

UNITED STATES OF AMERICA  
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS:     **Robert Pitofsky, Chairman**  
                          **Sheila F. Anthony**  
                          **Mozelle W. Thompson**  
                          **Orson Swindle**  
                          **Thomas B. Leary**

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In the Matter of                             )  
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                  **Glaxo Wellcome plc,**            )  
                  a corporation,                 )  
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   )  
                  **SmithKline Beecham plc,**       )  
                  a corporation.                 )  
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   )

Docket No. C-3990  
DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of the proposed merger of Respondent Glaxo Wellcome plc (“Glaxo”) and Respondent SmithKline Beecham plc (“SB”), hereinafter referred to as “Respondents,” and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition presented to the Commission for its consideration and which, if issued by the Commission, would charge Respondents 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

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents 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 Respondents 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 thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, 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 Glaxo is a corporation organized, existing and doing business under and by virtue of the laws of the United Kingdom, with its office and principal place of business located at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB6 0NN, England.

2. Respondent SB is a corporation organized, existing and doing business under and by virtue of the laws of the United Kingdom, with its office and principal place of business located at New Horizons Court, Brentford, Middlesex, TW8 9EP, England.

3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents, 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. "Glaxo" means Glaxo Wellcome plc, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Glaxo Wellcome plc (including, but not limited to, Glaxo Wellcome Inc., Glaxo Wellcome OTC Inc., Glaxo Wellcome Inc. (Canada), and Glaxo Group Limited), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. "SB" means SmithKline Beecham plc, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by SmithKline Beecham plc (including, but not limited to, SmithKline Beecham (Cork) Limited and SmithKline Beecham Corporation) and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. "Respondents" means Glaxo and SB, individually and collectively.

D. "Merger" means the proposed merger of Glaxo and SB by means of a scheme of arrangement pursuant to section 425 of the Companies Act 1985 (Eng.) announced on January 17, 2000, which was approved by the shareholders of SB and Glaxo at shareholders meetings held on July 31, 2000.

E. "Commission" means the Federal Trade Commission.

F. "Abbott Labs" means Abbott Laboratories, a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its offices and principal place of business located at 100 Abbott Park Road00 16the S9 t 19r022ess,, -28oc...Tj .56 4. sh io

- N. “Pfizer” means Pfizer, Inc., including, but not limited to, the former Warner-Lambert Company, a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its offices and principal place of business located at 235 East 42<sup>nd</sup> Street, New York, New York 10017.
- O. “Roche” means F.Hoffman-La Roche Ltd, 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 CH-4070 Basel, Switzerland.
- P. “Takeda” means Takeda Chemical Industries, Ltd., a corporation organized, existing and doing business under and by virtue of the laws of Japan, with its United States offices located at 600 Central Avenue, Suite 240, Highland Park, IL 60035.
- Q. “Vernalis” means Vernalis Limited, formerly known as Vanguard Medica Ltd., a company organized under English law and having its registered office at Chancellor Court, Surrey Research Park, Guildford, Surrey, GU2 7SF, England.
- R. “Agency(ies)” means any governmental regulatory authority or authorities in the world 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”).
- S. “Antiemetic Product” means any prescription pharmaceutical compound indicated for the prevention and treatment of nausea and vomiting associated with medical treatment, including chemotherapy, radiation therapy and surgery.
- T. “Assigned Contracts” means all contracts relating to a Product.
- U. “Business Day” means any day excluding Saturday, Sunday and any other United States Federal holiday.
- V. “Ceftazidime” means any Product that contains any form or formulation of the compound ceftazidime, any of its constituent elements, active ingredients or intermediaries, and all rights relating to the research, development, manufacture or sale of any such Product.
- W. “Closing Date” means the date on which Respondents and a Commission-approved Acquirer close on a transaction to divest or transfer relevant assets pursuant to this Order.
- X. “Commission-approved Acquirer” means an entity approved by the Commission to acquire particular assets the Respondents are required to divest or transfer pursuant to this Order.

- Y. “Confidential Business Information” means all information owned by Respondents that is not in the public domain relating to the research, development, manufacture, marketing, commercialization, distribution, importation, cost, pricing, supply, sales, sales support, or use of any of Respondents’ Products or Products in development.
- Z. “Contract Manufacture” means the manufacture of a Product supplied pursuant to a Divestiture Agreement by Respondents for sale to the Commission-approved Acquirer.
- AA. “Denavir” means any Product containing the drug compound Penciclovir, any of its

Famciclovir and Penciclovir Supply Agreement, the DISC-HSV Amended Development and Licence Agreement, the Kytril Asset Sale Agreement, the Kytril Supply Agreement, the Kytril Transition Support Agreement, the Zantac Agreements, the Renzapride Asset Sale Agreements, the Frovatriptan Asset Sale Agreement, the GI147211C Asset Sale Agreements, the Tazicef Asset Sale Agreement and the Tazicef Final Finished Pharmaceuticals Supply Agreement.

- HH. “Domain Name” means the domain name(s) (universal resource locators), and registration(s) thereof, issued by NetworkSolution, Inc. or any other entity or authority who issues and maintains the domain name registration. “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- II. “Drug Master Files” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 relating to any Product included in this Order.
- JJ. “Famciclovir” means the chemical compound 2-[2-(2-amino-9H-purin-9-yl) ethyl] -1,3-propanediol diacetate, its salts and esters in any form or formulation.
- KK. “Famciclovir and Penciclovir Assets” means all of Respondents’ rights, title and interest, worldwide, in and to all assets and businesses relating to the Product Denavir and/or to the Product Famvir, separately (where “Product,” as used in this paragraph and its subparts, means both Denavir and Famvir, separately), and to Penciclovir and to Famciclovir, separately, including the research, development, manufacture, distribution, marketing or sale of the Product Denavir, the Product Famvir, Penciclovir and/or Famciclovir, including, without limitation, the following:
1. all Product Intellectual Property (the Patents and Product Trademarks for Denavir and Famvir are listed in Appendix III);
  2. the Product and Product Registrations;
  3. lists of all current customers for the Products and the pricing of the Products for such customers;
  4. all Famciclovir and Penciclovir Assigned Contracts, each at the option of the Commission-approved Acquirer;
  5. Respondents’ records and files pertaining to the following, including, but not limited to, all specified documents: the Product Registrations; rights of reference to Drug Master Files; correspondence with the FDA and other Agencies; all validation documents and data; all market studies; all sales histories, including without limitation, all clinical data, sales force call activity, and physician

prescription activity for the Products on a per-physician basis from January 1, 1997, through the Closing Date; and quality control histories pertaining to the Products owned by Respondents, in each case such as is in existence, in the possession or control of Respondents, as of the Closing Date;

6. rights of reference to all Drug Master Files, including but not limited to, the pharmacology and toxicology data contained in all NDAs, ANDAs, SNDAs and MAAs;
7. all Product Marketing Materials;
8. the NDC Numbers relating to the Products;
9. Scientific and Regulatory Material;
10. all unfilled customer orders for finished goods as of the Closing Date (a list of such orders to be provided to the Commission-approved Acquirer within two business days after the Closing Date);
11. all books, records and files that relate to the following: Product Manufacturing Technology; Product manufacturing and manufacturing processes; and
12. all inventories on hand as of the Closing Date.

PROVIDED, HOWEVER, that the definition of “Famciclovir and Penciclovir Assets” does not include any rights, titles and interests in or to owned or leased real property or buildings, or to machinery, fixtures, equipment, or tools.

LL. “Famciclovir and Penciclovir Assigned Contracts” means all Assigned Contracts related to Famciclovir and/or Penciclovir (including, but not limited to, those related to Famvir and Denavir), including, but not limited to, all customer contracts, co-promotion agreements, co-distributorship agreements, supply agreements and intercompany license agreements relating to Penciclovir and/or Famciclovir.

MM. “Famciclovir and Penciclovir Asset Sale Agreement” means the *Asset Sale Agreement* entered into as of August 30, 2000, among SmithKline Beecham plc, Beecham Group plc, SmithKline Beecham Corporation, SmithKline Beecham (Cork) Limited, Novartis Pharma AG, and Novartis Pharmaceuticals Corporation, which is contained in non-public Appendix III attached to this Order.

NN. “Famciclovir and Penciclovir Supply Agreement” means the *Supply Agreement* dated as of the Closing Date, among SmithKline Beecham (Cork) Limited and Novartis Pharma AG, which is contained in non-public Appendix III attached to this Order.

- OO. “Famciclovir and Penciclovir Key Employees” means the individuals identified in Schedule 6.16 of the Famciclovir and Penciclovir Asset Sale Agreement, who represent SB’s United States marketing, regulatory and clinical employees and SB’s worldwide manufacturing employees with responsibility for Denavir and/or Famvir, which include all key marketing executives and personnel and key administrative and sales personnel (including, without limitation, executives and personnel having any responsibilities in the areas of sales management, brand management, sales training, market research, managed care, contracting, hospital market and other specialty markets, but excluding secretaries), who directly participated (irrespective of the portion of working time involved) in the marketing, contracting or promotion of Denavir and/or Famvir in the United States or the manufacture of Denavir and/or Famvir worldwide within the eighteen (18) month period immediately prior to the Closing Date.
- PP. “Famciclovir and Penciclovir Sales Employees” means all SB sales force personnel with responsibilities related to the sale of Denavir and/or Famvir worldwide, including, but not limited to, all sales representatives, sales managers, national account managers, and reimbursement managers.
- QQ. “Famvir” means any Product containing the drug compound Famciclovir, any of its constituent elements, active ingredients or intermediaries, and all rights relating to the research, development, manufacture or sale of Famvir.
- RR. “Finished Goods” means (1) Famciclovir, Penciclovir and Kytril packaged and ready for distribution to the ultimate customer in their current presentations, (2) Famciclovir and Kytril in finished tablet form but not packaged and ready for distribution to the ultimate customer, or (3) Penciclovir in finished topical cream form but not packaged and ready for distribution to the ultimate customer.
- SS. “Frovatriptan” means a drug compound in development for use in the treatment of migraine, also known as “SB209509.”
- TT. “Frovatriptan Assets” means all Product Intellectual Property related to Frovatriptan owned or controlled by Vernalis, including without limitation all rights, title and interest in and to



- VV. “GI147211C” means the chemical compound having the chemical structure 7-(4-methylpiperazinomethylene)-10,11-ethylenediary-20(s)-camptothecin hydrochloride, a topoisomerase I inhibitor Product currently being researched and developed by Gilead Sciences for use in treating cancer.
- WW. “GI147211C Assets” means the Intellectual Property related to the Product GI147211C and the GI147211C technology as described in the GI147211C Asset Sale Agreements.
- XX. “GI147211C Asset Sale Agreements” mean the *Letter Agreement* entitled “Amendments to the Licence Agreement” dated May 2, 2000, between Glaxo and Gilead Sciences that amends the *Licence Agreement* between the parties dated 27 May 1998, and the *Patent Assignment Agreement* dated November 16, 2000, between Glaxo and Gilead Sciences, which are contained in non-public Appendix IX attached to this Order.
- YY. “Granisetron” means the chemical compound endo-N-(9-methyl-9-azabicyclo [3.3.1] non-3-yl) - 1 methyl - 1H- indazole-3-carboxamide hydrochloride, its salts and esters in any form or formulation.
- ZZ. “Intellectual Property” means all: (1) Patents; (2) mask works and copyrights in works of authorship of any type, including, but not limited to, computer software and industrial designs, registrations and applications for registration thereof; (3) trademarks, including the goodwill of the business symbolized thereby and associated therewith, as well as registrations and applications for registration thereof; (4) trade secrets, know-how and other confidential or proprietary technical, business, research, development and other information, and all rights in any jurisdiction to limit the use or disclosure thereof; (5) rights to obtain and file for Patents and registrations thereof; and (6) rights to sue and recover damages or obtain injunctive relief for infringement, dilution, misappropriation, violation or breach thereof.
- AAA. “Kytril” means any Product containing Granisetron, any of its constituent elements, active ingredients or intermediaries, and all rights relating to the research, development, manufacture or sale of any such Product.
- BBB. “Kytril Asset Sale Agreement” means the *Asset Sale Agreement* entered into as of August 30, 2000, among SmithKline Beecham plc, Beecham Group plc, SmithKline Beecham Corporation, SB Pharmco Puerto Rico, Inc., Hoffmann-La Roche Inc., and F.Hoffmann-La Roche Ltd, and amended on November 22, 2000, which is contained in non-public Appendix II attached to this Order.
- CCC. “Kytril Assets” means all of Respondents’ rights, title and interest, worldwide, in and to all assets and businesses relating to Kytril and to Granisetron, including the research, development, manufacture, distribution, marketing or sale of Kytril, including without limitation, the following:

1. all Product Intellectual Property (the Patents and Product Trademarks for Kytril are listed in Appendix II);
2. the Product and Product Registrations;
3. lists of all current customers for the Product and the pricing of the Product for such customers;
4. all Kytril Assigned Contracts, each at the option of the Commission-approved Acquirer;
5. Respondents' records and files pertaining to the following, including, but not limited to, all specified documents: Product Registrations, rights of reference to Drug Master Files, correspondence with the FDA and other Agencies, all validation documents and data, all market studies, all sales histories, including without limitation, all clinical data, sales force call activity and physician prescription activity for the Product on a per-physician basis from January 1, 1997 through the Closing Date, and quality control histories pertaining to the Product owned by Respondents, in each case such as is in existence, in the possession or control of Respondents, as of the Closing Date;
6. rights of reference to all Drug Master Files, including but not limited to, the pharmacology and toxicology data contained all NDAs, ANDAs, SNDAs and MAAs;
7. all Product Marketing Materials;
8. the NDC Numbers relating to the Product;
9. Scientific and Regulatory Material;
10. all unfilled customer orders for finished goods as of the Closing Date (a list of such orders to be provided to the Commission-approved Acquirer within two business days after the Closing Date);
11. all books, records and files that relate to the following: Product Manufacturing Technology; Product manufacturing and manufacturing processes;
12. all inventories on hand as of the Closing Date; and
13. all equipment currently owned by SB and used to manufacture sachets for the Product for the Japanese market.

PROVIDED, HOWEVER, that the definition of “Kytril Assets” does not include any rights, titles and interests in or to owned or leased real property or building(s).

PROVIDED FURTHER, HOWEVER, that except for the machinery used to manufacture sachets for the Product for the Japanese market, the definition of “Kytril Assets” does not include any rights, titles and interests in or to machinery, fixtures, equipment, or tools.

- DDD. “Kytril Assigned Contracts” means all Assigned Contracts related to Kytril, including, but not limited to, contracts with managed care organizations and oncology distributors; hospital tenders/contracts for the United Kingdom; pricing agreements for Canada relating to Kytril; and the Kytril Loyalist Agreements.
- EEE. “Kytril Core Employees” means the individuals identified in Schedule 6.10(a) of the Kytril Asset Sale Agreement, who represent SB’s worldwide manufacturing, marketing, regulatory and clinical employees with responsibility for Kytril, which include all key marketing executives and personnel and key administrative and sales personnel (including, without limitation, executives and personnel having any responsibilities in the areas of sales management, brand management, sales training, market research, managed care, contracting, hospital market and other specialty markets, but excluding secretaries), who directly participated (irrespective of the portion of working time involved) in the manufacturing, marketing, contracting or promotion of Kytril worldwide within the eighteen (18) month period immediately prior to the Closing Date.
- FFF. “Kytril Sales Employees” means all SB worldwide oncology sales force personnel, including all sales representatives, sales managers, national account managers, reimbursement managers, oncology medical associates and oncology nurse educators.
- GGG. “Kytril Supply Agreement” means the *Supply Agreement*, dated as of the Closing Date, attached as Exhibit D to the Kytril Asset Sale Agreement among SmithKline Beecham plc, SB Pharmco Puerto Rico, Inc., SmithKline Beecham (Cork) Limited, SmithKline Beecham Seiyaku K.K., F.Hoffmann-La Roche Ltd, and Hoffmann-La Roche Inc., and any modifications and amendments thereto that have been approved by the Commission, which is contained in non-public Appendix II attached to this Order.
- HHH. “Kytril Transition Support Agreement” means the *Transition Support Agreement* entered into on August 30, 2000 by and between SmithKline Beecham plc and F.Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., and any modifications and amendments thereto that have been approved by the Commission, which is contained in non-public Appendix II attached to this Order.
- III. “Manufacturing Technology” means all technology, trade secrets, know-how, and proprietary information relating to the manufacture, validation, packaging, release testing,

stability and shelf life of the Product including the Product's formulation, in existence and in the possession of Respondents as of the Closing Date.

- JJJ. "New Drug Application" ("NDA"), "Abbreviated New Drug Application" ("ANDA"), "Supplemental New Drug Application" ("SNDA"), 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, or its foreign Agency equivalent, and all supplements, amendments, revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between Respondents and the FDA or other Agency relative thereto.
- KKK. "NDC Numbers" means the National Drug Code number(s) assigned by the FDA to the Product(s).
- LLL. "Ownership Interest" means any and all rights, present or contingent, of Respondents to hold any voting or nonvoting stock, share capital, equity or other interests or beneficial ownership in an entity.
- MMM. "Patents" mean all patents, patents pending, patent applications and statutory invention registrations, including reissues, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations 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 world, related to any product of or owned by Respondents as of the Closing Date.
- NNN. "Penciclovir" means the chemical compound 9-[4-hydroxy-3-(hydroxy methol) butyl] guanine, its salts and esters in any form or formulation.
- OOO. "Prescription Field of Use" means the market in which Products may be lawfully sold to consumers only by prescription.
- PPP. "Product" means any finished pharmaceutical composition containing any formulation or dosage of a compound referenced as its pharmaceutically active ingredient.
- QQQ. "Product Intellectual Property" means all worldwide (1) Product Patents, (2) Product Trademarks, (3) Manufacturing Technology, (4) the Website and the Domain Name, (5) Product Trade Dress, (6) all copyrights in and to the Product Marketing Materials, (7) all other Intellectual Property relating to a Product, and (8) all Confidential Business Information.
- RRR. "Product Marketing Materials" means all marketing materials used anywhere in the world with respect to the Products as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, price lists, mailing lists, sales materials,

marketing information (e.g., customer sales, IMS data and competitor data), promotional materials, artwork for the production of packaging components, television masters and other materials associated with the Products.

- SSS. “Product Registrations” means all registrations, permits, licenses, consents, authorizations and other approvals, and pending applications and requests therefor, required by applicable Agencies relating to the research, development, manufacture, distribution, finishing, packaging, marketing or sale of the Product worldwide, including all INDs (“Investigational New Drug Applications”), NDAs, ANDAs, SNDAs and MAAs, in existence for the Product as of the Closing Date.
- TTT. “Product Trade Dress” means the current trade dress of the Product, including, but not limited to, product packaging associated with the sale of the Product worldwide and the lettering of the Product’s trade name or brand name, but excluding the stripes, band and coloring used on the front panel of the packaging to the extent used on other of Respondents’ product packages.
- UUU. “Product Trademarks” means all trademarks, trade names and brand names including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized by and associated therewith, for a Product.
- VVV. “Programme” means the program of development for the purposes of developing a Product pursuant to the DISC-HSV Development and Licence Agreement.
- WWW. “Prophylaxis” means the prevention of a disease or infection through the administration of a vaccine with preventive efficacy in persons who have not been established as having the disease or infection prior to the administration of the vaccination.
- XXX. “Ranitidine” means a drug compound identified as N-[2-[[[5-(dimethylamino) methyl]-2-furanyl]methyl]thio]-ethyl]-N’-methyl-2-nitro-1,1-ethenediamine and its hydrochloride salt.
- YYY. “Renzapride” means a drug compound identified as (+)endo-4-amino-5-chloro-2-methoxy-N-(1'-azabicyclo[3.3.1]non-4'-yl)-benzamide, in development for use in the treatment of irritable bowel syndrome.
- ZZZ. “Renzapride Assets” means all Product Intellectual Property related to Renzapride owned or controlled by Alizyme, including without limitation all rights, title and interest in and to such Product Intellectual Property sold, transferred or otherwise conveyed by SB to Alizyme

an indication for the treatment and/or prophylaxis of irritable bowel syndrome and the exclusive right to use such an indication when regulatory approval is obtained.

- AAAA. “Renzapride Asset Sale Agreements” mean the agreement containing the *Sale of Renzapride IPR*, dated 22 May 2000, between SmithKline Beecham plc and Alizyme Therapeutics Limited relating to the sale and purchase of Renzapride technology and related intellectual property rights, and the Letter Agreement dated 10 November 2000, between SmithKline Beecham Pharmaceuticals and Alizyme Therapeutics Limited, which are contained in non-public Appendix VII attached to this Order.
- BBBB. “Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and clinical trial materials and information relating to the Product, and all rights thereto, in any and all jurisdictions.
- CCCC. “Tazicef” means SB’s Product containing the drug compound ceftazidime.
- DDDD. “Tazicef Asset Sale Agreement” means the *Asset Purchase Agreement* dated November 7, 2000, between SmithKline Beecham Corporation and Abbott Laboratories, which is contained in non-public Appendix VI attached to this Order.
- EEEE. “Tazicef Assets” means all of Respondents’ rights, title and interest in and to all assets and businesses relating to Tazicef for sales of Tazicef within and into the United States, including without limitation, all assets listed in subparagraphs 1-12 of this paragraph. These assets include, but are not limited to, all Product Intellectual Property necessary to enable the Commission-approved Acquirer or the Commission-approved Acquirer’s Designee to become qualified by the FDA to manufacture the finished Product Tazicef anywhere in the world for sale into the United States:
1. all Product Intellectual Property (the Patents and Product Trademarks for Tazicef are listed in Appendix VI);
  2. the Product and Product Registrations;
  3. lists of all current customers for the Product and the pricing of the Product for such customers;
  4. all Tazicef Assigned Contracts, each at the option of the Commission-approved Acquirer;
  5. Respondents’ records and files pertaining to the following, including, but not limited to, all specified documents: the Product Registrations, rights of reference to Drug Master Files, correspondence with the FDA and other Agencies, all validation documents and data, all market studies, all sales histories, including

without limitation, all clinical data, sales force call activity and physician prescription activity for the Product on a per-physician basis from January 1, 1997, through the Closing Date, and quality control histories pertaining to the Product owned by Respondents, in each case such as is in existence, in the possession or control of Respondents, as of the Closing Date;

6. rights of reference to all Drug Master Files, including but not limited to, the pharmacology and toxicology data contained all NDAs, ANDAs, SNDAs and MAAs;
7. all Product Marketing Materials;
8. the NDC Numbers relating to the Product;
9. Scientific and Regulatory Material;
10. all unfilled customer orders for finished goods as of the Closing Date (a list of such orders to be provided to the Commission-approved Acquirer within two business days after the Closing Date);
11. all books, records and files that relate to the following: Product Manufacturing Technology; Product manufacturing and manufacturing processes; and
12. all inventories on hand as of the Closing Date.

PROVIDED, HOWEVER, that the definition of “Tazicef Assets” does not include any rights, titles and interests in or to owned or leased real property or buildings.

FFFF. “Tazicef Final Finished Pharmaceuticals Supply Agreement” means the *Final Finished Pharmaceuticals Supply Agreement* dated November 7, 2000, between SmithKline Beecham Corporation and Abbott Laboratories, which is contained in non-public Appendix VI attached to this Order.

GGGG. “Valtrex” means a Product that contains any form or formulation of the compound valacyclovir and any similar oral or topical prescription Product for the treatment of herpes.

HHHH. “Website” means the website(s) located at the Domain Names and all copyrights in such website(s), to the extent owned by Respondents. “Website” shall not include content owned by third parties and other Intellectual Property not owned by Respondents that are incorporated in such website(s), such as stock photographs used in the website(s) except to the extent that Respondents can transfer their rights, if any, therein.

III. “Zantac” means all Products containing Ranitidine marketed by Warner-Lambert and Glaxo that are the subject of the *Purchase Agreement* between Warner-Lambert Company and Glaxo Wellcome plc dated as of December 18, 1998, contained in non-public Appendix V to this Order, including but not limited to, those Products marketed under the trademarks Zantac and Zantac75.

JJJ. “Zantac Assets” means:

- (1) the Product Trademarks relating to Ranitidine in the United States and Canada;
- (2) the Website relating to Ranitidine in the United States and Canada; and
- (3) all rights, title, and interest, in the United States, in and to the tablet shape, color, trade dress, logos, slogans and any unregistered marks, logos and slogans in commercial use by Glaxo or Warner-Lambert as of the Closing Date on any Ranitidine Product (other than Glaxo’s company name, corporate logos and other company indicia).

KKKK. “Zantac Agreements” mean the following agreements, contained in non-public Appendix V attached to this Order:

- (1) *Trademark Assignment and Trademark License Cancellation Agreement* between Glaxo Group Limited and Warner Lambert Company dated 26 October 2000;
- (2) *Assignment of U.S. Trademarks* between Glaxo Group Limited and Warner-Lambert Company dated 26 October 2000;
- (3) *Trademark License Agreement* between Warner-Lambert Company and Glaxo



(7) *Amended and Restated Documentation Agreement* between Glaxo Wellcome Inc., Glaxo Wellcome OTC Inc., and Warner-Lambert Company dated October 26, 2000;

(8) *Canadian Trademark Assignment and Trademark License Cancellation Agreement* between Glaxo Group Limited and Warner-Lambert Canada Inc. dated 26 October 2000;

(9) *Assignment of Canadian Trademarks* between Glaxo Group Limited and Warner-Lambert Canada Inc. dated 26 October 2000;

(10) *Canadian Trademark License Agreement* between Warner-Lambert Canada Inc. and Glaxo Group Limited dated 26 October 2000;

(11) *Amendment to Patent and Know-How License Agreement* between Glaxo Group Limited, Glaxo Wellcome Inc. and Warner-Lambert Canada Inc. dated 26 October 2000;

(12) *Amendment to the Purchase Agreement* between Warner-Lambert Canada Inc. and Glaxo Wellcome Inc. dated October 26, 2000; and

(13) *Amendment to Manufacturing and Supply Agreement* between Glaxo Wellcome Inc. and Warner-Lambert Canada Inc. dated October 26, 2000.

LLLL. “Zofran” means a Product containing the drug substance ondansetron hydrochloride, any of its constituent elements, active ingredients or intermediaries, and all rights relating to the research, development, manufacture or sale of Zofran, which is manufactured, marketed and distributed by Glaxo.

MMMM. “Zofran Assets” means all worldwide rights, title and interest of Respondents in and to the following assets relating to Zofran, regardless of where such assets are physically situated:

1. all Product Intellectual Property;
2. the Product and Product Registrations;
3. the existing lists of all current customers for the Product and the pricing of the Product for such customers;
4. all Assigned Contracts;
5. Respondents’ records and files pertaining to the following, including, but not limited to, all specified documents: the Product Registrations; rights of reference

to Drug Master Files, including but not limited to, the pharmacology and toxicology data contained in all New Drug Applications, all Abbreviated New Drug Applications, and all supplemental NDAs; correspondence with the FDA and other Agencies; all validation documents and data; all market studies; all sales histories, including without limitation, clinical data, sales force call activity, and physician prescription activity (to the extent Respondents have the right to transfer such information), for the Product on a per-physician basis from January 1, 1997, through the Closing Date, and quality control histories pertaining to the Product owned by Respondents, in each case such as is in existence, in the possession or control of Respondents, as of the Closing Date;

6. all Product Marketing Materials;
7. the NDC Numbers relating to the Product;
8. Scientific and Regulatory Material;
9. all unfilled customer orders for finished goods as of the Closing Date (a list of such orders to be provided to the Commission-approved Acquirer within two business days after the Closing Date);
10. all books, records and files that relate to the following: Product Manufacturing Technology; Product manufacturing and manufacturing processes; and
11. all inventories on hand as of the Closing Date.

PROVIDED, HOWEVER, that the definition of “Zofran Assets” may not include rights, titles and interests in or to owned or leased real property or buildings.

NNNN. “Zovirax” means a Product that contains any form or formulation of the compound acyclovir and any similar oral or topical prescription Product for the treatment of herpes.

## **II.**

**IT IS FURTHER ORDERED** that:

- A. Not later than ten (10) Business Days after the Merger is consummated, Respondents shall divest the Kytril Assets as an ongoing business to Roche pursuant to and in accordance with the Kytril Asset Sale Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order), and such agreement, if approved by the Commission as the Divestiture Agreement for the Kytril Assets, is incorporated by reference into this Order and made part hereof as non-public Appendix II. If Respondents do

not divest the Kytril Assets to Roche within ten (10) Business Days after the Merger is consummated, the Commission may appoint a trustee to divest either the Kytril Assets or the Zofran Assets. Provided, however, that if Respondents have divested the Kytril Assets to Roche prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that Roche is not an acceptable purchaser of the Kytril Assets or that the manner in which the divestiture was accomplished is not acceptable, then Respondents shall immediately rescind the transaction with Roche and the Commission may appoint a trustee to divest either the Kytril Assets or the Zofran Assets to a Commission-approved Acquirer.

- B. Failure to comply with all terms of the Kytril Asset Sale Agreement, Kytril Supply Agreement, or Kytril Transition Support Agreement, if approved by the Commission, shall constitute a failure to comply with this Order. Any Divestiture Agreement between Respondents (or a trustee appointed pursuant to Paragraph XI. of this Order) and an acquirer of the Kytril Assets that has been approved by the Commission shall be deemed incorporated by reference into this Order, and any failure by Respondents to comply with the terms of such Divestiture Agreement shall constitute a failure to comply with this Order.
- C. Respondents shall include in any Divestiture Agreement related to the Kytril Assets the following provisions, and Respondents shall commit to satisfy the following:
1. Respondents shall Contract Manufacture and deliver to the Commission-approved Acquirer in a timely manner and under reasonable terms and conditions, a supply of Granisetron, and of Kytril (including, as necessary, Kytril as Finished Goods), for a period of years sufficient to allow the Commission-approved Acquirer to become certified by the FDA to manufacture Kytril independently of Respondents.
  2. After Respondents commence delivery of Granisetron and of Kytril to the Commission-approved Acquirer pursuant to a Divestiture Agreement and for the term of the Contract Manufacture related to Granisetron and Kytril, Respondents will make inventory of Granisetron and of Kytril available for sale or resale only to the Commission-approved Acquirer.
  3. Respondents shall make representations and warranties that the Granisetron and the Kytril supplied through Contract Manufacture pursuant to the Divestiture Agreement meets FDA-approved specifications. Respondents 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 Granisetron or the Kytril supplied to the Commission-approved Acquirer pursuant the Divestiture Agreement by the Respondents to meet FDA specifications. This obligation shall be contingent upon the Commission-approved Acquirer's giving Respondents prompt, adequate notice of such claim and cooperating fully in the defense of such claim. The Divestiture Agreement shall be consistent with the obligations assumed by

Respondents under this Order. This obligation shall not require Respondents to be liable for any negligent act or omission of the Commission-approved Acquirer or for any representations and warranties, express or implied, made by the Commission-approved Acquirer that exceed the representations and warranties made by the Respondents to the Commission-approved Acquirer.

4. Respondents shall make representations and warranties that Respondents will hold harmless and indemnify the Commission-approved Acquirer for any liabilities or loss of profits resulting from the failure by Respondents to deliver Granisetron or Kytril in a timely manner as required by the Divestiture Agreement unless Respondents can demonstrate that their failure was entirely beyond the control of the Respondents and in no part the result of negligence or willful misconduct by Respondents.
  5. During the term of the Contract Manufacture between Respondents and the Commission-approved Acquirer, upon request of the Commission-approved Acquirer or the Monitor Trustee, Respondents shall make available to the Monitor Trustee all records that relate to the manufacture of Granisetron and of Kytril.
  6. Upon reasonable notice and request from the Commission-approved Acquirer to the Respondents, Respondents shall provide in a timely manner: (a) assistance and advice to enable the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) to obtain all necessary Agency approvals to manufacture and sell Kytril; (b) assistance to the Commission-approved Acquirer (or the Designee thereof) to manufacture Kytril in substantially the same manner and quality employed or achieved by SB; and (c) consultation with knowledgeable employees of Respondents 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 thereof) receives certification from the FDA, sufficient to satisfy management of the Commission-approved Acquirer that its personnel (or the Designee's personnel) are adequately trained in the manufacture of Kytril. Such assistance shall include on-site inspections of Respondents' manufacturing facilities related to Kytril, at the Commission-approved Acquirer's request.
- D. Respondents shall submit to the Commission-approved Acquirer, at Respondents' expense, all Confidential Business Information relating to Kytril. This provision shall not apply to any Confidential Business Information relating to Kytril that Glaxo can demonstrate it obtained without the assistance of SB prior to the consummation of the Merger.
- E. Respondents shall not use, directly or indirectly, any Confidential Business Information relating to the research, development, manufacturing or marketing of Kytril, and shall not disclose or convey such Confidential Business Information, directly or indirectly, to any person except the Commission-approved Acquirer. This provision shall not apply to any Confidential Business Information relating to Kytril that Glaxo can demonstrate it obtained

without the assistance of SB prior to the consummation of the Merger. Notwithstanding the foregoing, Respondents shall be permitted to disclose any such Confidential Business Information to the extent legally required or necessary for obtaining appropriate regulatory licenses or approvals or responding to Agency inquiries, or to the extent necessary to permit Respondents to comply with obligations under the Divestiture Agreements and this Order.

- F. Respondents shall provide the Commission-approved Acquirer with the opportunity to enter into employment contracts with the Kytril Sales Employees and the Kytril Core Employees for a period of six (6) months from the Closing Date (“the Access Period”), provided that such contracts are contingent upon the Commission’s approval of the Divestiture Agreement. Notwithstanding the foregoing, the Access Period for the Kytril Core Employees who are identified as manufacturing employees shall continue until the Commission-approved Acquirer is fully validated, qualified, and approved by the FDA, and able to manufacture Granisetron.
- G. Respondents shall provide the Commission-approved Acquirer an opportunity to inspect the personnel files and other documentation relating to the Kytril Sales Employees and the Kytril Core Employees, to the extent permissible under applicable laws, at the request of the Commission-approved Acquirer, at any time after execution of the Divestiture Agreement until the end of the Access Period.
- H. During the Access Period, Respondents shall not interfere with the hiring or employing by the Commission-approved Acquirer of Kytril Sales Employees or Kytril Core Employees, and shall remove any impediments that may deter these employees from accepting employment with the Commission-approved Acquirer, including, but not limited to, any non-compete provisions of employment or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by the Commission-approved Acquirer. In addition, Respondents shall not make any counteroffer to a Kytril Sales or Kytril Core Employee who receives a written offer of employment from the Commission-approved Acquirer. Provided, however, that if Roche is the Commission-approved Acquirer, the restrictions on making counteroffers shall end with respect to the Kytril Sales Employees in the United States on the date that the 20th Kytril Sales Employee has accepted employment with Roche. The restriction on making counteroffers shall end with respect to the Kytril Sales Employees in each country outside the United States on the date that 20% of Kytril Sales Employees in each such country have accepted employment with Roche.
- I. Respondents shall provide all Kytril Core Employees and all Kytril Sales Employees with reasonable financial incentives to continue in their positions until the Closing Date. Such incentives shall include a continuation of all employee benefits offered by Respondents until the Closing Date for the divestiture of the Kytril Assets has occurred, including regularly scheduled raises and bonuses, and a vesting of all pension benefits (as permitted by law). In addition, Respondents shall provide to each Kytril Core Employee and each Kytril Sales Employee incentives to accept employment with the Commission-approved Acquirer at the

time of the divestiture. Such incentives shall include a bonus for each such employee, equal to 10% of the employee's current annual salary and commissions (including any annual bonuses) as of the Closing Date, who accepts an offer of employment during the Access Period (as defined in Paragraph II.F.) from the Commission-approved Acquirer and remains employed by the Acquirer for a period of one (1) year, payable by Respondents one (1) year

- M. Respondents shall require, as a condition of continued employment post-divestiture, that each Kytril Sales Employee and each Kytril Core Employee sign a confidentiality agreement pursuant to which such employee shall be required to maintain all Kytril Confidential Business Information (including, without limitation, all field experience) strictly confidential, including the nondisclosure of such information to all other employees, executives or other personnel of Respondents. (A copy of this confidentiality agreement is contained in Schedule 6.10(e)(ii) of the Kytril Asset Sale Agreement).
- N. Respondents shall provide written notification of the restrictions on the use of the Confidential Business Information relating to Kytril by Respondents' personnel and of the restrictions on the sale of Zofran by certain SB personnel to all of the Respondents' employees involved in the manufacturing, distribution, sale or marketing of Kytril or Zofran, with such notification to be in substantially the form set forth in Schedule 6.10(e)(i) of the Kytril Asset Sale Agreement. Respondents shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the Closing Date. Respondents shall provide a copy of such notification to the Commission-approved Acquirer. Respondents shall also obtain from each employee covered by this Paragraph II. N. an agreement to abide by the applicable restrictions, with the agreement to be in substantially the form set forth in Schedule 6.10(e)(ii) of the Kytril Asset Sale Agreement. Respondents shall maintain complete records of all such agreements at Respondents' corporate headquarters and shall provide an officer's certificate to the Commission, stating that such acknowledgment program has been implemented and is being complied with. Respondents shall monitor the implementation by their sales forces of all applicable restrictions, including the provision of written reminders to all such sales personnel at three (3) month intervals until the expiration of the time periods set forth in all Divestiture Agreements, including those in the Kytril Asset Sale Agreement, and take corrective actions for the failure of sales personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order. Respondents shall provide the Commission-approved Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel.
- O. At the time of divestiture, Respondents shall make available to the Commission-approved Acquirer such personnel, assistance and training as the Commission-approved Acquirer might reasonably need to transfer the Kytril Assets, and shall continue providing such personnel, assistance and training, at the request of the Commission-approved Acquirer, until the Commission-approved Acquirer is fully validated, qualified, and approved by the FDA, and able to manufacture Kytril. At the time of divestiture, Respondents shall also divest any additional, incidental assets of Respondents and make any further arrangements for transitional services within the first twelve (12) months after divestiture that may be reasonably necessary to assure the viability and competitiveness of the Kytril Assets.
- P. Pending divestiture of the Kytril Assets, Respondents shall take such actions as are necessary to maintain the viability and marketability of the Kytril Assets and to prevent the destruction,

removal, wasting, deterioration, or impairment of any of the Kytril Assets except for ordinary wear and tear.

- Q. Respondents shall maintain manufacturing facilities for Kytril production that are ready, validated, qualified and approved by the FDA, and fully capable of producing Granisetron at a capacity of at least 60 kilograms per year, until either (1) the Commission-approved Acquirer, upon approval by the Commission, terminates, or elects not to extend, any Contract Manufacture arrangement with Respondents to supply Granisetron or Kytril, or (2) the Commission-approved Acquirer is fully validated, qualified, and approved by the FDA and able to manufacture Granisetron or Kytril (hereinafter referred to as the “Kytril Supply Period”).
- R. During the term of the Kytril Supply Period, Respondents shall manufacture at least 20 kilograms of Granisetron per year and shall not permit, at any time, the total amount of Granisetron available for Kytril production to fall below 30 kilograms. The total amount of Granisetron shall include the amount in both the Respondents’ and the Commission-approved Acquirer’s inventory.
- S. During the term of the Kytril Supply Period, should the amount of Granisetron available for Kytril production fall below 30 kilograms, or should Respondents fail to maintain a facility that is validated, qualified and approved by the FDA to manufacture Granisetron, the Commission may, in its sole discretion, require Respondents to divest the Zofran Assets; provided, however, that Respondents shall be allowed to demonstrate that such failure was entirely beyond the control of Respondents and in no part the result of negligence or willful misconduct by Respondents. If the Commission determines that the Zofran Assets are to be divested, the Commission may appoint a trustee to divest the Zofran Assets.
- T. The purpose of the divestiture of the Kytril Assets is to ensure the continued use of the Kytril Assets in the same business in which the Kytril Assets were engaged at the time of the announcement of the Merger, and to remedy the lessening of competition resulting from the Merger as alleged in the Commission's complaint.

### **III.**

**IT IS FURTHER ORDERED** that:

- A. Not later than ten (10) Business Days after the Merger is consummated, Respondents shall divest the Famciclovir and Penciclovir Assets as ongoing businesses to Novartis pursuant to and in accordance with the Famciclovir and Penciclovir Asset Sale Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order), and such agreement, if approved by the Commission as the Divestiture Agreement for the Famciclovir and Penciclovir Assets, is incorporated by reference into this



Order and made part hereof as non-public Appendix III. If Respondents do not divest the Famciclovir and Penciclovir Assets to Novartis within ten (10) Business Days after the Merger is consummated, the Commission may appoint a trustee to divest the Famciclovir and Penciclovir Assets, together. Provided, however, that if Respondents have divested the

approved Acquirer pursuant the Divestiture Agreement by the Respondents to meet FDA specifications. This obligation shall be contingent upon the Commission-approved Acquirer's giving Respondents prompt, adequate notice of such claim, and cooperating fully in the defense of such claim. The Divestiture Agreement shall be consistent with the obligations assumed by Respondents under this Order. This obligation shall not require Respondents to be liable for any negligent act or omission of the Commission-approved Acquirer or for any representations and warranties, express or implied, made by the Commission-approved Acquirer that exceed the representations and warranties made by the Respondents to the Commission-approved Acquirer.

4. Respondents shall make representations and warranties that Respondents will hold harmless and indemnify the Commission-approved Acquirer for any liabilities or loss of profits resulting from the failure by Respondents to deliver Famciclovir and Penciclovir as Finished Goods in a timely manner as required by the Divestiture Agreement unless Respondents can demonstrate that their failure was entirely beyond the control of the Respondents and in no part the result of negligence or willful misconduct by Respondents.
5. During the term of the Contract Manufacture between Respondents and the Commission-approved Acquirer, upon request of the Commission-approved Acquirer or the Monitor Trustee, Respondents shall make available to the Monitor Trustee all records that relate to the manufacture of Famciclovir and of Penciclovir as Finished Goods.
6. Upon reasonable notice and request from the Commission-approved Acquirer to the Respondents, Respondents shall provide in a timely manner: (a) assistance and advice to enable the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) to obtain all necessary Agency approvals to manufacture and sell Famciclovir and Penciclovir as Finished Goods; (b) assistance to the Commission-approved Acquirer

Confidential Business Information relating to Famciclovir or Penciclovir that Glaxo can demonstrate it obtained without the assistance of SB prior to the consummation of the Merger.

- E. Respondents shall not use, directly or indirectly, any Confidential Business Information relating to the research, development, manufacturing or marketing of Famciclovir, Penciclovir, Famciclovir Finished Goods or Penciclovir Finished Goods, and shall not disclose or convey such Confidential Business Information, directly or indirectly, to any person except the Commission-approved Acquirer. This provision shall not apply to any Confidential Business Information relating to Famciclovir or Penciclovir that Glaxo can demonstrate it obtained without the assistance of SB prior to the consummation of the Merger. Notwithstanding the foregoing, Respondents shall be permitted to disclose any such Confidential Business Information to the extent legally required or necessary for obtaining appropriate regulatory licenses or approvals or responding to Agency inquiries, or to the extent necessary to permit Respondents to comply with obligations under the Divestiture Agreements and this Order.
- F. Respondents shall provide the Commission-approved Acquirer with the opportunity to enter into employment contracts with the Famciclovir and Penciclovir Key Employees and the Famciclovir and Penciclovir Sales Employees for a period of six (6) months from the Closing Date (“the Access Period”), provided that such contracts are contingent upon the Commission’s approval of the Divestiture Agreement. Notwithstanding the foregoing, the Access Period for the Famciclovir and Penciclovir Key Employees who are identified as manufacturing employees shall continue until the Commission-approved Acquirer is fully validated, qualified, and approved by the FDA, and able to manufacture Famciclovir, Penciclovir, Famciclovir Finished Goods and Penciclovir Finished Goods.
- G. Respondents shall provide the Commission-approved Acquirer an opportunity to inspect the personnel files and other documentation relating to the Famciclovir and Penciclovir Sales Employees and the Famciclovir and Penciclovir Key Employees, to the extent permissible under applicable laws, at the request of the Commission-approved Acquirer, at any time after execution of the Divestiture Agreement until the end of the Access Period.
- H. During the Access Period, Respondents shall not interfere with the hiring or employing by the Commission-approved Acquirer of Famciclovir and Penciclovir Key Employees or Famciclovir and Penciclovir Sales Employees, and shall remove any impediments that may deter these employees from accepting employment with the Commission-approved Acquirer, including, but not limited to, any non-compete provisions of employment or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by the Commission-approved Acquirer. In addition, Respondents shall not make any counteroffer to any Famciclovir and Penciclovir Sales Employee or any Famciclovir and Penciclovir Key Employee who receives a written offer of employment from the Commission-approved Acquirer.

I. Respondents shall provide all Famciclovir and Penciclovir Key Employees and all Famciclovir and Penciclovir Sales Employees with reasonable financial incentives to continue in their positions until the Closing Date. Such incentives shall include a continuation of all employee benefits offered by Respondents until the Closing Date for the divestiture of the Famciclovir and Penciclovir Assets has occurred, including regularly scheduled raises and bonuses, and a vesting of all pension benefits (as permitted by law). In addition, Respondents shall provide to each Famciclovir and Penciclovir Key Employee and each Famciclovir and Penciclovir Sales Employee incentives to accept employment with the Commission-approved Acquirer at the time of the divestiture. Such incentives shall include a bonus for each such employee, equal to 10% of the employee's current annual salary and commissions (including any annual bonuses) as of the Closing Date, who accepts an offer of employment during the Access Period (as defined in Paragraph III.F.) from the Commission-approved Acquirer and remains employed by the Acquirer for a period of one (1) year, payable by Respondents one (1) year after the commencement of the employee's employment by the Commission-approved Acquirer.

J.

intravenous or topical prescription product for the treatment of herpes using the services of any employee who has directly participated in the marketing, contracting, promotion or sale of Famciclovir Finished Goods or Penciclovir Finished Goods within the eighteen (18) month period immediately prior to the Closing Date. The Moratorium/Waiting Period shall be as follows: (1) six (6) months from the Closing Date with respect to Famciclovir and Penciclovir Sales Employees; and (2) twelve (12) months from the Closing Date for all Famciclovir and Penciclovir Key Employees and all other employees who have had any decision-making responsibility relating to Famciclovir Finished Goods or Penciclovir Finished Goods, including, but not limited to, responsibilities for, or involvement in, strategic decision-making, sales management, brand management, sales training, market research and contracting with managed care organizations, hospitals and other institutions. Without limiting the foregoing, employees covered by this Paragraph III. L. shall include those individuals listed by name and title in Schedule 6.16 of the Famciclovir and Penciclovir Asset Sale Agreement, as well as all other employees subject to this Paragraph.

- M. Respondents shall require, as a condition of continued employment post-divestiture, that each Famciclovir and Penciclovir Key Employee and each Famciclovir and Penciclovir Sales Employee sign a confidentiality agreement pursuant to which such employee shall be required to maintain all Famciclovir and Penciclovir Confidential Business Information (including, without limitation, all field experience) strictly confidential, including the nondisclosure of such information to all other employees, executives or other personnel of Respondents.
  
- N. Respondents shall provide written notification of the restrictions on the use of the Famciclovir and Penciclovir Confidential Business Information by Respondents' personnel and of the restrictions on the sale of valacyclovir (Valtrex), acyclovir or any other oral, intravenous or topical prescription product for the treatment of herpes, cold sores, chicken pox or shingles, by certain SB personnel to all of the Respondents' employees involved in the manufacturing, distribution, sale or marketing of Famciclovir, Penciclovir, Famciclovir Finished Goods, Penciclovir Finished Goods, Valtrex or Zovirax. Respondents shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the Closing Date. Respondents shall provide a copy of such notification to the Commission-approved Acquirer. Respondents shall also obtain from each employee covered by this Paragraph III. N. an agreement to abide by the applicable restrictions. Respondents shall maintain complete records of all such agreements at Respondents' corporate headquarters and shall provide an officer's certificate to the Commission, stating that such acknowledgment program has been implemented and is being complied with. Respondents shall monitor the implementation by their sales forces of all applicable restrictions, including the provision of written reminders to all such sales personnel at three (3) month intervals until the expiration of the time periods set forth in all Divestiture Agreements, including those in the Famciclovir and Penciclovir Asset Sale Agreement, and take corrective actions for the failure of sales personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order. Respondents

shall provide the Commission-approved Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel.

- O. At the time of divestiture, Respondents shall make available to the Commission-approved Acquirer such personnel, assistance and training as the Commission-approved Acquirer might reasonably need to transfer the Famciclovir and Penciclovir Assets, and shall continue providing such personnel, assistance and training, at Respondents' cost, at the request of the Commission-approved Acquirer, until the Commission-approved Acquirer is fully validated, qualified, and approved by the FDA, and able to manufacture Famciclovir, Famciclovir Finished Goods, Penciclovir and Penciclovir Finished Goods. At the time of divestiture, Respondents shall also divest any additional, incidental assets of Respondents and make any further arrangements for transitional services within the first twelve (12) months after divestiture that may be reasonably necessary to assure the viability and competitiveness of the Famciclovir and Penciclovir Assets.
- P. Pending divestiture of the Famciclovir and Penciclovir Assets, Respondents shall take such actions as are necessary to maintain the viability and marketability of the Famciclovir and Penciclovir Assets, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Famciclovir and Penciclovir Assets except for ordinary wear and tear.
- Q. Respondents shall maintain manufacturing facilities for Famciclovir, Penciclovir, Famciclovir Finished Goods, and Penciclovir Finished Goods that are ready, validated, qualified and approved by the FDA, and fully capable of producing Penciclovir, Famciclovir, Penciclovir Finished Goods and Famciclovir Finished Goods, and shall manufacture Famciclovir Finished Goods and Penciclovir Finished Goods pursuant to all Divestiture Agreements until either: (1) the Commission-approved Acquirer, upon approval by the Commission, terminates, or

- A. Not later than ten (10) Business Days after the Merger is consummated, Respondents shall transfer and surrender, absolutely and in good faith, all of Glaxo's DISC-HSV Prophylactic Vaccine Assets to Cantab, pursuant to and in accordance with the DISC-HSV Amended Development and Licence Agreement, and such agreement is incorporated by reference into this Order and made a part hereof as non-public Appendix IV. Failure by Respondents to comply with the requirements of the DISC-HSV Amended Development and Licence Agreement shall constitute a failure to comply with this Order.
- B. Upon reasonable notice and request from Cantab to Respondents, Respondents shall provide to Cantab, in a timely manner and at no cost to Cantab, any assistance or advice as may be necessary for Cantab to obtain FDA approvals to research and develop a vaccine for the Prophylaxis of human infections with herpes simplex virus in connection with the use of the DISC Technology.
- C. Respondents shall not, directly or indirectly: (i) exercise dominion or control over, or otherwise seek to influence, the management, direction or supervision of the business of Cantab; (ii) seek or obtain representation on the Board of Directors of Cantab; (iii) exercise any voting rights attached to any Ownership Interest in Cantab, except in accordance with directions given by the Board of Cantab; (iv) seek or obtain access to any confidential or proprietary information of Cantab relating to the research or development of a vaccine for the Prophylaxis of human infections with herpes simplex virus and not otherwise necessary to comply with this Order; or (v) take any action or omit to take any action in a manner that would be incompatible with the status of Respondents as passive investors in Cantab. The requirements of this Paragraph shall continue and remain in effect so long as Respondents retain any Ownership Interest in Cantab.
- D. Pending the completion of the transfer of the DISC-HSV Prophylactic Vaccine Assets, Respondents shall take such actions as are necessary to maintain the viability and marketability of the DISC-HSV Prophylactic Vaccine Assets, and to prevent the destruction, deterioration, or impairment of any of the DISC-HSV Prophylactic Vaccine Assets.
- E. The purpose of Paragraph IV of this Order is to ensure the continued use of the DISC-HSV Prophylactic Vaccine Assets in the same business in which the DISC-HSV Prophylactic Vaccine Assets were engaged at the time of the announcement of the Merger, and to remedy the lessening of competition resulting from the Merger as alleged in the Commission's complaint.
- F. For a period commencing on the date this Order becomes final and continuing for ten (10) years, Respondents shall not, without providing advance written notification to the Commission, acquire, directly or indirectly, through subsidiaries or otherwise, any additional or greater Ownership Interest in Cantab than that which exists as of the Closing Date, or any other interest(s), in whole or in part, in any of the DISC-HSV Prophylactic Vaccine Assets. Said notification 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 the Respondents and not of any other party to the transaction. Respondents shall provide two (2) complete copies (with all attachments and exhibits) of 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 or documentary material (within the meaning of 16 C.F.R. § 803.20), Respondents shall not consummate the transaction until twenty (20) days after substantially complying with such request. Early termination of the waiting periods in this Paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition. Provided, however, that 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.

**V.**

**IT IS FURTHER ORDERED** that:

- A. Not later than ten (10) Business Days after the Merger is consummated, Respondents shall divest and transfer the Zantac Assets to Pfizer, pursuant to and in accordance with the Zantac Agreements, and such agreements are incorporated by reference into this Order and made a part hereof as non-public Appendix V. Provided, however, Respondents may obtain a license from Pfizer to use the Product Trademarks relating to Zantac within the Prescription Field of Use.
- B. Failure to comply with all terms of the Zantac Agreements shall constitute a failure to comply with this Order.
- C.



## VI.

### **IT IS FURTHER ORDERED** that:

- A. Not later than ten (10) Business Days after the Merger is consummated, Respondents shall divest the Tazicef Assets as an ongoing business to Abbott Labs pursuant to and in accordance with the Tazicef Asset Sale Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order), and such agreement, if approved by the Commission as the Divestiture Agreement for the Tazicef Assets, is incorporated by reference into this Order and made part hereof as non-public Appendix VI. If Respondents fail to divest the Tazicef Assets within ten (10) Business Days after the Merger is consummated, the Commission may appoint a trustee to divest the Tazicef Assets. Provided, however, that if Respondents have divested the Tazicef Assets to Abbott Labs prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that Abbott Labs is not an acceptable purchaser of the Tazicef Assets or that the manner in which the

demands, liabilities, expenses or losses alleged to result from the failure of the Ceftazidime supplied to the Commission-approved Acquirer pursuant the Divestiture Agreement by the Respondents to meet FDA specifications. This obligation shall be contingent upon the Commission-approved Acquirer's giving Respondents prompt, adequate notice of such claim and cooperating fully in the defense of such claim. The Divestiture Agreement shall be consistent with the obligations assumed by Respondents under this Order. This obligation shall not require Respondents to be liable for any negligent act or omission of the Commission-approved Acquirer or for any representations and warranties, express or implied, made by the Commission-approved Acquirer that exceed the representations and warranties made by the Respondents to the Commission-approved Acquirer.

3. Respondents shall make representations and warranties that Respondents will hold harmless and indemnify the Commission-approved Acquirer for any liabilities or loss of profits resulting from the failure by Respondents to deliver Ceftazidime in a timely manner as required by the Divestiture Agreement unless Respondents can demonstrate that their failure was entirely beyond the control of the Respondents and in no part the result of negligence or willful misconduct by Respondents.
  4. During the term of the Contract Manufacturing between Respondents and the Commission-approved Acquirer, upon request of the Commission-approved Acquirer or the Monitor Trustee, Respondents shall make available to the Monitor Trustee all records that relate to the manufacture of Ceftazidime.
  5. Upon reasonable notice and request from the Commission-approved Acquirer to the Respondents, Respondents shall provide in a timely manner: (a) assistance and advice to enable the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) to obtain all necessary Agency approvals to manufacture and sell Tazicef; (b) assistance to the Commission-approved Acquirer (or the Designee thereof) to manufacture Tazicef in substantially the same manner and quality employed or achieved by SB; and (c) consultation with knowledgeable employees of Respondents 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 thereof) receives certification from the FDA, sufficient to satisfy management of the Commission-approved Acquirer that its personnel (or the Designee's personnel) are adequately trained in the manufacture of Tazicef. Such assistance shall include on-site inspections of Respondents' manufacturing facilities related to Ceftazidime and/or Tazicef, at the Commission-approved Acquirer's request.
- D. Respondents shall submit to the Commission-approved Acquirer, at Respondents' expense, all Confidential Business Information relating to Tazicef. This provision shall not apply to any Confidential Business Information relating to Tazicef that was obtained by Glaxo without the assistance of SB prior to the consummation of the Merger.

- E. Respondents shall not use, directly or indirectly, any Confidential Business Information relating to the research, development, manufacturing or marketing of Tazicef, and shall not disclose or convey such Confidential Business Information, directly or indirectly, to any person except the Commission-approved Acquirer. This provision shall not apply to any Confidential Business Information relating to Tazicef that was obtained by Glaxo without the assistance of SB prior to the consummation of the Merger. Notwithstanding the foregoing, Respondents shall be permitted to use or disclose any such Confidential Business Information to the extent legally required or necessary for obtaining appropriate regulatory licenses or approvals or responding to Agency inquiries, or to the extent necessary to permit Respondents to comply with obligations under the Divestiture Agreements and this Order.
- F. Respondents shall secure, prior to divestiture, all consents and waivers from all private entities that are necessary for the divestiture of the Tazicef Assets or are necessary for the continued research, development, manufacture, sale, marketing or distribution of Tazicef by the Commission-approved Acquirer, including, but not limited to, all necessary consents and waivers from Lilly and Takeda.
- G. At the time of divestiture, Respondents shall make available to the Commission-approved Acquirer such personnel, assistance and training as the Commission-approved Acquirer might reasonably need to transfer the Tazicef Assets, and shall continue providing such personnel, assistance and training, at the request of the Commission-approved Acquirer, until the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) is fully validated, qualified, and approved by the FDA, and able to manufacture Ceftazidime. At the time of divestiture, Respondents shall also divest any additional, incidental assets of Respondents and make any further arrangements for transitional services within the first twelve (12) months after divestiture that may be reasonably necessary to assure the viability and competitiveness of the Tazicef Assets.
- H. Pending divestiture of the Tazicef Assets, Respondents shall take such actions as are necessary to maintain the viability and marketability of the Tazicef Assets and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Tazicef Assets except for ordinary wear and tear.
- I. During the term of the Tazicef Final Finished Pharmaceuticals Supply Agreement, Respondents shall ensure that no interruption in the supply of Tazicef to the Commission-approved Acquirer occurs. Provided, however, that if any interruption (expected or unexpected) in the supply of Tazicef to the Commission-approved Acquirer does occur, or if Respondents' supply of Tazicef is depleted, Respondents shall immediately provide a substitute Ceftazidime Product to the Commission-approved Acquirer. Provided further, that to ensure an immediate supply of a substitute Ceftazidime Product is available for the Commission-approved Acquirer in the event of an interruption or depletion in the supply of Tazicef, Respondents shall take all actions necessary to obtain all FDA approvals required to qualify another Ceftazidime Product as a substitute for Tazicef, and Respondents shall give

priority to the Commission-approved Acquirer in supplying a substitute Ceftazidime Product during any such interruption or depletion in the supply of Tazicef, including before Respondents satisfy their own requirements for any Ceftazidime Product.

- J. Respondents shall reimburse the Commission-approved Acquirer for any annual minimum royalty(ies) due to any owner of U.S. Patent 5,710,146 (including, but not limited to Lilly), that are paid by the Commission-approved Acquirer under existing license agreements, to the extent those amounts are not offset by the royalties earned from the Commission-approved Acquirer. Such reimbursement by Respondents shall continue through the expiration of U.S. Patent 5,710,146.
- K. Respondents shall be responsible for all costs involved in ensuring that (1) the FDA approves the manufacturing facility of the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) in which the Commission-approved Acquirer's Ceftazidime Product will be manufactured; and (2) such facility satisfies the Commission-approved Acquirer's requirements for third-party vendors. Respondents shall pay for the cost of a third-party consultant hired by the Commission-approved Acquirer to supervise such efforts as well as any costs incurred by the Commission-approved Acquirer as a result of the inability of the Designee of the Commission-approved Acquirer to supply Tazicef to the Commission-approved Acquirer that is not otherwise assumed by the Designee.
- L. The purpose of the divestiture of the Tazicef Assets is to ensure the continued use of the Tazicef Assets in the same business in which the Tazicef Assets were engaged at the time of the announcement of the Merger, and to remedy the lessening of competition resulting from the Merger as alleged in the Commission's complaint.

## **VII.**

**IT IS FURTHER ORDERED** that:

- A. Not later than ten (10) Business Days after the Merger is consummated, Respondents shall transfer and surrender, absolutely and in good faith, all Renzapride Assets, pursuant to and in accordance with the Renzapride Asset Sale Agreements, to Alizyme, and such agreements are incorporated by reference into this Order and made a part hereof as non-public Appendix VII. Failure by Respondents to comply with all terms of the Renzapride Asset Sale Agreements shall constitute a failure to comply with this Order.
- B. Pending the completion of the transfer of the Renzapride Assets to Alizyme, Respondents shall take such actions as are necessary to maintain the viability and marketability of the Renzapride Assets, and to prevent the destruction, deterioration, or impairment of any of the Renzapride Assets.

- C. The purpose of Paragraph VII of this Order is to ensure the continued use of the Renzapride Assets in the same business in which the Renzapride Assets were engaged at the time of the announcement of the Merger, and to remedy the lessening of competition resulting from the Merger as alleged in the Commission's complaint.
  
- D. For a period commencing on the date this Order becomes final and continuing for ten (10) years, Respondents shall not, without providing advance written notification to the Commission, acquire, directly or indirectly, through subsidiaries or otherwise, any additional or greater Ownership Interest in Alizyme than that which exists as of the Closing Date, or any other interest(s), in whole or in part, in any of the Renzapride Assets. Said notification 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 the Respondents and not of any other party to the transaction. Respondents shall provide two (2) complete copies (with all attachments and exhibits) of 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 or documentary material (within the meaning of 16 C.F.R. § 803.20), Respondents shall not consummate the transaction until twenty (20) days after substantially complying with such request. Early termination of the waiting periods in this Paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition. Provided, however, that 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.

## VIII.

### **IT IS FURTHER ORDERED** that:

- A. Not later than ten (10) Business Days after the Merger is consummated, Respondents shall transfer and surrender, absolutely and in good faith, all Frovatriptan Assets, pursuant to and in accordance with the Frovatriptan Asset Sale Agreement, to Vernalis, and such agreement is incorporated by reference into this Order and made a part hereof as non-public Appendix VIII. Failure by Respondents to comply with all terms of the Frovatriptan Asset Sale Agreement shall constitute a failure to comply with this Order.
  
- B. Pending the completion of the transfer of the Frovatriptan Assets to Vernalis, Respondents shall take such actions as are necessary to maintain the viability and marketability of the

Frovatriptan Assets, and to prevent the destruction, deterioration, or impairment of any of the Frovatriptan Assets.

- C. The purpose of Paragraph VIII of this Order is to ensure the continued use of the Frovatriptan Assets in the same business in which the Frovatriptan Assets were engaged at the time of the announcement of the Merger, and to remedy the lessening of competition resulting from the Merger as alleged in the Commission's complaint.
- D. For a period commencing on the date this Order becomes final and continuing for ten (10) years, Respondents shall not, without providing advance written notification to the Commission, acquire, directly or indirectly, through subsidiaries or otherwise, any ownership or other interest, in whole or in part, in any of the Frovatriptan Assets. Said notification 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 the Respondents and not of any other party to the transaction. Respondents shall provide two (2) complete copies (with all attachments and exhibits) of 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 or documentary material (within the meaning of 16 C.F.R. § 803.20), Respondents shall not consummate the transaction until twenty (20) days after substantially complying with such request. Early termination of the waiting periods in this Paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition. Provided, however, that 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.

## IX.

**IT IS FURTHER ORDERED** that:

- A. Not later than ten (10) Business Days after the Merger is consummated, Respondents shall transfer and surrender, absolutely and in good faith, all GI147211C Assets, pursuant to and in accordance with the GI147211C Asset Sale Agreements, to Gilead Sciences, and such agreements are incorporated by reference into this Order and made a part hereof as non-public Appendix IX. Failure by Respondents to comply with all terms of the GI147211C Asset Sale Agreements shall constitute a failure to comply with this Order.

- B. Pending the completion of the transfer of the GI147211C Assets to Gilead Sciences, Respondents shall take such actions as are necessary to maintain the viability and marketability of the GI147211C Assets, and to prevent the destruction, deterioration, or impairment of any of the GI147211C Assets.
- C. The purpose of Paragraph IX of this Order is to ensure the continued use of the GI147211C Assets in the same business in which the GI147211C Assets were engaged at the time of the announcement of the Merger, and to remedy the lessening of competition resulting from the Merger as alleged in the Commission's complaint.
- D. For a period commencing on the date this Order becomes final and continuing for ten (10) years, Respondents shall not, without providing advance written notification to the Commission, acquire, directly or indirectly, through subsidiaries or otherwise, any ownership or other interest, in whole or in part, in any of the GI147211C Assets. Said notification 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 the Respondents and not of any other party to the transaction. Respondents shall provide two (2) complete copies (with all attachments and exhibits) of 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 or documentary material (within the meaning of 16 C.F.R. § 803.20), Respondents shall not consummate the transaction until twenty (20) days after substantially complying with such request. Early termination of the waiting periods in this Paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition. Provided, however, that 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.

## **X.**

### **IT IS FURTHER ORDERED** that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint a Monitor Trustee to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order and the Divestiture Agreements. The Commission may appoint one or more Monitor Trustees to assure Respondents' compliance with the requirements of Paragraph II, III, IV, V, VI, VII, VIII and IX, respectively, of this Order, and the related Divestiture Agreements.

- B. If one or more Monitor Trustees is appointed pursuant to Paragraph X.A. of this Order, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of each Monitor Trustee:
1. The Commission shall select the Monitor 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 Monitor Trustee within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Monitor Trustee, Respondents shall be deemed to have consented to the selection of the proposed Monitor Trustee.
  2. The Monitor Trustee shall have the power and authority to monitor Respondents' compliance with the terms of this Order and with the relevant Divestiture Agreement(s) made a part of this Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor Trustee in a manner consistent with the purposes of this Order and in consultation with the Commission.
  3. Within ten (10) days after appointment of the Monitor Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, confers on the Monitor Trustee all the rights and powers necessary to permit the Monitor Trustee to monitor Respondents' compliance with the terms of this Order and with the relevant Divestiture Agreement(s) in a manner consistent with the purposes of this Order.
  4. The Monitor Trustee shall serve until the last obligation under each of the Divestiture Agreements has been fully performed and each of the Commission-approved Acquirers pursuant to Paragraphs II., III., and VI. of this Order (or as otherwise specified by the Commission) has received all necessary FDA approvals to manufacture and sell the Product(s) acquired pursuant to a Divestiture Agreement; provided, however, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of this Order.
  5. The Monitor Trustee shall have full and complete access to Respondents' personnel, books, records, documents, facilities and technical information relating to the research, development and manufacture of the relevant Product, or to any other relevant information, as the Monitor Trustee may reasonably request, including, but not limited to, all documents and records kept in the normal course of business that relate to the manufacture of the relevant Product and all materials and information relating to FDA and other Agency approvals. Respondents shall cooperate with any reasonable request of the Monitor Trustee. Respondents shall



take no action to interfere with or impede the Monitor Trustee's ability to monitor Respondents' compliance with this Order and the relevant Divestiture Agreement(s).

6. The Monitor Trustee shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The Commission may, among other things, require the Monitor Trustee to sign an appropriate confidentiality agreement relating to Commission materials and information received in connection with the performance of the Monitor Trustee's duties. The Monitor Trustee shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor Trustee's duties and responsibilities. The Monitor Trustee shall account for all expenses incurred, including fees for his or her services, subject to the approval of the Commission.
7. Respondents shall indemnify the Monitor Trustee and hold the Monitor Trustee harmless against any losses, claims, damages, liabilities or expenses arising out of, or in connection with, the performance of the Monitor Trustee's duties.

Agreement(s). These responsibilities of the Monitor Trustee shall continue until the last obligation under the relevant Divestiture Agreement(s) has been fully performed, unless otherwise directed by the Commission.

## **XI.**

### **IT IS FURTHER ORDERED** that:

- A. If Respondents have not fully complied with the obligations specified in Paragraphs II through IX of this Order, the Commission may appoint a trustee or trustees to divest or transfer the assets required to be divested or transferred pursuant to each of the relevant Paragraphs in a manner that satisfies the requirements of each such Paragraph, as applicable (“Divestiture Trustee(s)”). The Commission may appoint a different Divestiture Trustee to accomplish each of the divestitures described in Paragraphs II, III, IV, V, VI, VII, VIII, and IX, respectively. 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 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 the Respondents to comply with this Order.
- B. If a Divestiture Trustee is appointed by the Commission or a court pursuant to Paragraph XI.A. of this Order, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee’s powers, duties, authority, and responsibilities:
  1. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture 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 Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
  2. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to divest or transfer the relevant assets that are required by this Order to be divested or transferred.

3. Within ten (10) days after appointment of the Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission and, in the case of a court-appointed Divestiture Trustee, of the court, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the relevant divestiture(s) or transfer(s) required by the Order.
4. The Divestiture Trustee shall have twelve (12) months from the date the Commission approves the trust agreement described in Paragraph XI.B.3. to accomplish the divestiture(s), which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve-month period, the Divestiture Trustee has submitted a plan of divestiture or believes that the divestiture(s) can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or, in the case of a court-appointed Divestiture Trustee, by the court; provided, however, the Commission may extend the divestiture period only two (2) times.
5. The Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities relating to the relevant assets that are required to be divested by this Order or to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture(s). 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 Divestiture Trustee, by the court.
6. The Divestiture Trustee shall use his or her best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest at no minimum price. The divestiture(s) shall be made in the manner and to an acquirer as required by this Order; provided, however, if the Divestiture Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondents from among those approved by the Commission; provided further, however, that Respondents shall select such entity within five (5) business days of receiving notification of the Commission's approval.
7. The Divestiture 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 Divestiture 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 Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the

divestiture(s) and all expenses incurred. After approval by the Commission and, in the case of a court-appointed Divestiture Trustee, by the court, of the account of the Divestiture Trustee, including fees for his or her services, all remaining monies shall be paid at the direction of the Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

8. Respondents 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.
9. If the Divestiture Trustee ceases to act or fails to act diligently, a substitute Divestiture Trustee shall be appointed in the same manner as provided in Paragraph XI.B. of this Order.
10. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture(s) required by this Order.
11. In the event that the Divestiture Trustee determines that he or she is unable to divest the assets required to be divested pursuant to each of the relevant Paragraphs in a manner that preserves their marketability, viability and competitiveness and ensures their continued use in the research, design, development, manufacture, distribution, marketing or sale of the relevant Product or Products, the Divestiture Trustee may divest such additional assets related to the relevant Product or Products of the Respondents and effect such arrangements as are necessary to satisfy the requirements of this Order.
12. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order.
13. The Divestiture Trustee shall report in writing to Respondents and the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture(s).

## **XII.**

**IT IS FURTHER ORDERED** that:

- A. Respondents shall submit to the Commission (with simultaneous copies to the Monitor Trustee(s) and the Divestiture Trustee(s), as appropriate) verified written reports setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order. These reports are due as follows: the initial report is due thirty (30) days after the date this Order becomes final; the second report is due sixty (60) days after the initial report; and all subsequent reports are due every ninety (90) days thereafter

all other records and documents in the possession or under the control of Respondents relating to compliance with this Order; and

- B. Upon five (5) days' notice to Respondents and without restraint or interference from Respondents, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

**XV.**

**IT IS FURTHER ORDERED**

**CONFIDENTIAL APPENDIX I**

**[Redacted Public Record Version]**

**CONFIDENTIAL APPENDICES II-IX**

**[Redacted From Public Record Version]**