0510106

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Deborah Platt Majoras, Chairman**
Thomas B. Leary
Pamela Jones Harbour
Jon Leibowitz

In the Matter of	)	
	)	
NOVARTIS AG,	)	**Docket No. C-**
a corporation.	)	
	)	
	)	
	)	

DECISION AND ORDER

The Federal Trade Commission ("Commission") having initiated an investigation of the proposed acquisition by Respondent NOVARTIS AG (hereinafter "NOVARTIS," "Respondent," or "Respondent NOVARTIS") of the interest in Eon Labs, Inc. held by Santo Holding AG ("SANTO") and Respondent having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations 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

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order ("Consent Agreement"), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having therea

issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

1. Respondent NOVARTIS is a corporation organized, existing and doing business under and by virtue of the laws of Switzerland, with its offices and principal place of business located at Lichtstrasse 35, CH-4002 Basel, Switzerland.

2. The Federal Trade Commission has jurisdiction over the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

ORDER

I.

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

A. "NOVARTIS" means NOVARTIS AG, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries (including, but not limited to, Sandoz Inc.), divisions, groups and affiliates controlled by NOVARTIS AG, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition Date, the term "NOVARTIS" shall include Eon.

B. "SANTO" means Santo Holding AG, a corporation organized, existing, and doing business under and by virtue of the laws of Switzerland, with its registered office located at Alte Landstrasse 106, CH-8702 Zollikon/Zurich, Switzerland; and all joint ventures, subsidiaries, divisions, groups, and affiliates controlled by SANTO, including, but not limited to, Eon.

C. "Eon" means Eon Labs, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of Delaware, with its principal place of business located at 1999 Marcus Avenue, Lake Success, New York 11042; and all joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Eon.

D. "Respondent" means NOVARTIS.

E. "Commission" means the Federal Trade Commission.

F. "Acquisition" means the acquisition contemplated by the "Agreement for Purchase and Sale of Stock" dated as of February 20, 2005, by and between NOVARTIS and SANTO, whereby NOVARTIS agreed to acquire 60,000,000 shares of Eon from SANTO for approximately Euro 1.3 billion in cash.

G. "Acquisition Date" means the date the Acquisition is consummated.

H. "Agency(ies)" means any governmental regulatory authority or authorities in the United States responsible for granting approval(s), clearance(s), qualification(s), license(s) or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution or sale of a Product. The term "Agency" includes, but is not limited to, the United States Food and Drug Administration ("FDA").

I. "AMIDE" means AMIDE PHARMACEUTICAL, INC., a corporation organized, existing, and doing business under and by virtue of the laws of the State of New Jersey, with its principal place of business located at 101 East Main Street, Little Falls, New Jersey 07424.

J. "AMIDE Divestiture Agreement" means the Asset Purchase Agreement, the Supply Agreement and the Quality Agreement between NOVARTIS' subsidiary, Sandoz Inc., and AMIDE, dated June 13, 2005, if such agreement has not been rejected by the Commission pursuant to Paragraph II.A., III.A. or IV.A. of this Order, and all related amendments, exhibits, attachments, agreements, and schedules, by and between Respondent NOVARTIS and AMIDE. The AMIDE Divestiture Agreement is attached to this Order as non-public Appendix I.

K. "Application," "New Drug Application" ("NDA"), "Abbreviated New Drug Application" ("ANDA"), "Supplemental New Drug Application" ("SNDA"), "Supplemental Abbreviated New Drug Application" ("SANDA") or "Marketing Authorization Application" ("MAA") mean the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314, and all supplements, amendments, and revisions thereto, any data necessary for the preparation thereof, and all correspondence between Respondent NOVARTIS or SANTO and the FDA or other Agency relative thereto.

L. "Closing Date" means, with respect to each of the divestitures required by Paragraphs II.A., III.A. and IV.A. of this Order, the date on which Respondent NOVARTIS or a Divestiture Trustee and a Commission-approved Acquirer consummate a transaction to divest relevant assets pursuant to this Order. (Pursuant to Paragraphs II.A., III.A. and IV.A. of this Order, the Closing Date is required to occur not later than ten (10) Days after the Acquisition Date.)

M. "Commission-approved Acquirer" means the following:

1. AMIDE, provided AMIDE has not been rejected by the Commission pursuant to Paragraph II.A., III.A. or IV.A. of this Order; or

2. an entity approved by the Commission to acquire assets that Respondent NOVARTIS is required to divest, grant, license, deliver or otherwise convey pursuant to this Order.

N. "Confidential Business Information" means all information owned by, or in the possession or control of, Respondent NOVARTIS that is not in the public domain.

O. "Contract Manufacture" means the manufacture of a Product to be supplied by Respondent NOVARTIS (or a Designee specifically identified in this Order) to the Commission-approved Acquirer.

P. "Day(s)" means the period of time prescribed under this Order as computed pursuant to 16 C.F.R. § 4.3 (a).

Q. "Designee" means any Person other than Respondent NOVARTIS designated by the Commission-approved Acquirer.

R. "Desipramine" means the chemical substance known by the international non-proprietary name desipramine and/or all pharmaceutically active derivatives thereof including, without limitation, esters, salts, hydrates, solvates, polymorphs, prodrugs, metabolites and isomers thereof and all hydrates, solvates, polymorphs, prodrugs and isomers of such salts, as manufactured, marketed and sold by SANTO under ANDA numbers 74-430, 71-601, 71-588, 71-602, and 71-766 at any time during the six months preceding the Acquisition Date.

S. "Desipramine Assets" means all of Respondent NOVARTIS' rights, title and interest in and to all assets, tangible and intangible, acquired from SANTO pursuant to the Acquisition, related to SANTO's Desipramine business in the United States to the extent legally transferable, including the research, Development, manufacture, distribution, marketing or sale of Desipramine, including, without limitation, the following:

1. all Product Intellectual Property;

2. all Product Registrations;

3. all Product Scientific and Regulatory Material;

4. all Product Manufacturing Technology;

5. all Confidential Business Information relating to Desipramine;

6. all Rights of Reference or Use to: (a) the Drug Master Files related to SANTO's Desipramine business in the United States, including, but not limited to, the pharmacology and toxicology data contained in all Applications, NDAs, ANDAs, SNDAs, SANDAs and MAAs; and (b) information similar to such Drug Master Files submitted to any Agency other than the FDA, if such rights exist;

7. all Respondent NOVARTIS' books, records and files related to the foregoing, including, but not limited to, the following specified documents:

a. the Product Registrations;

b. all pharmacology and toxicology data contained in or related to all Applications, Drug Master Files, NDAs, ANDAs, SNDAs, SANDAs and MAAs; all data submitted to and all correspondence with the FDA and other Agencies; all validation documents and data; including, without limitation, clinical data, and quality control histories pertaining to the Product owned by, or in the possession of, NOVARTIS, or to which NOVARTIS has a right of access;

c. all customer lists, vendor lists, catalogs, sales promotion literature, advertising materials, research materials, technical information, dedicated management information systems, specifications, designs, drawings, processes and quality control data, all in a form and to an extent deemed satisfactory by the Commission-approved Acquirer;

d. all customer purchase orders, customer product specifications and requirements, records of historical customer purchases, customer correspondence, customer information, invoices, payment records, customer records, and customer files, all in a form and to a

export, transport, promotion, marketing and sale of a Product, Product approval and registration, and regulatory affairs related to the foregoing. "Develop" means to engage in Development.

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all customer lists, vendor lists

3. all Product Scientific and Regulatory Material;

4. all Product Manufacturing Technology;

5. all Confidential Business Information relating to Orphenadrine Citrate ER;

6. all Rights of Reference or Use to: (a) the Drug Master Files related to NOVARTIS' Orphenadrine Citrate ER business in the United States, including, but not limited to, the pharmacology and toxicology data contained in all Applications, NDAs, ANDAs, SNDAs, SANDAs and MAAs; and (b) information similar to such Drug Master Files submitted to any Agency other than the FDA, if such rights exist;

7. all Respondent NOVARTIS' books, records and files related to the foregoing, including, but not limited to, the following specified documents:

   a. the Product Registrations;

   b. all pharmacology and toxicology data contained in or related to all Applications, Drug Master Files, NDAs, ANDAs, SNDAs, SANDAs and MAAs; all data submitted to any Agency in connection therewith or in correspondence with the FDA or other Agencies; all validation documents and data; including, without limitation, clinical data, and quality control histories pertaining to the Product owned by, or in the possession or control of, NOVARTIS, or to which NOVARTIS has a right of access;

   c. all customer lists, vendor lists, catalogs, sales geA00 0.y documents and data; including

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b. all Orphenadrine Citrate ER inventories, stores, and supplies held by, or under the control of, NOVARTIS, including, but not limited to, the active pharmaceutical ingredient, goods in process, finished goods, and specific packaging and labels.

Provided, however, that "Orphenadrine Citrate ER Assets" does not include: (i) any real property; (ii) any personal property; (iii) any plant or other facility; (iv) any equipment; or (v) any asset or business owned by SANTO prior to the Acquisition Date.

DD. "Patents" means all United States patents and patent applications, in each case existing on the Closing Date, and includes all reissues, divisions, continuations, continuations-in-part, substitutions, reexaminations, restorations, and/or patent term extensions thereof, all inventions disclosed therein, all rights therein provided by international treaties and conventions, and all rights to obtain and file for patents and registrations thereto in the United States, related to a Product of or owned by Respondent on the Closing Date.

EE. "Person" means any company, natural person, incorporated or unincorporated entity, partnership, association, joint venture, government entity, non-profit organization, university, trust or other entity, except for NOVARTIS.

FF. "Product" means each of Desipramine, Orphenadrine Citrate ER and Rifampin.

GG. "Product Contracts" means all contracts and agreements solely relating to a Product between Respondent and any Person.

HH. "Product Intellectual Property" means all of the following related to the Product(s):

1. Patents;

2. Product Copyrights;

3. Product Software, other than Product Intellectual Property;

4. Product Trademarks;

5. Product trade secrets, know-how, techniques, data, inventions, practices, methods and other confidential or proprietary technical, business, research, Development and other information;

6. Rights to obtain and file for Patents and registrations thereof; and

7. Rights to sue and recover damages or obtain injunctive relief for infringement, dilution, misappropriation, violation, or breach of any of the foregoing;

provided, however, "Product Intellectual Property" does not include the names "Sandoz," "NOVARTIS," "Geneva," "Eon" or the names of any other corporations or companies owned by Respondent NOVARTIS or related logos to the extent used on other of SANTO's or Respondent NOVARTIS' products; however, the right to use the name Rimactane in the United States shall be included in Product Intellectual Property related to Rifampin.

II. "Product Manufacturing Technology" means all technology, trade secrets, know-how, and proprietary information (whether patented, patentable or otherwise) related to the manufacture, validation, packaging, release testing, stability and shelf life of the Product, including all product formulations, product specifications, processes, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering and other manuals and drawings, standard operating procedures, flow diagrams, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, safety, efficacy, bioequivalency, quality assurance, quality control and clinical data, research records, compositions, annual product reviews, process validation reports, analytical method validation reports, specifications for stability trending and process controls, testing and reference standards for impurities in and degradation of products, technical data packages, chemical and physical characterizations, dissolution test methods and results, formulations for administration, clinical trial reports, regulatory communications and labeling and all other information related to the manufacturing process, and supplier lists, in each case with respect to a Product and as in existence and in the possession of Respondent NOVARTIS or SANTO on the Closing Date.

JJ. "Product Registrations" means all United States registrations, permits, licenses, consents, authorizations and other approvals, and pending applications and requests therefore, required by applicable Agencies related to the research, Development, manufacture, finishing, packaging, distribution, marketing or sale of any Product, including all NDAs and ANDAs. "Product Registrations" includes all underlying information, data, filings, reports, correspondence or other materials used to obtain or apply for any of the foregoing, including, without limitation, all data submitted to and all correspondence with the FDA and other Agencies.

KK. "Product Scientific and Regulatory Material" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and clinical trial materials and information related to the Product, and full rights to use such materials, in the United States.

LL. "Product Trademark(s)" means all United States trademarks related to the Product, including, but not limited to any trademark or trade dress covering:

1. the size, shape and color of a single dose entity of any generic version of the Product; and

2. the appearance, structure, textual or graphical content and/or color scheme of any labeling, dosing information, product inserts, storage containers and/or other

materials, to the extent that the FDA or any other Agency requires the Commission-approved Acquirer to duplicate such appearance, structure, textual or graphical content and/or color scheme of any labeling, dosing information, product inserts, storage containers and/or other materials.

MM. "Proposed Acquirer" means AMIDE or an entity proposed by Respondent NOVARTIS (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets required to be divested, granted, licensed, delivered or otherwise conveyed by Respondent NOVARTIS pursuant to this Order.

NN. "Remedial Agreement" means the following: (1) any agreement between Respondent and a Commission-approved Acquirer (including, but not limited to, the AMIDE Divestiture Agreement) that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final; and/or (2) any agreement between the Respondent and a Commission-approved Acquirer (or between a Divestiture Trustee and a Commission-approved Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of this Order.

OO. "Rifampin" means the chemical substance known by the international non-proprietary name rifampin and/or all pharmaceutically active derivatives thereof including, without limitation, esters, salts, hydrates, solvates, polymorphs, prodrugs, metabolites and isomers thereof and all hydrates, solvates, polymorphs, prodrugs and isomers of such salts, as marketed and sold by NOVARTIS under NDA number 50-429 at any time during the six months preceding the Acquisition Date.

PP. "Rifampin Agreement" means the Manufacture and Supply Agreement, dated July 7, 1999, entered into by and between NOVARTIS and AMIDE.

QQ. "Rifampin Assets" means all of Respondent NOVARTIS' rights, title and interest in and to all assets, tangible and intangible, in existence on the day preceding the Acquisition Date, related to NOVARTIS' Rifampin business in the United States to the extent legally transferable, including the research, Development, manufacture, distribution, marketing or sale of Rifampin, including, without limitation, the following:

1. all Product Intellectual Property;

2. all Product Registrations;

3. all Product Scientific and Regulatory Material;

4. all Product Manufacturing Technology;

5. all Confidential Business Information relating to Rifampin;

6. all Rights of Reference or Use to: (a) the Drug Master Files related to NOVARTIS' Rifampin business in the United States, including, but not limited to, the pharmacology and toxicology data contained in all Applications, NDAs, ANDAs, SNDAs, SANDAs and MAAs; and (b) information similar to such Drug Master Files submitted to any Agency other than the FDA, if such rights exist;

7. all Respondent NOVARTIS' books, records and files related to the foregoing, including, but not limited to, the following specified documents:

   a. the Product Registrations;

   b. all pharmacology and toxicology data contained in or related to all Applications, Drug Master Files, NDAs, ANDAs, SNDAs, SANDAs and MAAs; all data submitted to and all correspondence with the FDA and other Agencies; all validation documents and data; including, without limitation, clinical data, and quality control histories pertaining to the Product owned by respondent (not toxicology).

b. all Rifampin inventories, stores, and supplies held by, or under the control of, NOVARTIS, including, but not limited to, the active pharmaceutical ingredient, goods in process, finished goods, and specific packaging and labels.

Provided, however, that "Rifampin Assets" does not include: (i) any real property; (ii) any personal property; (iii) any plant or other facility; (iv) any equipment; or (v) any asset or business owned by SANTO prior to the Acquisition Date.

RR. "Right of Reference or Use" means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an Application, including the ability to make available the underlying raw d

2. the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent NOVARTIS, or appoint a Divestiture Trustee, pursuant to Paragraph VI. of this Order, to effect such modifications (including, but not limited to, entering into additional agreements or arrangements) as may be necessary to satisfy the requirements of this Order.

B. Any Remedial Agreement that has been approved by the Commission between Respondent NOVARTIS (or a Divestiture Trustee) and a Commission-approved Acquirer of the Desipramine Assets shall be deemed incorporated into this Order, and any failure by Respondent NOVARTIS to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.

C. Respondent NOVARTIS shall not enforce any agreement against any Person to the extent that such agreement may limit or otherwise impair the ability of the Commission-approved Acquirer to operate the Desipramine Assets as such assets were engaged at the time of the announcement of the Acquisition. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information relating to Desipramine.

D. Respondent NOVARTIS shall secure, prior to the Closing Date, all consents and waivers from all Persons that are necessary for the divestiture of the Desipramine Assets to the Commission-approved Acquirer, or for the continued research, Development, manufacture, use, import, sale, marketing or distribution of Desipramine in the United States by the Commission-approved Acquirer.

E. Respondent NOVARTIS shall maintain manufacturing facilities for the Desipramine finished drug product that are validated, qualified and approved by the FDA, and fully capable of producing Desipramine finished drug product and shall Contract Manufacture and supply such finished drug product to the Commission-approved Acquirer until the earlier of (i) the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) obtains all FDA approvals necessary to manufacture and sell Desipramine independently of Respondent NOVARTIS; or (ii) four (4) years from the Closing Date for the Desipramine Assets;

provided, however, the Commission may eliminate, or further limit the duration of, the Respondent's obligation under this provision should the Commission determine that the Commission-approved Acquirer is not using commercially reasonable best efforts to obtain all FDA approvals necessary to manufacture and sell Desipramine independently of Respondent NOVARTIS.

F. Upon reasonable notice and request from the Commission-approved Acquirer to the Respondent NOVARTIS, Respondent NOVARTIS shall provide (in a timely manner and at no greater than Direct Cost) to the Commission-approved Acquirer consultation with, assistance, training, and advice from, knowledgeable employees of Respondent NOVARTIS with respect to the Development and manufacture of Desipramine that the

manufacturing practices of the FDA, as set forth in 21 C.F.R. Parts 210 and 211. Respondent NOVARTIS shall agree to indemnify, defend and hold the Commission-approved Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Desipramine supplied to the Commission-approved Acquirer pursuant to the Remedial Agreement by Respondent NOVARTIS to meet such specifications. This obligation shall be contingent upon the Commission-approved Acquirer giving Respondent NOVARTIS prompt, adequate notice of such claim and cooperating fully in the defense of such claim. The Remedial Agreement shall be consistent with the obligations assumed by Respondent NOVARTIS under this Order;

provided, however, Respondent NOVARTIS may reserve the right to control the defense of any such litigation, including the right to settle the litigation, so long as such settlement is consistent with Respondent NOVARTIS' responsibilities to supply Desipramine in the manner required by this Order;

provided further, however, this obligation shall not require Respondent NOVARTIS to be liable for any act or omission or misconduct whether willful or negligent of the Commission-approved Acquirer nor for any representations and warranties, express or implied, made by the Commission-approved Acquirer that exceed the representations and warranties made by Respondent NOVARTIS to the Commission-approved Acquirer.

5. Respondent NOVARTIS shall make representations and warranties to the Commission-approved Acquirer that Respondent NOVARTIS will hold harmless and indemnify the Commission-approved Acquirer for any liabilities including, but not limited to, indirect damages, special damages, consequential damages, lost profits, legal fees and costs resulting from the failure by Respondent NOVARTIS to deliver Desipramine in a timely manner as required by the Remedial Agreement unless Respondent NOVARTIS can demonstrate that its failure was entirely beyond the control of the Respondent NOVARTIS and in no part the result of negligence or willful misconduct by Respondent NOVARTIS.

6. During the term of the Contract Manufacture between Respondent NOVARTIS and the Commission-approved Acquirer, upon request of the Commission-approved Acquirer or Interim Monitor (if applicable), Respondent NOVARTIS shall make available to the Commission-approved Acquirer or the Interim Monitor (if applicable) all records that relate to the Contract Manufacture of Desipramine that are generated or created after the Closing Date.

7. Upon reasonable notice and request from the Commission-approved Acquirer to the Respondent NOVARTIS, Respondent NOVARTIS shall provide in a timely manner at no greater than Direct Cost the following:

a. assistance and advice to enable the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) to obtain all necessary permits and approvals from any Agency or Governmental Entity to manufacture and sell Desipramine;

b. assistance to the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) to manufacture Desipramine in substantially the same manner and quality employed or achieved by Respondent NOVARTIS; and

c. consultation with knowledgeable employees of Respondent NOVARTIS and training, at the request of the Commission-approved Acquirer and at a facility chosen by the Commission-approved Acquirer, until the Commission-approved Acquirer (or the Designee of the Commission-

1. Except as permitted under the Remedial Agreement or this Order, Respondent NOVARTIS shall not (i) provide, disclose, or otherwise make available any Confidential Business Information relating to Desipramine to any Person or (ii) use any Confidential Business Information relating to Desipramine for any reason or purpose;

2. Nothing in this Order prohibits Respondent NOVARTIS from disclosing Confidential Business Information relating to Desipramine if required by United States federal or state law, regulation, court order, or subpoena; *provided, however*, that Respondent NOVARTIS shall use its reasonable best efforts to protect the confidentiality of such information, including, but not limited to, obtaining a protective order during an adjudication; and

3. If disclosure of any Confidential Business Information relating to Desipramine is permitted under this Order, Respondent NOVARTIS shall provide, disclose, or otherwise make available such information (i) only to those Persons who require such information for the permitted purposes, (ii) only to the extent that such Confidential Business Information is required, and (iii) only to those Persons who agree in writing or otherwise are required to maintain the confidentiality of such information.

K. Pending the divestiture of the Desipramine Assets, Respondent NOVARTIS shall take such actions as are necessary to maintain the full economic viability, marketa

III.

IT IS FURTHER ORDERED that:

A. Not later than ten (10) Days after the Acquisition Date, Respondent NOVARTIS shall divest the Orphenadrine Citrate ER Assets, absolutely and in good faith, to AMIDE pursuant to and in accordance with the AMIDE Divestiture Agreement. The AMIDE Divestiture Agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of AMIDE or to reduce any obligations of Respondent NOVARTIS under such agreement.

provided, however, that, if Respondent NOVARTIS has divested the Orphenadrine Citrate ER Assets to AMIDE prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondent NOVARTIS that:

1. AMIDE is not an acceptable purchaser of the Orphenadrine Citrate ER Assets, then Respondent shall immediately rescind the transaction with AMIDE and, within six (6) months from the date the Order becomes final, shall divest the Orphenadrine Citrate ER Assets to a Commission-approved Acquirer absolutely and in good faith, at no minimum price, and only in a manner that receives the prior approval of the Commission; or

2. the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent NOVARTIS, or appoint a Divestiture Trustee, pursuant to Paragraph VI. of this Order, to effect such modifications (including, but not limited to, entering into additional agreements or arrangements) as may be necessary to satisfy the requirements of this Order.

B. Any Remedial Agreement that has been approved by the Commission between Respondent NOVARTIS (or a Divestiture T0.0000t,(w00 a Commission-f,2400 TD0.0000 Tc0or4u cm0

Assets to the Commission-approved Acquirer, or for the continued research, Development, manufacture, use, import, sale, marketing or distribution of Orphenadrine Citrate ER in the United States by the Commission-approved Acquirer.

E. Respondent NOVARTIS shall maintain manufacturing facilities for the Orphenadrine Citrate ER finished drug product that are validated, qualified and approved by the FDA, and fully capable of producing Orphenadrine Citrate ER finished drug product and shall Contract Manufacture and supply such finished drug product to the Commission-approved Acquirer until the earlier of (i) the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) obtains all FDA approvals necessary to manufacture and sell Orphenadrine Citrate ER independently of Respondent NOVARTIS; or (ii) six (6) years from the last Closing Date for the Orphenadrine Citrate ER Assets;

provided, however, the Commission may eliminate, or further limit the duration of, the Respondent's obligation under this provision should the Commission determine that the Commission-approved Acquirer is not using commercially reasonable best efforts to obtain all FDA approvals necessary to manufacture and sell Orphenadrine Citrate ER independently of Respondent NOVARTIS.

F. Upon reasonable notice and request from the Commission-approved Acquirer to the Respondent NOVARTIS, Respondent NOVARTIS shall provide (in a timely manner and at no greater than Direct Cost) to the Commission-approved Acquirer consultation with, assistance, training, and advice from, knowledgeable employees of Respondent NOVARTIS with respect to the Development and manufacture of Orphenadrine Citrate ER that the Commission-approved Acquirer might reasonably need in order to receive and use the Orphenadrine Citrate ER Assets in a manner consistent with this Order, and shall continue providing such consultation, assistance, training and advice, at the request of the Commission-approved Acquirer, until the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) obtains all FDA approvals necessary to manufacture and sell Orphenadrine Citrate ER independently of Respondent NOVARTIS; *provided, however,* Respondent NOVARTIS' obligation to provide such assistance as required by this paragraph shall not exceed six (6) years from the last Closing Date relating to Orphenadrine Citrate ER;

G. Upon request of the Commission-approved Acquirer and subject to the approval of the Commission, Respondent NOVARTIS shall include in any Remedial Agreement the following provisions:

1. Respondent NOVARTIS shall Contract Manufacture and deliver to the Commission-approved Acquirer, in a timely manner and under reasonable terms and conditions, a supply of Orphenadrine Citrate ER in Final Finished Form, at Respondent NOVARTIS' Supply Cost, EXW (Incoterms 2000) the manufacturing facility, for a period of time sufficient to allow the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) to

obtain all FDA approvals necessary to manufacture and sell Orphenadrine Citrate ER independently of Respondent NOVARTIS; *provided*, *however*, Respondent NOVARTIS' obligation to Contract Manufacture shall not exceed six (6) years from the last Closing Date relating to Orphenadrine Citrate ER; *provided further*, *however*, that commencing twenty-nine (29) months after the last Closing Date relating to Orphenadrine Citrate ER, Respondent NOVARTIS' supply of Orphenadrine Citrate ER to the Commission-approved Acquirer may be at a price that is increased by ten (10) percent per year above Respondent NOVARTIS' Supply Cost.

2. For the term of the Contract Manufacture related to Orphenadrine Citrate ER, Respondent NOVARTIS will make inventory of Orphenadrine Citrate ER available for sale or resale only to the Commission-approved Acquirer (not for use in Respondent NOVARTIS' own business after the Acquisition Date); *provided*, *however*, nothing in this Order shall prohibit Respondent NOVARTIS from researching, developing, manufacturing, using, importing, selling, marketing or distributing products that compete with Orphenadrine Citrate ER.

3. Respondent NOVARTIS' obligation to supply Orphenadrine Citrate ER to the Commission-approved Acquirer pursuant to the terms of the Remedial Agreement shall take priority over the manufacture and supply of any product for Respondent NOVARTIS' own use or sale.

4. Respondent NOVARTIS shall make representations and warranties to the Commission-approved Acquirer that the Orphenadrine Citrate ER supplied through Contract Manufacture pursuant to the Remedial Agreement meets current good manufacturing practices of the FDA, as set forth in 21 C.F.R. Parts 210 and 211. Respondent NOVARTIS shall agree to indemnifyTjct

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negligent of the Commission-approved Acquirer nor for any representations and warranties, express or implied, made by the Commission-approved Acquirer that exceed the representations and warranties made by Respondent NOVARTIS to the Commission-approved Acquirer.

5. Respondent NOVARTIS shall make representations and warranties to the Commission-approved Acquirer that Respondent NOVARTIS will hold harmless and indemnify the Commission-approved Acquirer for any liabilities including, but not limited to, indirect damages, special damages, consequential damages, lost profits, legal fees and costs resulting from the failure by Respondent NOVARTIS to deliver Orphenadrine Citrate ER in a timely manner as required by the Remedial Agreement unless Respondent NOVARTIS can demonstrate that its failure was entirely beyond the control of the Respondent NOVARTIS and in no part the result of negligence or willful misconduct by Respondent NOVARTIS.

6. During the term of the Contract Manufacture between Respondent NOVARTIS and the Commission-approved Acquirer, upon request of the Commission-approved Acquirer or Interim Monitor (if applicable), Respondent NOVARTIS shall make available to the Commission-approved Acquirer or the Interim Monitor (if applicable) all records that relate to the Contract Manufacture of Orphenadrine Citrate ER that are generated or created after the Closing Date.

7. Upon reasonable notice and request from the Commission-approved Acquirer to the Respondent NOVARTIS, Respondent NOVARTIS shall provide in a timely manner at no greater than Direct Cost the following:

   a. assistance and advice to enable the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) to obtain all necessary permits and approvals from any Agency or Governmental Entity to manufacture and sell Orphenadrine Citrate ER;

   b. assistance to the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) to manufacture Orphenadrine Citrate ER in substantially the same manner and quality employed or achieved by Respondent NOVARTIS; and

   c. consultation with knowledgeable employees of Respondent NOVARTIS and training, at the request of the Commission-approved Acquirer and at a facility chosen by the Commission-approved Acquirer, until the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) obtains all FDA approvals necessary to manufacture and sell Orphenadrine Citrate ER independently of Respondent NOVARTIS and sufficient to satisfy management of the Commission-

approved Acquirer that its personnel (or the Designee's personnel) are adequately trained in the manufacture of Orphenadrine Citrate ER.

H. Respondent NOVARTIS shall delete Orphenadrine Citrate ER from any customer contracts in effect as of the Closing Date that are not divested to the Commission-approved Acquirer.

I. Not later than ten (10) Days after the Closing Date, Respondent NOVARTIS shall begin to deliver to the Commission-approved Acquirer, at Respondent NOVARTIS' expense, copies of all Confidential Business Information relating to Orphenadrine Citrate ER. Not later than one hundred eighty (180) Days after the Closing Date, Respondent NOVARTIS shall complete delivery of all such Confidential Business Information relating to Orphenadrine Citrate ER to the Commission-approved Acquirer and certify to the Commission that such delivery has occurred in accordance with this Order. Respondent NOVARTIS shall deliver such Confidential Business Information relating to Orphenadrine Citrate ER as follows: (1) in good faith; (2) as soon as practicable, avoiding any delays in transmission of such information; and (3) in a manner that insures its completeness and accuracy and that fully preserves its usefulness. Pending complete delivery of all such Confidential Business Information relating to Orphenadrine Citrate ER to the Commission-approved Acquirer, Respondent NOVARTIS shall provide the Interim Monitor (if any has been appointed) with reasonable access to all such Confidential Business Information relating to Orphenadrine Citrate ER and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files related to the Orphenadrine Citrate ER Assets that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order.

J. Respondent NOVARTIS shall take all necessary steps to maintain the confidentiality of the Confidential Business Information relating to Orphenadrine Citrate ER. *Provided, further*, that:

1. Except as permitted under the Remedial Agreement or this Order, Respondent NOVARTIS shall not (i) provide, disclose, or otherwise make available any Confidential Business Information relating to Orphenadrine Citrate ER to any Person or (ii) use any Confidential Business Information relating to Orphenadrine Citrate ER for any reason or purpose;

2. Nothing in this Order prohibits Respondent NOVARTIS from disclosing Confidential Business Information relating to Orphenadrine Citrate ER if required by United States federal or state law, regulation, court order, or subpoena; *provided, however*, that Respondent NOVARTIS shall use its reasonable best efforts to protect the confidentiality of such information, including, but not limited to, obtaining a protective order during an adjudication; and

3. If disclosure of any Confidential Business Information relating to Orphenadrine Citrate ER is permitted under this Order, Respondent NOVARTIS shall provide, disclose, or otherwise make available such information (i) only to those Persons who require such information for the permitted purposes, (ii) only to the extent that such Confidential Business Information is required, and (iii) only to those Persons who agree in writing or otherwise are required to maintain the confidentiality of such infor

2. the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent NOVARTIS, or appoint a Divestiture Trustee, pursuant to Paragraph VI. of this Order, to effect such modifications (including, but not limited to, entering into additional agreements or arrangements) as may be necessary to satisfy the requirements of this Order.

B. Any Remedial Agreement that has been approved by the Commission between Respondent NOVARTIS (or a Divestiture Trustee) and a Commission-approved Acquirer of the Rifampin Assets shall be deemed incorporated into this Order, and any failure by Respondent NOVARTIS to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.

C. Respondent NOVARTIS shall not enforce any agreement against any Person to the extent that such agreement may limit or otherwise impair the ability of the Commission-approved Acquirer to operate the Rifampin Assets as such assets were engaged at the time of the announcement of the Acquisition. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information relating to Rifampin.

D. Respondent NOVARTIS shall secure, prior to the Closing Date, all consents and waivers from all Persons that are necessary for the divestiture of the Rifampin Assets to the Commission-approved Acquirer, or for the continued research, Development, manufacture, use, import, sale, marketing or distribution of Rifampin in the United States by the Commission-approved Acquirer. If Respondent NOVARTIS assigns the Rifampin Agreement, its obligations under this Paragraph IV.D. include, but are not limited to, obtaining all consents and waivers from all Persons necessary to effect the assignment of the Rifampin Agreement in a manner that provides the Commission-approved Acquirer with all of the economic and competitive benefits of the Rifampin Agreement.

E. Respondent NOVARTIS shall assign the Rifampin Agreement to the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer);

F. Respondent NOVARTIS shall delete Rifampin from any customer contracts in effect as of the Closing Date that are not divested to the Commission-approved Acquirer.

G. Not later than ten (10) Days after the Closing Date, Respondent NOVARTIS shall begin to deliver to the Commission-approved Acquirer, at Respondent NOVARTIS' expense, copies of all Confidential Business Information relating to Rifampin. Not later than one hundred eighty (180) Da

in a manner that insures its completeness and accuracy and that fully preserves its usefulness. Pending complete delivery of all such Confidential Business Information relating to Rifampin to the Commission-approved Acquirer, Respondent NOVARTIS shall provide the Interim Monitor (if any has been appointed) with reasonable access to all such Confidential Business Information relating to Rifampin and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files related to the Rifampin Assets that contain such Confidential Business Information relating to Rifampin and facilitating the delivery in a manner consistent with this Order.

H. Respondent NOVARTIS shall take all necessary steps to maintain the confidentiality of the Confidential Business Information relating to Rifampin. *Provided, further, that*

Provided

1. Except as permitted under the Remedial Agreement or this Order, Respondent NOVARTIS shall not (i) provide, disclose, or otherwise make available any Confidential Business Information relating to Rifampin to any Person or (ii) use

Provided

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the Acquisition, and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

V.

IT IS FURTHER ORDERED that:

A. At any time after Respondent NOVARTIS signs the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondent NOVARTIS expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order and the Remedial Agreements.

B. The Commission shall select the Interim Monitor, subject to the consent of Respondent NOVARTIS, which consent shall not be unreasonably withheld. If Respondent NOVARTIS has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) Days after notice by the staff of the Commission to Respondent NOVARTIS of the identity of any proposed Interim Monitor, Respondent NOVARTIS shall be deemed to have consented to the selection of the proposed Interim Monitor.

C. Not later than ten (10) Days after the appointment of the Interim Monitor, Respondent NOVARTIS shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondent NOVARTIS' compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.

D. If an Interim Monitor is appointed, Respondent NOVARTIS shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:

1. The Interim Monitor shall have the power and authority to monitor Respondent NOVARTIS' compliance with the divestiture and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.

2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.

3. The Interim Monitor shall serve until the earlier of:

   a. the completion by Respondent NOVARTIS of the divestiture of all relevant assets required to be granted, licensed, delivered, or otherwise conveye

7. Respondent NOVARTIS shall provide copies of reports to the Interim Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted by Respondent NOVARTIS, and any reports submitted by the Commission-approved Acquirer with respect to the performance of Respondent NOVARTIS' obligations under the Order or the Remedial Agreement. Within thirty (30) Days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondent NOVARTIS of its obligations under the Order.

8. Respondent NOVARTIS may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.

E. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.

F. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.

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

H. The Interim Monitor appointed pursuant to this Order may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

VI.

IT IS FURTHER ORDERED that:

A. If Respondent NOVARTIS has not fully complied with the obligations to divest assets as required by this Order (including the obligation to divest to AMIDE within ten (10) days), the Commission may appoint a trustee ("Divestiture Trustee") to divest the assets required to be divested pursuant to each of the relevant Paragraphs in a manner that satisfies the requirements of each such Paragraph. 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, Respondent NOVARTIS shall consent to the appointment of a Divestiture Trustee in such action to divest the relevant assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture 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 Divestiture Trustee, pursuant to § 5(*l*) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent NOVARTIS to comply with this Order.

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

C. Not later than ten (10) Days after the appointment of a Divestiture Trustee, Respondent NOVARTIS shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by the Order.

D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondent NOVARTIS shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:

1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to divest the assets that are required by this Order to be divested.

2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of

divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondent NOVARTIS shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture 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 losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

7. If, at the end of the term provided for in Paragraph VI.D.2. of this Order, the Divestiture Trustee determines that he or she is unable to grant, license, deliver or otherwise convey the relevant assets required to be granted, licensed, delivered or otherwise conveyed in a manner that preserves their marketability, viability and competitiveness and ensures their continued use in the research, Development, manufacture, import, distribution, marketing, promotion, sale, or after-sales support of the relevant Product, the Divestiture Trustee may assign, grant, license, transfer, divest, deliver or otherwise convey such additional relevant Product assets of Respondent NOVARTIS to a Commission-approved Acquirer as necessary to achieve divestitures and to satisfy the purposes and requirements of this Order.

8. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be granted, licensed, transferred, delivered or otherwise conveyed by this Order.

9. The Divestiture Trustee shall report in writing to Respondent NOVARTIS and to the Commission every sixty (60) Days concerning the Divestiture Trustee's efforts to accomplish the divestiture.

10. Respondent NOVARTIS may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission. The Divestiture Trustee shall

6. a description of all technical assistance provided to any Commission-approved Acquirer during the reporting period.

C. Respondent NOVARTIS shall file annually on the anniversary of the date this Order becomes final a verified written report with the Secretary of the Commission. Each such report shall set forth in detail the manner and form in which Respondent NOVARTIS has complied and is complying with this Order. Respondent NOVARTIS shall include in this report a full description of any claims (whether outstanding or resolved) by any Commission-approved Acquirer that Respondent NOVARTIS has breached or failed to comply fully with this Order or any Remedial Agreement. Respondent NOVARTIS shall include with this report a copy of any written communication (including e-mails) from any Commission-approved Acquirer that includes or relates to a claim that Respondent NOVARTIS has breached or failed to comply fully with this Order or a Remedial Agreement. Respondent NOVARTIS shall file its verified written report:

1. one (1) year after the date this Order becomes final;

2. annually until the earlier of (i) ten (10) years after this Order becomes final, and, (ii) the date Respondent NOVARTIS has fully satisfied all of its obligations under Paragraphs II.A., E. and F.; III.A., E. and F. and IV.A. and E. of this Order and any Remedial Agreement; and,

3. at other times as the Commission may require.

VIII.

IT IS FURTHER ORDERED that Respondent NOVARTIS shall notify the Commission at least thirty (30) Days prior to any (1) proposed dissolution of Novartis AG or Sandoz Inc., (2) proposed acquisition, merger or consolidation of Novartis AG, or (3) any other change in Novartis AG or Sandoz Inc. or other relevant affiliates that may affect compliance obligations arising out of the order, including, but not limited to, assignment, the creation or dissolution of relevant subsidiaries.

IX.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondent NOVARTIS made to its principal United States offices, Respondent NOVARTIS shall permit any duly authorized representative of the Commission:

A. Access, during office hours of Respondent NOVARTIS and in the presence of counsel, to all facilities and access to insOVART

X.

IT IS FURTHER ORDERED that this Order shall terminate upon the earlier of:

A. Ten (10) years from the date on which the Order becomes final; and,

B. The date Respondent NOVARTIS has fully satisfied all of its obligations under Paragraphs II.A., E. and F.; III.A., E. and F. and IV.A. and E. of this Order and any Remedial Agreement.

By the Commission.

Donald S. Clark
Secretary

SEAL

ISSUED:

APPENDIX I
NON-PUBLIC
AMIDE DIVESTITURE AGREEMENT
[Redacted From the Public Record Version But Incorporated By Reference]

APPENDIX II
NON-PUBLIC
DESIPRAMINE AND ORPHENADRINE CITRATE ER
SUPPLY COSTS
[Redacted From the Public Record Version But Incorporated By Reference]