substantial barriers on the introduction of products which do not meet those agencies' regulations.

V. STRUCTURE OF THE MARKETS

Gene Therapy

1. The market for the research and development of gene therapy is highly concentrated. Ciba and Chiron together, and Sandoz, are two of only a few entities capable of commercially developing gene therapy products. Only Ciba together with Chiron, and Sandoz control the substantial proprietary rights necessary to commercialize gene therapy products and possess the technological, manufacturing, clinical, regulatory expertise and manufacturing capability to commercially develop gene therapy products. Each is either in clinical development or near clinical development for the treatment of human diseases for which there are large unmet medical needs.

1. Ciba and Chiron together, and Sandoz are the two leading commercial developers of gene therapy technologies and control critical gene therapy proprietary portfolios, including patents, patent applications, and know-how.

1. The market for the research and development of HSV-tk gene therapy for the treatment of cancer is highly concentrated. Only two companies are capable of commercially developing HSV-tk gene therapy products with viral vectors and are either in clinical development or near clinical development to treat cancer. Sandoz and Chiron are the leading commercial developers of these gene therapy technologies and control critical proprietary intellectual property portfolios, including patents, patent applications, and know-how.

1. The market for the research and development of HSV-tk gene therapy for the treatment of graft versus host disease is also highly concentrated. Only two companies are capable of commercially developing HSV-tk gene therapy products with viral vectors, and are either in clinical development or near clinical development to treat graft versus host disease. Chiron and Sandoz are the leading commercial developers of these gene therapy technologies and/or control critical proprietary intellectual property portfolios, including patents, patent applications, and know-how.

1. The market for the research and development of gene therapy for the treatment of hemophilia is highly concentrated. Only two companies are capable of commercially developing gene therapy products for the treatment of hemophilia using the Factor VIII gene with viral vectors. Chiron and Sandoz are the leading commercial developers of these gene therapy technologies and control critical proprietary intellectual property portfolios, including patents, patent applications, and know-how.

1. The market for the research and development of chemoresistance gene therapy is highly concentrated. Only three companies are capable of commercially developing gene therapy products for the treatment of chemoresistance using the MDR-1 gene and only two companies are capable of commercially developing gene therapy products for the treatment of chemoresistance using the MRP gene. Chiron and Sandoz are the leading commercial developers of these gene therapy technologies and/or control critical proprietary intellectual property portfolios, including patents, patent applications, and know-how.

Corn Herbicides

1. The market for corn herbicide, and the relevant markets included therein, herbicide for pre-emergent control of grasses and herbicide for post-emergent control of broadleaf weeds, are each highly concentrated, as measured by the Herfindahl-Hirschman Index ("HHI") and other measures of concentration. Ciba is the leading developer, manufacturer and seller of corn herbicide in the United States with a share of over 35 percent of sales and over 40 percent of treated acres. Sandoz has approximately a 10 percent share by either measure. United States sales of corn herbicide totaled $1.4 billion in 1995. The proposed merger would increase concentration, as measured by the HHI, by approximately 700 points for dollar sales, and by approximately 1000 points for treated acres, to approximately 3000 for sales and approximately 3300 for treated acres.

1. Ciba's metholachlor herbicides, sold under the brands Dual® and Bicep®, are the leading corn herbicides for pre-emergent control of grasses in the United States. Ciba products accounted for over 40 percent of pre-emergent treatment of corn acres for grasses in 1995. In 1996, Sandoz doubled its sales of its recently introduced dimethenamid herbicides, sold under the brands Frontier® and Guardsman®, which accounted for approximately 3 percent of pre-emergent treatment of corn acres for grasses in 1995. Based on 1995 treated acres, the proposed merger would increase concentration, as measured by the HHI, by approximately 300 points to approximately 3400.

1. Sandoz's dicamba herbicides, sold under the brands Banvel®, Marksman®, and Clarity®, are the leading corn herbicides for post-emergent control of broadleaf weeds in the United States. Sandoz products accounted for over 30 percent of post emergent treatment of corn acres for broadleaf weeds in 1995. In 1996, Ciba tripled its sales of its recently introduced sulfonyl urea herbicide, sold under the brand Exceed®, which accounted for approximately 5 percent of post emergent treatment of corn acres for broadleaf weeds in 1995. Based on 1995 post emergent broadleaf treated acres, the proposed merger would increase concentration, as measured by the HHI, by approximately 1900 points to over 4000. Moreover, Ciba and Sandoz recognize that current users of Sandoz's dicamba herbicides are the principal target for expected market share gain by Ciba's Exceed® herbicide.

1. Prior to the merger described in Paragraph 8, Ciba and Sandoz each cooperated and coordinated with other producers of corn herbicide through supply agreements for corn herbicide active ingredients and through joint development and promotion of corn herbicide formulations. Ciba is the dominant supplier of atrazine, a broadleaf weed control product that is widely used as a

component in premixed herbicide formulations, including Marksman®, Guardsman® and Bicep®, as well as in pre-emergent and post emergent herbicides sold by competitors of Ciba and Sandoz. Supply agreements, joint product development agreements, and joint marketing agreements among producers of corn herbicides increase coordinated interaction and the recognition of mutual interdependence among competitors in each of the relevant markets for corn herbicide.

Flea Control Products

1. The flea control products market is very highly concentrated as measured by the HHI and other measures of concentration. Sales of flea control products in the U.S. amounted to approximately $400 million in 1995. Ciba is the leading developer, manufacturer and seller of flea control products with a share of approximately 50 percent. Ciba's Program® has a dominant share of the flea control products market. Sandoz ranks second in flea control products sales from sales of Vetkem® and Zodiac® flea control products and sales of base active methoprene. The proposed merger would increase concentration as measured by the HHI by approximately 3050 points to a level of approximately 6600. Moreover, prior to the merger described in Paragraph 8, Sandoz and Ciba were developing additional flea control products, which likely would be direct and substantial competitors.

VI. ENTRY CONDITIONS

1. Entry into the relevant markets would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract anticompetitive effects of the merger. Regulations by the Food and Drug Administration ("FDA") covering gene therapy products and systemic flea control products and by the Environmental Protection Agency ("EPA") covering corn herbicides and externally applied flea control products create long lead times for the introduction of new products. Additionally, patents and other intellectual property create large and potentially insurmountable barriers to entry.

Gene Therapy

1. Entry into the gene therapymarkets requires lengthy clinical trials, data collection and analysis, and expenditures of significant resources over many years to qualify manufacturing facilities with the FDA. Entry into each gene therapy market can extend up to and beyond 10 to 12 years. The most significant barriers to entry include technical, regulatory, patent, clinical and production barriers. The FDA must approve all phases of gene therapy development, including extensive preclinical and clinical work. No company may reach advanced stages of development in the relevant gene therapy markets without: (1) clinical gene therapy expertise; (2) scientific research that requires years to complete; (3) patent rights to all the necessary proprietary inputs into the gene therapy product sufficient to provide the company with reasonable assurances of freedom to operate; and (4) clinical grade product manufacturing expertise, regulatory approvals and capacity to complete clinical development. The necessary proprietary inputs include genes, vectors and vector manufacturing technology, and cytokines, proteins necessary for many gene therapy applications.

Corn Herbicides

1. Despite the expiration of United States patents on dicamba and metolachlor, post-patent strategies pursued by Ciba and Sandoz, including product reformulation, distribution agreements, purchase and supply contracts with manufacturers, and joint product development agreements, have limited entry of generic competition to Ciba's leading pre-emergent grass herbicides and Sandoz's leading post emergent broadleaf herbicides.

1. Entry into the corn herbicide markets requires over a decade for chemical synthesis; laboratory and greenhouse testing; formulation; process development; pilot production; pilot trials; field trials; testing for acute, subchronic and chronic toxicity, carcinogenic and genetic effects, and incidence of birth defects that may be associated with the product; environmental toxicology testing; measurement of plant, animal, soil, water and air residues and testing of degradation of plant, animal, soil, and water environment; data collection; product registration and EPA review; construction of production facilities; and use optimization. Once a product is introduced to the market, several years are often required to gain customer acceptance through demonstrated safety, performance and reliability, over a variety of weather conditions.

Flea Control Products

1. Entry into the flea control products market requires over a decade for chemical synthesis, lengthy clinical trials, data collection and analysis, and expenditures of significant resources over many years as well as qualified manufacturing facilities in order to achieve the required EPA or FDA approvals for commercial sale of these products. Once a product is introduced to the market, extensive sunk costs must be incurred for advertising and promotion to gain significant customer and pet owner acceptance.

1. Despite the expiration of United States patents on methoprene, the base active ingredient used in Sandoz's second generation flea control products, the EPA registrations and proprietary technology involved in the production of methoprene, have prevented entry of generic competition to Sandoz' flea control products.

VII. EFFECTS OF THE PROPOSED MERGER

1. The effects of the merger, if consummated, may be substantially to lessen competition or tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C.§ 18, and Section 5 of the FTC Act, as amended, 15U.S.C. § 45. Specifically the merger will:

a. eliminate Ciba and Sandoz as substantial, independent competitors; eliminate actual, direct, and substantial competition between Ciba and Sandoz, including the reduction in, delay of or redirection of research and development projects; and increase the level of concentration in the relevant markets;

b. eliminate actual potential and perceived potential competition in the relevant markets;

c. increase barriers to entry into the relevant markets;

Gene Therapy

d. combine alternative technologies, and reduce innovation competition among researchers and developers of gene therapy products, including reduction in, delay of or redirection of research and development tracks;

e. increase the merged firm's ability to exercise market power, either unilaterally or through coordinated interaction with Chiron, in the gene therapy markets, because the merged firm will have both complete ownership of the Sandoz gene therapy research and development and a 46.5% stock ownership interest in Chiron, the only other firm in a position to commercialize work in gene therapy;

f. heighten barriers to entry by combining portfolios of patents and patent applications of uncertain breadth and validity, requiring potential entrants to invent around or declare invalid a greater array of patents;

g. create a disincentive in the merged firm to license intellectual property rights to or collaborate with other companies as compared to premerger incentives;

Corn herbicides

h. eliminate the potential for increased actual, direct and substantial price competition and cause consumers to pay higher prices for corn herbicides;

i. increase the merged firm's ability unilaterally to exercise market power in the market for corn herbicide for post-emergent control of broadleaf weeds, by combining the two closest substitutes in the market;

j. increase the likelihood and degree of coordinated interaction between or among competitors in the market for corn herbicide for pre-emergent control of grasses;

Flea Control Products

k. increase the mergedfirm's ability unilaterally to exercise market power in the flea control products market by combining the two closest substitutes in the market;

l. increase the likelihood and degree of coordinated interaction between or among competitors in the flea control products market; and

m. eliminate the potential for actual, direct and substantial price competition and cause consumers to pay higher prices for flea control products, as well as reduce innovation competition among producers of flea control products by eliminating, delaying or redirecting the introduction of new products under development.

VIII. VIOLATIONS CHARGED

1. The merger agreement described in Paragraph 8 constitutes a violation of Section 5 of the FTC Act, 15 U.S.C.§ 45.

1. The merger, if consummated, would constitute a violation of Section 5 of the FTC Act, 15 U.S.C. § 45, and Section 7 of the Clayton Act, 15 U.S.C§ 18.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this Complaint to be signed by the Secretary and its official seal to be affixed, at Washington, D.C. this day of A.D., 1997.

By the Commission.

SEAL

Donald S. Clark
Secretary

ANALYSIS OF PROPOSED CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an agreement containing a proposed Consent Order ("Order") to resolve anticompetitive concerns raised by the proposed merger of Ciba-Geigy Limited ("Ciba") and Sandoz Ltd. ("Sandoz") into a new entity, Novartis AG ("Novartis"). The agreement is between the Commission and Ciba, Sandoz, and Chiron Corporation ("Chiron"). Ciba, which owned 46.5% of Chiron's voting stock as of September 30, 1996, participates in the field of gene therapy through Chiron. Under the proposed Order, the companies have agreed to license certain Sandoz and Chiron gene therapy technologies, to divest Sandoz' corn herbicide business, and to divest Sandoz' United States and Canadian flea control business. In addition, the parties have entered into an Agreement to Hold Separate Sandoz's agricultural chemicals business, including herbicides and other pesticides, and Sandoz's flea control business until the required divestitures have been accomplished.

The proposed Order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed Order.

On March 6, 1996, Ciba and Sandoz signed a merger agreement providing that both companies will merge to form Novartis AG ("Novartis"). The total value of the stock involved in the transaction is in excess of $63 billion. The merged entity, Novartis, will control worldwide assets valued at approximately $80 billion.

The proposed complaint alleges that the merger violates Section 7 of the Clayton Act, as amended, 15 U.S.C.§ 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, by lessening competition or tending to create a monopoly in markets involving three general areas: (1) gene therapy research and development; (2) corn herbicides; and (3) flea control products. According to the complaint, the merger will increase the level of concentration and increase barriers to entry in each of the relevant markets and eliminate Ciba and Sandoz as substantial, independent competitors both for currently marketed products as well as products that are under development.

According to the proposed complaint, entry into the relevant markets would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract anticompetitive effects of the merger. Regulations by the Food and Drug Administration ("FDA") covering gene therapy products and systemic flea control products, and by the Environmental Protection Agency ("EPA") covering corn herbicides and externally applied flea control products, create long lead times for the introduction of new products. Additionally, patents and other intellectual property create large and potentially insurmountable barriers to entry.

Gene Therapy Research and Development

The proposed complaint alleges that gene therapy technology and the research and development of gene therapies constitute relevant markets in which to analyze the effects of the proposed merger. The proposed complaint also alleges that there are four specific gene therapy product markets. These are the markets for the research, development, manufacture and sale of : (1) herpes simplex virus-thymidine kinase ("HSV-tk") gene therapy for the treatment of cancer; (2) HSV-tk gene therapy for the treatment of graft versus host disease; (3) gene therapy for the treatment of hemophilia A; and (4) chemoresistance gene therapy. Sandoz and Ciba/Chiron are two

of only a very small number of entities capable of commercially developing gene therapy products. They possess the intellectual property, the technological, manufacturing, clinical, and regulatory expertise, and the manufacturing assets to commercially develop gene therapy products.

Gene therapy involves treating diseases or medical conditions by modifying genes and then inserting the modified genes into a patient's cells. Patients' genes may be altered using one of two broad approaches: *ex vivo*, outside the body, for subsequent administration into the patient; or *in vivo*, inside the body, by gene therapy products that are given directly to the patients. Gene therapy research today targets fatal or disabling diseases such as cancer for which there are no current effective treatments and for which no drugs are in advanced development.

While no gene therapy product has yet been approved by the FDA for commercial sale, gene therapy treatments now in clinical trials offer patients the prospect of significant medical improvements or cures for diseases, particularly in oncology, transplantation and central nervous system diseases. Gene therapy may be useful in treating a wide array of diseases and conditions. Sales of all gene therapy products are projected to reach up to $45 billion by 2010.

The first regulatory approvals for commercial sales of gene therapy products, expected by the year 2000, will most likely be in the area of cancer treatment of brain tumors. Gene therapy offers brain cancer patients their first hope of a real cure. The brain cancer gene therapy products closest to market use retroviral vectors, the delivery vehicle for genes, to place an HSV-tk gene into the cancerous cells and are anticipated to have sales exceeding $600 million by 2002. HSV-tk gene therapy is also expected to be used to treat graft versus host disease, an acute, chronic and sometimes fatal complication occurring in a significant percentage of all bone marrow transplantations. Gene therapy treatments for hemophilia A are likely to be used prophylactically for

many sufferers; in cases of trauma, gene therapy products would likely be used in combination with recombinant and purified Factor VIII proteins. Cancer patients could benefit significantly from gene therapy for chemoresistance by providing protection to patients' blood systems and allowing higher, more effective doses of cancer chemotherapy to be administered. If chemoresistance gene therapy research is successful, sales are projected to exceed $1 billion by 2004.

The complaint alleges that each of the gene therapy markets is highly concentrated and that Ciba/Chiron and Sandoz are two of only a few entities capable of commercially developing a broad range of gene therapy products. Ciba/Chiron and Sandoz control crucial inputs into the development of gene therapy products and the merger creates an unmatchable portfolio of intellectual property assets that are necessary to commercialize gene therapy products. In addition, they both possess the technological, manufacturing, clinical, and regulatory expertise and manufacturing capability to commercially develop gene therapy products. A substantial number of other companies are able to conduct gene therapy research. Without licenses to crucial intellectual property held by Ciba/Chiron and Sandoz, however, these other researchers would not be likely to continue development. The critical intellectual property rights for gene therapy held by Ciba/Chiron and Sandoz include a broad patent covering all *ex vivo* approaches used in gene therapy and the use of cytokines, a protein necessary for many *ex vivo* gene therapy applications that is used to increase the number of cells taken from a patient. The parties also have vital intellectual property rights in retroviral vectors, the only delivery vehicle for gene therapy that has been proven safe and relatively effective.

The complaint alleges that only two companies, Ciba/Chiron and Sandoz, are capable of commercially developing HSV-tk gene therapy products with retroviral vectors and are either in clinical development or near clinical development to treat cancer and to treat graft versus host

disease. Similarly, these two companies are the most advanced of all companies capable of commercially developing viral vectors using the Factor VIII gene for the treatment of hemophilia A and using the MDR-1 gene and the MRP gene for the treatment of chemoresistance. In each instance, Ciba/Chiron and Sandoz are either in clinical development or near clinical development for the treatment of these diseases, are the leading commercial developers of these gene therapy technologies and control critical proprietary intellectual property portfolios, including patents, patent applications, and know-how. For example, with respect to the HSV-tk gene therapy products, both Ciba/Chiron and Sandoz control intellectual property portfolios sufficient to make it likely that they could market HSV-tk gene therapy products in competition with one another. The merger would eliminate that competition, and because of the parties' patent portfolios, it is extremely unlikely that any other firm would be able to enter to replace that lost competition.

The complaint alleges that entry into the gene therapy markets requires lengthy FDA approved clinical trials, data collection and analysis, and expenditures of significant resources over many years. No company may reach advanced stages of development in the relevant gene therapy markets without: (1) clinical gene therapy expertise; (2) scientific research that requires years to complete; (3) patent rights to all the necessary proprietary inputs into the gene therapy product sufficient to provide the company with reasonable assurances of freedom to operate; and (4) clinical grade product manufacturing expertise, regulatory approvals and capacity to complete clinical development. The necessary proprietary inputs may include genes, vectors and vector manufacturing technology, and cytokines.

Ciba/Chiron and Sandoz each possess virtually all of the gene therapy intellectual property needed to ensure their ability to independently perform gene therapy development. Through the

merger, the companies' alternative competing gene therapy technologies will be combined, reducing innovation competition. That combination changes the competitive incentives of the merged entity. It will likely lead to a reduction in development of gene therapy products, as the parties combine their research and development pipelines and eliminate or slow down their parallel development projects.

In addition, Novartis, the merged firm, will have a disincentive to license intellectual property rights to or collaborate with other companies as compared to the pre-merger incentives of the independent competitors, Ciba/Chiron and Sandoz. Although Ciba/Chiron and Sandoz had substantial individual intellectual property portfolios pre-merger, they had the incentive and did act as rival centers from which others could obtain needed intellectual property rights. Ciba/Chiron and Sandoz would grant limited intellectual property rights to other developers and researchers in return for receiving marketing or other valuable rights back from them. Consequently, as the complaint alleges, the merger may heighten barriers to entry by resulting in one entity holding so extensive a portfolio of patents and patent applications, of uncertain breadth and validity, as to diminish its incentives to license, thus impeding the ability of other gene therapy researchers and developers to continue developing their products.

To remedy the alleged competitive harm, the proposed Order provides for a set of patent licenses to allow other companies to replace the competition otherwise lost due to the merger. The Commission believes that licensing, rather than divestiture of assets, is sufficient because access to certain key intellectual property rights held by the merged firm is a crucial component of successful commercialization of many potential gene therapy products. Competitors already have (to varying

degrees) the hard assets, *e.g.*, production facilities, researchers and scientists, needed to compete. Rivals and other scientists confirm that licensing would enable them to develop gene therapy products and replace the competition lost due to the merger. Further, an asset divestiture might create substantial disruption in the parties' research and development efforts. In this case, therefore, a licensing remedy appears to be the preferred approach to restoring the competition lost by the merger.

The proposed Order includes the following remedy provisions. First, in the research, development, manufacture, and sale of gene therapy, the proposed Order would require Sandoz and Chiron to provide to all gene therapy researchers and developers non-exclusive licenses or sublicenses to certain proprietary and patented technologies essential for the competitive development and commercialization of gene therapy products. In the United States, Chiron owns the rights to commercialize cytokine Interleukin 2 ("IL-2"), and Sandoz has exclusive rights to the Anderson *ex vivo* patent, and claims arising there-under, and owns the rights to cytokines Interleukin 3 ("IL-3") and Interleukin 6 ("IL-6"). Within thirty (30) days of the date the Order becomes final, the companies are required to grant to other gene therapy researchers non-exclusive licenses to each of these essential gene therapy technologies. In addition, each licensee must be given access to drug master files, the data filed with the FDA establishing the safety and purity of these cytokines. These licensing arrangements will remedy the reduction in competition in research and development of gene therapy caused by the merger.

As detailed in the Order, the IL-2, IL-3 and IL-6 cytokines and the Anderson *ex vivo* patent licenses include a right to a royalty payment at low rates (based upon net sales with no minimum amount). In the past, the Commission has had concerns with royalty payments in connection with

licenses that are meant to restore competition eliminated by a merger. This is because continuing entanglements between the divesting company and the acquirer might provide opportunities for information exchange between competitors and interfere with their economic incentives to compete vigorously. These risks are relatively slight under the terms of the proposed Order, particularly because of the low royalties and potential number of non-exclusive licenses to the industry required under the proposed Order. In addition, to minimize further the financial relationships and the exchange of competitively sensitive information among Novartis, Chiron and potential competitor-licensees, an independent auditor will be appointed to collect and aggregate the royalty payments. Sandoz, Ciba, Chiron, and Novartis will be prohibited from gaining access to this confidential sales information. Each license will also include a binding arbitration clause to resolve disputes regarding the royalties or any other terms, a provision that further insulates Sandoz, Ciba, Chiron, and Novartis from interactions with the potential licensees.

Second, the proposed Order provides for further remedies regarding the anticompetitive harm alleged with respect to the HSV-tk product markets. Both Sandoz and Ciba/Chiron are developing HSV-tk gene therapies for cancer and graft versus host disease. After the merger, Ciba/Chiron and Sandoz would control dominating intellectual property portfolios for HSV-tk gene therapy. The proposed Order restores the pre-merger incentives for research, development, manufacture and sale of HSV-tk gene therapy products for cancer and graft versus host disease by requiring licensing of the Sandoz' and Chiron's worldwide HSV-tk patent rights, including rights relating to vectors. By September 1, 1997, Sandoz and Chiron each are required to grant a non-exclusive license to Rhône-Poulenc Rorer ("RPR"), with whom Ciba, Sandoz and Chiron have entered into a letter of intent for this purpose. If the agreement between RPR and Ciba, Sandoz, and Chiron were to fall through,

Ciba, Sandoz and Chiron would be required to license these assets to another licensee who has received Commission approval by September 1, 1997. Under the terms of the proposed Order, the license granted to RPR, or an alternative licensee, must include the right to sublicense in fields that are not developed by RPR or the licensee, as well as a technology transfer from Sandoz of necessary HSV-tk know-how, including know-how relating to vectors, within one year of execution of the license.

Third, to ensure the continued research, development, manufacture and sale of Factor VIII gene therapy products for the treatment of hemophilia A, the proposed Order requires that by September 1, 1997, Sandoz shall either: 1) convert its exclusive license for the use in gene therapy of the partial Factor VIII gene to a non-exclusive license; or 2) grant to RPR a sublicense to those gene therapy Factor VIII rights. At the option of the sublicensee, Sandoz may be required to provide technical information and know-how relating to Factor VIII gene therapy products.

Finally, to ensure the continued research, development, manufacture and sale of chemoresistance gene therapy products in the United States, the proposed Order requires that neither Ciba, Chiron, Sandoz nor Novartis shall acquire exclusive rights in intellectual property and technology related to the MDR-1 and/or MRP genes. With exclusive rights to the genes necessary for this treatment area, both parties would have potentially dominating intellectual property rights for the use of the MDR-1 or MRP chemoresistance genes in gene therapy. The merger combines the parties' two competing chemoresistance gene therapy programs and potentially concentrates the important intellectual property rights for these genes. Thus, the proposed restriction on exclusive licensing of the MDR-1 and MRP genes will ensure access to the chemoresistance genes to at least one other competing company.

The proposed Order also provides for the appointment of a trustee if Novartis and/or Chiron fail to grant any of these licenses within the appropriate time period. In that event, the trustee is authorized to divest either Sandoz or Chiron's HSV-tk businesses in their entirety.

Corn Herbicides

According to the Commission's proposed complaint, the merger of Ciba and Sandoz into Novartis, absent relief, would have adverse effects on various markets for corn herbicide. United States sales of corn herbicides -- chemical products designed to kill or control weeds that interfere with corn production -- totaled $1.4 billion in 1995. According to the proposed complaint, the markets for corn herbicide are distinguished by the types of weeds -- broadleaf or grass -- against which the herbicide is chemically effective as well as by the stage of growth of the corn crop or weed -- pre-emergent or post-emergent -- at which the herbicide is safe for use on the corn crop and chemically effective against the weeds to be controlled.

The Commission's proposed complaint alleges that Ciba's metolachlor herbicides, sold under the brands Dual® and Bicep®, are the leading corn herbicides for pre-emergent control of grasses. The complaint alleges that Sandoz recently introduced dimethenamid grass herbicides, sold under the brands Frontier® and Guardsman®, are gaining share against Ciba's metolachlor grass herbicides.

The complaint also alleges that Sandoz dicamba herbicides, sold under the brands Banvel®, Marksman®, and Clarity®, are the leading corn herbicides for post-emergent control of broadleaf weeds. According to the complaint, Ciba's recently introduced sulfonyl urea broadleaf herbicide, sold under the brand Exceed®, is rapidly gaining share against Sandoz dicamba broadleaf herbicides, and Ciba and Sandoz recognize that current users of Sandoz dicamba herbicides are the principal

target for expected market share gain by Ciba's Exceed® herbicide. Ciba is also the dominant supplier of atrazine, a broadleaf weed control product that is widely used as a component in premixed herbicide formulations sold by Ciba, Sandoz and their competitors.

According to the complaint, each of the corn herbicide markets is highly concentrated, as measured by the Herfindahl-Hirschman Index ("HHI") and other measures of concentration. Ciba accounts for over 35 percent of corn herbicide sales in the United States and over 40 percent of treated acres, while Sandoz has approximately a 10 percent share by either measure. Further, the complaint alleges that the proposed merger would increase concentration, as measured by the HHI, by approximately 700 points for dollar sales, and by approximately 1000 points for treated acres, to approximately 3000 for sales and approximately 3300 for treated acres.

In the market for pre-emergent treatment of corn acres for grasses, the complaint alleges that Ciba products accounted for over 40 percent and that Sandoz accounted for approximately 3 percent in 1995. The proposed merger would increase concentration in that market, as measured by the HHI, by approximately 300 points to approximately 3400. In addition, in the market for post-emergent treatment of corn acres for broadleaf weeds, the complaint alleges that Sandoz products accounted for over 30 percent and that Ciba's Exceed® brand accounted for approximately 5 percent in 1995. Combining Exceed® and other Ciba products with Sandoz's products, the proposed merger would increase concentration in that market, as measured by the HHI, by approximately 1900 points to over 4000.

The complaint alleges that entry into the corn herbicide markets requires over a decade for chemical synthesis; laboratory and greenhouse testing; formulation; process development; pilot production; pilot trials; field trials; testing for acute, subchronic and chronic toxicity, possible

carcinogenic and mutagenic effects and effects on prenatal deformation; environmental toxicology testing; measurement of plant, animal, soil, water and air residues and testing of degradation of plant, animal, soil, and water environment; data collection; product registration and EPA review; construction of production facilities; and use optimization. Further, according to the complaint, once a product is introduced to the market, several years are often required to gain customer acceptance through demonstrated safety, performance and reliability, over a variety of weather conditions.

Additionally, the complaint alleges that, despite the expiration of United States patents on dicamba and metolachlor, post-patent strategies pursued by Ciba and Sandoz, including product reformulation, distribution agreements, purchase and supply contracts with manufacturers, and joint product development agreements, have limited entry of generic competition to Ciba's leading pre-emergent grass herbicides and Sandoz's leading post-emergent broadleaf herbicides.

Further, according to the complaint, supply agreements, joint product development agreements, and joint marketing agreements among producers of corn herbicide increase coordinated interaction and the recognition of mutual interdependence among competitors in each of the relevant markets for corn herbicide.

The complaint further alleges that the proposed merger of Ciba and Sandoz would eliminate Ciba and Sandoz as substantial, independent competitors; eliminate actual, direct, and substantial competition between Ciba and Sandoz, including the reduction in, delay of or redirection of research and development projects; eliminate the potential for increased actual, direct and substantial price competition and cause consumers to pay higher prices for corn herbicides; increase barriers to entry; increase the level of concentration in the corn herbicide markets; increase the merged firm's ability unilaterally to exercise market power in the market for corn herbicide for post-emergent control of

broadleaf weeds by combining the two closest substitutes in the market; and increase the likelihood and degree of coordinated interaction between or among competitors in the market for corn herbicide for pre-emergent control of grasses.

The Order accepted for public comment contains provisions that would require Sandoz to divest its corn herbicide business, including Sandoz's dicamba and dimethenamid plants in Beaumont, Texas, and United States and Canadian assets to BASF Aktiengesellschaft ("BASF"), no later than ten days after the Order becomes final, pursuant to an agreement between Sandoz and BASF for approximately $780 million. If, through no fault of Sandoz, BASF fails to acquire the business, the Order requires Sandoz to divest its corn herbicide business, within sixty days after the Order becomes final, to an alternative acquirer approved by the Commission and in a manner that receives the approval of the Commission, and to divest such additional ancillary assets and businesses and effect such arrangements as are necessary to assure the marketability, independence, viability and competitiveness of the divested business. The Order further provides for appointment of a trustee to divest Sandoz' agricultural chemicals business, including herbicides and other pesticides, in the event Sandoz is unable to complete the required corn herbicide divestiture within the specified period.

Flea Control Products

According to the proposed complaint, the proposed merger will have anticompetitive effects in the market for the research, development, manufacture and sale of flea control products in the United States. Flea control products are chemical products designed to treat and prevent flea infestation in cats and dogs. They are sold in various forms, including pills, collars, shampoos, sprays, and foggers and are sold through various channels of distribution: veterinarians, pet specialty stores, lawn and garden centers, mass merchandisers, and grocery stores. The complaint

alleges that there are no economic substitutes for flea control products for the treatment and prevention of flea infestation in cats and dogs.

The complaint further alleges that the flea control products market is a very highly concentrated market that had sales in the U.S. of approximately $400 million in 1995. Ciba is the leading developer, manufacturer and seller of flea control products, and Ciba's market share is approximately 50 percent. Ciba's Program® brand flea control products have a dominant share of the flea control products market. Sandoz ranks second in flea control products sales from sales of its flea control products, under the Vetkem® and Zodiac® brands, and from sales of the active ingredient, methoprene, used by other companies in flea control products. The complaint also alleges that, prior to the merger, Sandoz and Ciba were both developing additional flea control products, which likely would be in direct and substantial competition with each other's products.

The proposed complaint alleges that entry into the flea control products market requires over a decade for chemical synthesis, lengthy clinical trials, data collection and analysis, and expenditures of significant resources over many years as well as qualified manufacturing facilities in Order to achieve the required EPA or FDA approvals for commercial sale of these products. Once a product is introduced to the market, extensive sunk costs must be incurred for advertising and promotion to gain significant customer and pet owner acceptance. Despite the expiration of United States patents on methoprene, the base active ingredient used in Sandoz's second generation flea control products, the EPA registrations and proprietary technology involved in the production of methoprene have prevented entry of generic competition to Sandoz's flea control products.

The complaint further alleges that the proposed merger of Ciba and Sandoz would increase the merged firm's ability unilaterally to exercise market power in the flea control products market by

combining the two closest substitutes in the market. According to the complaint, the proposed merger would increase the likelihood of coordinated interaction between or among competitors in the flea control products market and eliminate the potential for actual, direct and substantial price competition between them. Consumers would then pay higher prices for flea control products and would not receive the benefits of innovation competition among producers of flea control products.

The proposed Order seeks to remedy the anticompetitive effects of the proposed merger by requiring Sandoz to divest its flea control business for the United States and Canada. Under the Order, the Sandoz flea control business and the Sandoz Dallas facility, which is largely devoted to production of flea control products for the United States and Canada, must be sold to Central Garden and Pet Supply ("Central Garden") within thirty days after the Order becomes final pursuant to an agreement between Central Garden and Sandoz that will be modified to conform to the terms of the consent Order. Alternatively, Novartis is required by the Order to divest the assets to an alternative acquirer that has received Commission approval, within ninety days after the Order is final. The Order further provides for appointment of a trustee to divest these assets in the event Sandoz is unable to complete the required divestiture within the specified period. Ciba, Sandoz, and Novartis have entered into an agreement to hold these assets separate from the rest of Ciba, Sandoz, and Novartis pending completion of the divestiture.

The proposed Order also includes a technology transfer agreement to enable the acquirer to produce its own methoprene, the principal active ingredient in the products to be sold pursuant to the Order, as well as a temporary supply agreement to provide methoprene to the acquirer until its own manufacturing capability has achieved necessary government approvals. Some products currently produced at the Dallas facility that are manufactured for sale outside the United States and Canada

may continue to be manufactured for Sandoz on behalf of the acquirer for two years. To ensure the viability of the flea products acquirer, Novartis is prohibited from re-entering the U.S. market with a methoprene-based flea control product for six years. In addition, Novartis is required under the proposed Order to notify the Commission if it plans to acquire flea control assets in the U.S. during the next ten years.

The purpose of this analysis is to facilitate public comment on the proposed Order, and it is not intended to constitute an official interpretation of the agreement and proposed Order or to modify in any way its terms.

SEPARATE STATEMENT OF COMMISSIONER MARY L. AZCUENAGA
in Ciba Geigy Limited , File No. 961-0055

The Commission today accepts a proposed consent order for public comment to settle allegations that the planned merger of Ciba Geigy Ltd. and Sandoz Ltd. would violate Section 7 of the Clayton Act in certain agricultural chemical, pet flea control and gene therapy markets.

There appears to be reason to believe that the proposed merger would be unlawful in the corn herbicide and flea control markets identified in the complaint and that divestiture in each market is the appropriate remedy. Because BASF makes and sells a specialized corn herbicide, the proposed divestiture of Sandoz's corn herbicide business to BASF would not entirely restore pre-merger conditions, but BASF's product is sufficiently differentiated from the divested assets that the minor overlap does not appear to be significant.

It is premature, in my view, to select Central Garden and Pet Supply to acquire Sandoz's flea control business, because the Commission has virtually no information about Central beyond that contained in the proposed order and the Analysis To Aid Public Comment. While the early identification of a candidate to acquire assets to be divested under an order is to be preferred in order to restore competition quickly, the Commission does not yet have the information to evaluate the competitive implications of a proposed divestiture to Central Garden and Pet Supply.

The alleged gene therapy markets involve products now in clinical trials and others that appear to be more distant in time and perhaps more speculative. The proposed complaint also alleges a technology market, comprising the technology that firms use to develop gene therapies. The theory is that the post-merger combination of Sandoz and Ciba Geigy will control such a critical mass of proprietary information that its incentives to cross license will be diminished, either deterring entry or raising the price of it. I would be interested in public comment on these allegations.

Assuming a violation, it is not entirely clear that the proposed licensing relief is preferable or adequate. A divestiture is the preferred remedy in a Section 7 case. The proposed order, among other things, requires a license of the ex vivo patent, also called the Anderson patent, which was licensed to Sandoz by the National Institutes of Health. The merger does not add to the scope of the patent monopoly, and I see no basis in the proposed complaint for this aspect of the relief. Nor is there any apparent reason why a divestiture in these markets could not be accomplished. I look forward to reviewing the comments on this issue as well.