## UNITED STATES OF AMERICA BEFORE FEDERAL TRADE COMMISSION

Timothy J. Muris, Chairman

**COMMISSIONERS:** 

M O	neila F. Anthony Iozelle W. Thompson rson Swindle homas B. Leary	
In the Matter of	) ) )	
<b>BAXTER INTERNATION</b> a corporation;	JAL INC.,	
and  WYETH, a corporation.	) ) ) )	Docket No. DECISION AND ORDER
	)	

The Federal Trade Commission ("Commission") having initiated an investigation of the proposed acquisition by Respondent Baxter International Inc. ("Baxter") of certain assets of Respondent Wyeth, hereinafter referred to as "Respondents," and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge 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 Baxter is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at One Baxter Parkway, Deerfield, Illinois 60015.
- 2. Respondent Wyeth is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at Five Giralda Farms, Madison, New Jersey 07940.
- 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. "Baxter" means Baxter International Inc., its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Baxter International Inc. (including, but not limited to, Baxter Healthcare Corporation), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. "Wyeth" means Wyeth, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Wyeth (including, but not limited to, Wyeth Pharmaceuticals Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. "Respondents" means Baxter and Wyeth individually and collectively.
- D. "Acquisition" means the proposed acquisition by Baxter of certain assets of Wyeth's human generic injectable pharmaceutical business, operated by Wyeth's ESI Lederle division, pursuant to an Asset Purchase Agreement dated June 8, 2002, by and among Wyeth, Wyeth Pharmaceuticals Inc. and Baxter Healthcare Corporation.

- E. "Commission" means the Federal Trade Commission.
- F. "Faulding" means Faulding Pharmaceutical Co., 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 650 From Road (Mack-Cali Centre II), 5<sup>th</sup> Floor South, Paramus, New Jersey, 07652.
- G. "Acquisition Date" means the date the Acquisition is consummated.
- H. "Access Period" means the period described in Paragraph II.H. of this Order.
- I. "Agency" means any governmental, legislative, regulatory, judicial or other authority in the world responsible for granting approvals, consents, licenses, registrations, permits, waivers or other authorizations for any aspect of the research, development, manufacture, finishing, packaging, validation, distribution, marketing or sale of any of Respondents' products. The term "Agency" includes, but is not limited to, the FDA.
- J. "ANDA" means an Abbreviated New Drug Application filed or to be filed with the FDA pursuant to 21 C.F.R. 314, or its foreign Agency equivalent, and all supplements, amendments and revisions thereto.
- K. "Anesthesia/Sedation Product" means any pharmaceutical product indicated for the induction or maintenance of general anesthesia or sedation in connection with a surgical procedure or an invasive non-surgical procedure (including, but not limited to, sedation of intubated, mechanically ventilated individuals), but excluding any product marketed by Wyeth on the day following the Divestiture Date.
- L. "Business Day" means any day excluding Saturday, Sunday and any United States Federal holiday.
- M. "Confidential Propofol Information" means all information that is not in the public domain relating to Propofol that was obtained in any manner by Respondent Wyeth. "Confidential Propofol Information" does not include (1) any information that Respondent Baxter demonstrates it obtained without the assistance of Respondent Wyeth prior to the Acquisition Date or (2) the Propofol Licensed Intellectual Property.
- N. "Confidential PV&M Information" means all information that is not in the public domain relating to Sicor's Pancuronium, Vecuronium, and Metoclopramide that was obtained in any manner by Respondent Baxter.
- O. "Copyrights" means all rights to all original works of authorship of any kind in any form related to any of Respondents' products, and any registrations and applications for registrations thereof.

- P. "Direct Cost" means the pro rata share of salary or wages and reasonable expenses.
- Q. "Divestiture Agreement" means the Faulding Divestiture Agreement or any other agreement to divest the Propofol Assets that has been approved by the Commission to accomplish the requirements of this Order, between Respondents and a Propofol Acquirer (or between a trustee appointed pursuant to Paragraph VI. of this Order and a Propofol Acquirer) and all amendments, exhibits, attachments, agreements, and schedules thereto.
- R. "Divestiture Date" means the date on which Respondents and a Propofol Acquirer close on a transaction to divest, license, or otherwise convey relevant assets pursuant to this Order.
- S. "Divestiture Trustee" means the trustee appointed by the Commission pursuant to Paragraph VI.A. of this Order.
- T. "Drug Master Files" means the information required by the FDA as described in 21 C.F.R. Part 314.420 related to Propofol.
- U. "Faulding Divestiture Agreement" means the Asset Purchase Agreement (including all related agreements, amendments, schedules, exhibits, and appendices) by and between Respondent Baxter and Faulding dated November 20, 2002 that is attached hereto as Confidential Appendix I.
- V. "FDA" means the United Stated Food and Drug Administration.
- W. "Iron Gluconate" means any injectable pharmaceutical composition containing any formulation or dosage of the active ingredient generically known as iron gluconate or sodium ferric gluconate.
- X. "Iron Gluconate Agreement" means the Ferrlecit® Co-Promotion Agreement dated June 28, 2002, between Baxter Healthcare Corporation and Watson Pharmaceuticals, Inc. relating to Watson's product Ferrlecit®.
- Y. "Know-how" means any product specifications, processes, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, safety, quality control and clinical data, technical information, test results, data, research records, invention disclosures, literature, supplier lists and similar data and information and all other confidential and proprietary technical or business information in each case in whatever medium (electronic, magnetic or otherwise), and all rights in any jurisdiction to limit the use or disclosure thereof.
- Z. "Metoclopramide" means any injectable pharmaceutical composition containing any formulation or dosage of the active ingredient generically known as metoclopramide or

- metoclopramide hydrochloride.
- AA. "NDA" means the New Drug Application filed or to be filed with the FDA pursuant to C.F.R. Part 314, or its foreign Agency equivalent, and all supplements, amendments and revisions thereto.
- BB. "NDC Numbers" means the National Drug Code numbers(s) assigned by the FDA.
- CC. "Pancuronium" means any injectable pharmaceutical composition containing any formulation or dosage of the active ingredient generically known as pancuronium or pancuronium bromide.
- DD. "Patents" means all patents, patent applications, and statutory invention registrations, including all reissues, renewals, 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 of Respondents' products.
- EE. "Person" includes the company and means any natural person, incorporated or unincorporated entity, partnership, association, joint venture, government entity, non-profit organization, university, trust or other entity.
- FF. "Product Registrations" means all registrations, permits, licenses, consents, authorizations and other approvals, and pending applications and requests therefore, required by applicable Agencies related to the research, development, manufacture, finishing, packaging, distribution, marketing or sale of any of Respondents' products, including all NDAs and ANDAs. "Product Registrations" includes all underlying information, data, filings, reports, correspondence or other materials used to obtain or apply for any of the foregoing, including, without limitation, all data submitted to and all correspondence with the FDA and other Agencies.
- GG. "Propofol" means any pharmaceutical composition containing any formulation or dosage of the active ingredient generically known as propofol.
- HH. "Propofol Acquirer" means an entity approved by the Commission to acquire the Propofol Assets.
  - II. "Propofol Assets" means all of Respondent Wyeth's rights, title and interest, in and to all assets, tangible or intangible, related to Propofol in any market anywhere in the world, in existence as of the Acquisition Date, including the research, development, registering, manufacture, packaging, distribution, marketing or sale of Propofol, including, without limitation, the following:

- 1. all personal property owned, leased or otherwise held by Wyeth;
- 2. all Propofol Intellectual Property;
- 3. all Confidential Propofol Information;
- 4. all Product Registrations;
- 5. at the Propofol Acquirer's option, any of the Propofol Contracts;
- 6. all Propofol Manufacturing Technology, Propofol Scientific and Regulatory Materials, and Propofol Marketing Materials;
- 7. a list of all of the NDC Numbers related to Propofol;
- 8. all Drug Master Files including all rights of reference to the Drug Master Files and rights of reference (if such rights exist) to information similar to the Drug Master Files submitted to any Agency other than the FDA;
- 9. all inventories, stores, and supplies held by, or under the control of, Wyeth, including, but not limited to, raw materials, goods in process, finished goods, and Propofol specific packaging and labels; and
- 10. all books, records and files.

<u>Provided, however</u>, that "Propofol Assets" does not include (i) any assets exclusively relating to Sicor's Propofol that Baxter markets pursuant to an agreement dated September 30, 1993 between Baxter and Sicor, (ii) any real property relating to Wyeth's Propofol Assets, and (iii) any Propofol Licensed Intellectual Property.

- JJ. "Propofol Contracts" means all contracts and agreements relating to Propofol between Wyeth and any Person, including, but not limited to, contracts and agreements with manufacturers, raw material suppliers, customers, and group purchasing organizations.
- KK. "Propofol Employees" means all of Respondent Wyeth's employees who participated (irrespective of the portion of working time involved), within the eighteen (18) month period immediately prior to the Divestiture Date, in the following activities: (i) the regulatory approval process, including clinical, bioequivalence or stability studies of Propofol; (ii) the planning, engineering, procurement, or analysis of the means to produce Propofol; (iii) the manufacture of (or attempt to manufacture) Propofol, including, but not limited to, those involved in the quality assurance and quality control of Propofol; or (iv) legal work on Patents or litigation related to Propofol. "Propofol Employees" also includes all of Respondent Wyeth's employees who participated (irrespective of the portion of working time

involved), within the five (5) year period immediately prior to the Divestiture Date, in the research and development of Propofol. These employees are identified in Confidential Appendix II, attached hereto.

- LL. "Propofol Intellectual Property" means all of each of the following that relate to Propofol:
  - 1. inventions and discoveries related to Propofol that are or may be patentable, and rights to obtain or file for Patents and registrations thereof;
  - 2. Patents, including, but not limited to (a) U.S. Patents 6,177,477 and 6,028,108 and (b) all pending applications in Brazil, Canada, and the European Patent Office, that are the counterparts to U.S. Patents 6,177,477 and 6,028,108, and any patents issuing therefrom;
  - 3. Copyrights, including, without limitation, all such rights relating to Propofol Marketing Materials, Propofol Manufacturing Technology, and Propofol Scientific and Regulatory Materials:
  - 4. Software;
  - 5. Trademarks, Trade Dress, and mask works;
  - 6. Know-how; and
  - 7. rights to sue and recover damages or obtain injunctive relief for infringement, dilution, misappropriation, violation or breach of any of the foregoing.

<u>Provided</u>, <u>however</u>, that "Propofol Intellectual Property" does not include any Propofol Licensed Intellectual Property.

- MM. "Propofol Launch Date" means the earliest date on which the Proposed Acquirer (1) obtains all final approvals from any Agency necessary to manufacture and sell 20 ml, 50 ml, and 100 ml dosage forms of Propofol, each as a finished good, in the United States and (2) is able to legally sell 20 ml, 50 ml, and 100 ml dosage forms of Propofol, each as a finished good, in the United States.
- NN. "Propofol Licensed Intellectual Property" means all of Respondent Wyeth's rights, title, and interest, in and to all Know-how that relates to (but does not exclusively relate to) Propofol as of the Divestiture Date.
- OO. "Propofol Manufacturing Technology" means all technology, trade secrets, know-how, techniques, processes, practices, methods, and proprietary information, materials, or data relating to the manufacture, engineering, safety, quality control, validation, packaging, finishing, release testing, stability or shelf life of Propofol, and any rights thereto, in all

- jurisdictions, including, but not limited to, all Propofol specifications, formulations, manufacturing and engineering records, manuals, and drawings, all sampling records, standard operating procedures, batch records, stability studies, supplier lists, and all specifications for commercial field equipment.
- PP. "Propofol Marketing Materials" means all marketing information, materials or data used (or that Wyeth planned for use) anywhere in the world relating to Propofol, including, but not limited to (i) all advertising, promotional, educational, training, display, and sales (e.g., forecasting models, detailing reports, sales force call activity reports) information, materials, or data, (ii) all vendor lists, price lists, and reimbursement data, (iii) all market, competitor, and customer information (e.g., customer lists, customer contact information, mailing lists, research data and market intelligence reports), (iv) all statistical programs (if any) used for marketing and sales research, (v) all artwork for packaging, and (vi) all marketing, strategic, sales or other plans.
- QQ. "Propofol Patent Litigation" means the action filed by AstraZeneca Pharmaceuticals LP and AstraZeneca UK Ltd. against Wyeth for patent infringement in the United States District Court for the Southern District of New York (Case No. 02 CV 7936) relating to the Propofol Assets.
- RR. "Propofol Scientific and Regulatory Materials" means all technical, scientific, clinical, pharmaceutical, chemical, pharmacological, toxicological, physical, analytical, regulatory, process development, bioequivalence, and stability information, materials, or data relating to Propofol, and all rights thereto, in any and all jurisdictions, including, but not limited to, all information, data, and materials used in or relating to the research, development, registration, and Agency approval of Propofol, including (i) all raw data used to support any information submitted to an Agency (*e.g.*, clinical or bioequivalence data), (ii) all case report forms, (iii) all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze data, (iv) all data contained in laboratory notebooks, and (v) all adverse experience reports, files, and underlying data (including source documentation).
- SS. "Propofol Services" means the services described in Paragraph II.E. of this Order.
- TT. "PV&M Assets" means all of Respondent Baxter's right, title and interest, in and to all assets, tangible or intangible, related to Pancuronium, Vecuronium, and Metoclopramide, in existence as of the date Respondents sign the Consent Agreement, including, but not limited to:
  - 1. all Confidential PV&M Information;
  - 2. at Sicor's option, any of the PV&M Contracts;
  - 3. all Copyrights, including, without limitation, all such rights relating to the PV&M

#### Marketing Materials;

- 4. all PV&M Marketing Materials;
- all inventories, stores, and supplies held by, or under the control of, Respondent Baxter;
- 6. all books, records and files.
- UU. "PV&M Contracts" means all of the contracts and agreements relating to Pancuronium, Vecuronium, and Metoclopramide between Respondent Baxter and any Person, including, but not limited to, group purchasing organizations and hospitals.
- VV. "PV&M Customers" means all of Baxter's Pancuronium, Vecuronium, and Metoclopramide customers as of the date Respondents sign the Consent Agreement.
- WW. "PV&M Marketing Materials" means all marketing information, materials or data used anywhere in the world relating to Pancuronium, Vecuronium, and Metoclopramide, including, but not limited to (i) all advertising, promotional, educational, training, display, and sales (e.g., forecasting models, detailing reports, sales force call activity reports) information, materials, or data, (ii) all vendor lists, price lists, and reimbursement data, (iii) all market, competitor, and customer information (e.g., customer lists, customer contact information, mailing lists, research data and market intelligence reports), (iv) all statistical programs (if any) used for marketing and sales research, (v) all artwork for packaging, and (vi) all marketing, strategic, sales or other plans.
- XX. "PV&M Services" means the term described in Paragraph III.D. of this Order.
- YY. "PV&M Term" means the term described in Paragraph III.D. of this Order.
- ZZ. "Restricted Period" means the period described in Paragraph III.E. of this Order.
- AAA. "Sicor" means Sicor Inc. (including Gensia Sicor Pharmaceuticals, Inc. and Gensia Sicor Pharmaceuticals Sales, Inc.), 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 19 Hughes Irvine, CA 92618.
- BBB. "Software" means computer programs (including all software implementations of algorithms, models, and methodologies whether in source code or object code form), databases and compilations, including any and all data and collections of data, all documentation, including user manuals and training materials, related to any of the foregoing and the content and information contained on any website; <a href="mailto:provided">provided</a>, <a href="mailto:however">however</a>, that "Software" does not include software that is readily purchasable or licensable and which has not been modified in a

- manner material to the use or function thereof (other than through user preference settings).
- CCC. "Trade Dress" means any current or planned trade dress related to any of Respondents' products, 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.
- DDD. "Trademarks" means all (i) trademarks, trade names and brand names, including registrations and applications for registration therefor, (ii) all renewals, modifications, and extensions thereof, and (iii) all common law rights, and the goodwill symbolized thereby and associated therewith.
- EEE. "Vecuronium" means any injectable pharmaceutical composition containing any formulation or dosage of the active ingredient generically known as vecuronium or vecuronium bromide.
- FFF. "Watson" means Watson Pharmaceuticals, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Nevada, with its corporate headquarters located at 311 Bonnie Circle, Corona, California, 92880.

II.

- A. No later than ten (10) Business Days after the Acquisition Date, Respondents shall divest the Propofol Assets, absolutely and in good faith, at no minimum price to Faulding.
  - 1. To the extent that any of the Propofol Assets are conveyed to Respondent Baxter on the Acquisition Date, Respondent Baxter shall divest all such Propofol Assets to Faulding in accordance with Paragraph II.A. of this Order. The Faulding Divestiture Agreement is incorporated by reference into this Order and made a part hereof, and shall not be construed to vary or contradict the terms of this Order. Any failure to comply with the terms of the Faulding Divestiture Agreement shall constitute a violation of this Order by Respondent Baxter.
  - 2. To the extent that any of the Propofol Assets are not conveyed to Respondent Baxter on the Acquisition Date, Respondent Wyeth shall divest all such Propofol Assets to Faulding in accordance with Paragraph II.A. of this Order.
- B. <u>Provided, however,</u> that, if, at the time the Commission determines to make this Order final, the Commission notifies Respondent Baxter that Faulding is not an acceptable purchaser of the Propofol Assets or that the Faulding Divestiture Agreement is not an acceptable manner of divestiture: (i) Respondent Baxter shall immediately rescind the Faulding Divestiture Agreement; (ii) Respondents shall divest the Propofol Assets at no minimum price, absolutely

and in good faith, no later than ninety (90) Business Days from the date this Order becomes final, to a Person that receives the prior approval of the Commission and only in a manner that receives the prior approval of the Commission; and (iii) Respondents shall comply with all terms of the Divestiture Agreement. The Divestiture Agreement shall not be construed to vary or contradict the terms of this Order, and any breach by Respondents of any term of the Divestiture Agreement shall constitute a violation of this Order.

- C. No later than the date Respondents divest the Propofol Assets, Respondents shall grant to the Propofol Acquirer a worldwide, royalty-free, fully paid-up, perpetual, irrevocable, transferable, assignable license (with the right to grant sublicenses) to the Propofol Licensed Intellectual Property to make, distribute, offer for sale, promote, advertise, sell, import or export or have used, made, distributed, offered for sale, promoted, advertised, sold, imported or exported, any product anywhere in the world. Such license shall be (i) exclusive (even as to Respondents) for any Propofol product and (ii) non-exclusive for any other product; provided, however, that Respondents may require that the Propofol Acquirer not sublicense the Propofol Intellectual Property to any Person (other than third-party manufacturing contractor(s) or third-party developer(s) working on behalf of the Propofol Acquirer), to make, distribute, offer for sale, promote, advertise, sell, import or export or have used, made, distributed, offered for sale, promoted, advertised, sold, imported or exported, any non-Propofol or non-Anesthesia/Sedation product. Respondents shall disclose, provide or otherwise make available all of the Propofol Licensed Intellectual Property to the Propofol Acquirer no later than the Divestiture Date.
- D. Nothing in this Order shall prohibit the Propofol Acquirer from granting to Wyeth a non-exclusive license to any Know-how conveyed to the Propofol Acquirer pursuant to this Order; <u>provided</u>, <u>however</u>, that Respondent Wyeth shall not use any such Know-how licensed from the Propofol Acquirer for (1) any Propofol product or (2) any Anesthesia/Sedation Product.
- E. Upon request and reasonable notice from the Propofol Acquirer to Respondents, Respondents shall provide the following services (hereinafter "Propofol Services") in a timely manner:
  - 1. assistance and training from knowledgeable Propofol Employees to enable the Propofol Acquirer (or its designee) to obtain all necessary approvals from any Agency to manufacture and sell all formulations and dosages of Propofol, including, but not limited to, conducting stability studies, preparing filings, addressing FDA deficiency letters, and assisting with pre-approval inspections, until the Propofol Acquirer (or its designee) obtains all such necessary approvals; provided, however, that such assistance and training may be limited to applications for approvals that were filed, or requests for approvals that were made, on or before the Propofol Launch Date;
  - 2. assistance and training from knowledgeable Propofol Employees at a facility chosen by the Propofol Acquirer, until the Propofol Acquirer or its designee is able to manufacture

- all formulations and dosages of Propofol for commercial sale, including, but not limited to, assistance with production batches, scale-up, commercial field equipment, and transferring Know-how related to Propofol; and
- 3. assistance from knowledgeable personnel to enable the Propofol Acquirer to defend against, respond to, or otherwise participate in any litigation (including the Propofol Patent Litigation), investigation, audit, process, subpoena or other proceeding relating to Propofol, until the litigation (including the Propofol Patent Litigation), investigation, audit, process, subpoena or other proceeding relating to Propofol is settled or finally disposed of without any right to appeal; provided, however, that such assistance may be limited to litigation, investigations, audits, processes, subpoenas or other proceedings relating to Propofol that are initiated on or before the Propofol Launch Date.

<u>Provided, further, however,</u> that Respondents shall not: (i) require the Propofol Acquirer to pay compensation for Propofol Services that exceeds the Direct Cost of providing such services; (ii) terminate its obligation to provide Propofol Services because of a material breach by the Propofol Acquirer of any agreement to provide such services, in the absence of a final order of a court of competent jurisdiction; or (iii) seek to limit the damages (such as indirect, special or consequential damages) that the Propofol Acquirer would be entitled to receive in the event of Respondents' breach of any agreement to provide Propofol Services.

- F. At the time of divestiture, Respondents shall also divest any additional, incidental assets of Respondents and make any further arrangements for transitional services that may be reasonably necessary to ensure the marketability, viability and competitiveness of the Propofol Assets.
- G. Respondents shall secure, prior to the Divestiture Date, all consents and waivers from all Persons that are necessary for the divestiture of the Propofol Assets to the Propofol Acquirer, or for the continued research, development, manufacture, sale, marketing or distribution of Propofol by the Propofol Acquirer.
- H. For a period of six (6) months from the Divestiture Date (hereinafter "Access Period"), Respondents shall allow the Propofol Acquirer an opportunity to enter into an employment contract with any Propofol Employee, provided that such contracts are contingent upon the Commission's approval of the Divestiture Agreement. <u>Provided, further,</u> that:
  - At the request of the Propofol Acquirer, any time during the Access Period, Respondents shall (i) allow the Propofol Acquirer an opportunity to interview any Propofol Employee, and (ii) allow the Propofol Acquirer to inspect the personnel files and other documentation relating to any Propofol Employee, to the extent permissible under applicable laws.
  - 2. During the Access Period, Respondents shall (i) not interfere with the hiring or employing

by the Propofol Acquirer of Propofol Employees, (ii) remove any impediments within the control of Respondents that may deter these employees from accepting employment with the Propofol 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 Propofol Acquirer, and (iii) not make any counteroffer to a Propofol Employee who receives a written offer of employment from the Propofol Acquirer. Provided, however, that Paragraph II.H.2. does not prohibit Respondents from making offers of employment to or employing any Propofol Employee during the Access Period where the Propofol Acquirer has notified Respondents in writing that the Propofol Acquirer does not intend to make an offer of employment to that employee.

- 3. Respondents shall provide all Propofol Employees with reasonable financial incentives to continue in their positions until the Divestiture Date. Such incentives shall include a continuation of all employee benefits offered by Respondents until the Divestiture Date, including regularly scheduled raises and bonuses, and a vesting of all pension benefits (as permitted by law).
- 4. Respondents shall provide to each Propofol Employee incentives to accept employment with the Propofol Acquirer. Such incentives shall include a bonus equal to 10% of the employee's current salary and commissions (including any annual bonuses), to any Propofol Employee as of the Divestiture Date, who accepts an offer of employment from the Propofol Acquirer during the Access Period, and remains employed by the Propofol Acquirer for a period of one (1) year, payable by Respondents one (1) year after the commencement of the employee's employment with the Propofol Acquirer.
- 5. For a period of one (1) year following the Divestiture Date, Respondents shall not, directly or indirectly, hire or enter into any arrangement for the services of any employee employed by the Propofol Acquirer with any amount of responsibility related to Propofol, unless the individual's employment has been terminated by the Propofol Acquirer.
- I. Respondents shall take all necessary steps to maintain the confidentiality of the Confidential Propofol Information. <u>Provided</u>, <u>further</u>, that:
  - Except as permitted under the Divestiture Agreement or this Order, Respondents shall not
     (i) provide, disclose, or otherwise make available any Confidential Propofol Information
     to any Person or (ii) use any Confidential Propofol Information for any reason or
     purpose.
  - 2. If use of any Confidential Propofol Information is permitted under this Order, Respondents shall provide, disclose, or otherwise make available such information (i) only to those Persons who require such information for the permitted purposes, (ii) only such part of the Confidential Propofol Information that is so required, and (iii) only to those

Persons who agree in writing to maintain the confidentiality of such information.

- 3. Respondents shall (i) require that any Propofol Employee who continues his or her employment with either Respondent sign a confidentiality agreement pursuant to which such employee shall be required to maintain the confidentiality of all Confidential Propofol Information, including the obligation not to disclose such information to any other employee, executive, consultant, agent or other personnel of Respondents, and (ii) enforce the terms of this Paragraph II.I. as to any Person and take such action as is necessary to cause each such Person to comply with the terms of this Paragraph II.I., including notification and training of employees and all other actions that Respondents would take to protect their own trade secrets and proprietary information.
- 4. Nothing in this Order prohibits Respondents from disclosing Confidential Propofol Information if required by United States federal or state law, regulation, court order, or subpoena; <u>provided</u>, <u>however</u>, that Respondents shall use their best efforts to protect the confidentiality of such information, including, but not limited to, obtaining a protective order during an adjudication.
- J. The purpose of the divestiture of the Propofol Assets and of related obligations is to ensure the continued use of the Propofol Assets in the same business in which the Propofol Assets were used by Respondent Wyeth at the time of the announcement of the Acquisition, and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

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- A. No later than five (5) Business Days after the Acquisition Date, Respondent Baxter shall (i) terminate all of its rights and interests in Sicor's Pancuronium, Vecuronium, and Metoclopramide, and (ii) divest the PV&M Assets to Sicor.
- B. Respondent Baxter shall secure, prior to the Acquisition Date, all consents and waivers from all Persons that are necessary for the divestiture of the PV&M Assets to Sicor.
- C. No later than five (5) Business Days after the date Respondents sign the Consent Agreement, Respondent Baxter shall notify in writing all PV&M Customers that (i) Baxter intends to transfer all of its rights and interests in Pancuronium, Vecuronium, and Metoclopramide back to Sicor, (ii) Baxter intends to transfer all contracts relating to these products to Sicor, and (iii) following a transition period not to exceed ninety (90) Business Days, PV&M Customers will be able to purchase these products under the Sicor label. Respondent Baxter shall provide Sicor with a copy of such notification, together with a list of the names and

addresses of all PV&M Customers to whom such notification was sent, no later than five (5) Business Days after the date Respondents sign the Consent Agreement. Prior to the date Respondent Baxter terminates all of its rights and interests in Sicor's Pancuronium, Vecuronium, and Metoclopramide pursuant to Paragraph III.A. of this Order, Respondent Baxter shall permit Sicor to contact the PV&M Customers solely for the purpose of (i) introducing Sicor and its sales representatives to the PV&M Customers, (ii) informing such customers of how orders may be placed during the transition period, and (iii) addressing ways to ensure the uninterrupted supply of Pancuronium, Vecuronium, and Metoclopramide.

- D. For a period not to exceed ninety (90) Business Days after the Acquisition date (hereinafter "PV&M Term"), at the request of Sicor, Respondent Baxter shall provide to Sicor at no cost and in a timely manner the following services (hereinafter "PV&M Services"):
  - 1. Baxter shall continue to take customer orders, ship product, invoice customers, collect customer remittances, and provide any other additional services that are necessary to ensure an uninterrupted supply of Sicor's Pancuronium, Vecuronium, and Metoclopramide (including any such Baxter-labeled products); provided, however, that for the term of the PV&M Services, Baxter may share a dual award on any group purchasing organization contracts for the sole purpose of performing its obligations under this Paragraph III.D.; provided further, however, that Respondent Baxter shall not market, distribute, sell or otherwise convey Pancuronium, Vecuronium, or Metoclopramide manufactured by Sicor after the PV&M Term.
  - 2. Respondent Baxter shall not: (i) terminate its obligation to provide PV&M Services because of a material breach by Sicor of any agreement to provide such services, in the absence of a final order of a court of competent jurisdiction; or (ii) seek to limit the damages (such as indirect, special or consequential damages) that Sicor would be entitled to receive in the event of Respondent Baxter's breach of any agreement to provide PV&M Services.
- E. For a period of six (6) months from the Acquisition Date (hereinafter "Restricted Period"), Respondent Baxter shall not solicit, induce or attempt to induce any PV&M Customer to transfer to Respondent Baxter any business relating to Pancuronium, Vecuronium, or Metoclopramide; <a href="mailto:provided">provided</a>, <a href="however">however</a>, that nothing in this paragraph shall prevent Respondent Baxter from responding to an unsolicited invitation to bid on a contract from any Person during the Restricted Period.
- F. For a period of ten (10) years beginning on the date this Order becomes final, Respondent Baxter shall not enter into any agreements with Sicor relating to Pancuronium, Vecuronium or Metoclopramide without the prior approval of the Commission.
- G. Respondent Baxter shall take all necessary steps to maintain the confidentiality of the Confidential PV&M Information. <u>Provided, further,</u> that:

- 1. Except as permitted under this Order, Respondent Baxter shall not (i) provide, disclose, or otherwise make available any Confidential PV&M Information to any Person or (ii) use any Confidential PV&M Information for any reason or purpose.
- 2. If use of any Confidential PV&M Information is permitted under this Order, Respondent Baxter shall provide, disclose, or otherwise make available such information (i) only to those Persons who require such information for the permitted purposes, (ii) only such part of the Confidential PV&M Information that is so required, and (iii) only to those Persons who agree in writing to maintain the confidentiality of such information.
- 3. Respondent Baxter shall (i) require that each of its employees with any responsibility for Pancuronium, Vecuronium, and Metoclopramide sign a confidentiality agreement pursuant to which such employee shall be required to maintain the confidentiality of all Confidential PV&M Information, including the obligation not to disclose such information to any other employee, executive, consultant, agent or other personnel of Respondent Baxter, and (ii) enforce the terms of this Paragraph III.G. as to any Person and take such action as is necessary to cause each such Person to comply with the terms of this Paragraph III.G., including notification and training of employees and all other actions that Respondent Baxter would take to protect its own trade secrets and proprietary information.
- H. The purpose of the requirements in Paragraph III. is to ensure the continued use of the PV&M Assets and related obligations in the same business in which the PV&M Assets were used by Respondent Baxter at the time of the announcement of the proposed Acquisition, and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

IV.

- A. No later than ten (10) Business Days after the Acquisition Date, Respondent Baxter shall notify Watson in writing of Respondent Baxter's intention to terminate the Iron Gluconate Agreement by March 14, 2004.
- B. Respondent Baxter shall terminate the Iron Gluconate Agreement no later than March 14, 2004.
- C. For a period of ten (10) years beginning on the date this order becomes final, Respondent Baxter shall not enter into any agreement with Watson relating to Iron Gluconate without the prior approval of the Commission.

D. The purpose of the requirements in Paragraph IV. is to ensure the continued development of Respondent Wyeth's Iron Gluconate in the market, and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

V.

- A. At any time after Respondents sign the Consent Agreement, the Commission may appoint one or more persons to serve as Monitor to ensure that Respondents expeditiously perform their obligations as required by this Order and the Order to Maintain Assets.
- B. If a Monitor is appointed pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
  - The Commission shall select the Monitor, 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 within fourteen
    (14) days after notice by the staff of the Commission to Respondents of the identity of
    any proposed Monitor, Respondents shall be deemed to have consented to the selection of
    the proposed Monitor.
  - 2. The Monitor shall have the power and authority to monitor Respondents' compliance with the terms of this Order and the Order to Maintain Assets and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor pursuant to the terms of this Order and in a manner consistent with the purposes of this Order and the Order to Maintain Assets.
  - 3. Within fourteen (14) days after appointment of the Monitor, Respondents shall execute an agreement that, subject to the approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondents' compliance with the terms of this Order and the Order to Maintain Assets in a manner consistent with the purposes of such Orders. Respondents may require the Monitor to sign a confidentiality agreement prohibiting the use, or disclosure to anyone other than the Commission, of any competitively sensitive or proprietary information gained as a result of his or her role as Monitor.
  - 4. The Monitor's power and duties under this Paragraph V. shall terminate sixty (60) days after the Monitor has completed his or her final report pursuant to Paragraph V.B.9., or at such other time as directed by the Commission.

- 5. The Monitor shall have full and complete access to Respondents' books, records, documents, personnel, facilities, and technical information relating to compliance with this Order and the Order to Maintain Assets, or to any other relevant information, as the Monitor may reasonably request. Respondents shall cooperate with any reasonable request of the Monitor. Respondents shall take no action to interfere with or impede the Monitor's ability to monitor Respondents' compliance with this Order and the Order to Maintain Assets.
- 6. The Monitor 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 Monitor 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's duties and responsibilities. The Monitor 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 and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor'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 the Monitor's gross negligence or willful misconduct. For purposes of this Paragraph V.B.7., the term "Monitor" shall include all Persons retained by the Monitor pursuant to Paragraph V.B.6. of this Order.
- 8. If at any time the Commission determines that the Monitor has ceased to act or failed to act diligently, or is unwilling or unable to continue to serve, the Commission may appoint a substitute in the same manner as provided in this Paragraph V.
- 9. The Monitor shall report in writing to the Commission (i) every sixty (60) days from the date this Order becomes final, (ii) no later than thirty (30) days from the date Respondents have completed all obligations required by Paragraphs II. through IV. of this Order, and (iii) at any other time as requested by the staff of the Commission, concerning Respondents' compliance with this Order.
- C. The Commission may on its own initiative or at the request of the Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order.

- A. If Respondents have not divested, absolutely and in good faith, the Propofol Assets within the time and in the manner required by Paragraph II. of this Order, the Commission may at any time appoint one or more Persons as Divestiture Trustee to divest such assets to an acquirer and to execute a Divestiture Agreement that satisfies the requirements and purposes of this Order.
- B. In the event that the Commission or the Attorney General brings an action pursuant to § 5(1) of the Federal Trade Commission Act, 15 U.S.C. § 45(1), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action. 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(1) 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.
- C. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, 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 the Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures and may be the same Person as the Monitor appointed pursuant to Paragraph V. of this Order. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within fourteen (14) days after receipt of written notice from 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 accomplish the divestiture for which he or she has been appointed pursuant to the terms of this Order and in a manner consistent with the purposes of this Order and to enter into a Divestiture Agreement with another acquirer.
  - 3. Within ten (10) days after appointment of the Divestiture Trustee, Respondents shall execute an 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 accomplish

the divestiture required by this Order.

- 4. The Divestiture Trustee shall have twelve (12) months from the date the Commission approves the agreement described in Paragraph VI.C.3. of this Order to accomplish the divestiture, 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 divestiture 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 this period only two (2) times.
- 5. The Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the assets to be divested, 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 reasonably 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. 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, but shall divest expeditiously at no minimum price. The divestiture shall be made only to an acquirer that receives the prior approval of the Commission, and the divestiture shall be accomplished only in a manner that receives the prior approval of the Commission; provided, however, if the Divestiture Trustee receives bona fide offers for the assets required to be divested 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, that Respondents shall select such entity within five (5) Business Days of receiving written 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 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 Divestiture Trustee's compensation shall be based at least in significant part on a commission arrangement contingent on the Divestiture Trustee's divesting the assets 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 liabilities, losses, damages, claims, or expenses result from gross negligence or willful misconduct by the Divestiture Trustee. For purposes of this Paragraph VI.C.8., the term "Divestiture Trustee" shall include all Persons retained by the Divestiture Trustee pursuant to Paragraph VI.C.7. of this Order.
- 9. If the Divestiture Trustee ceases to act or fails to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in Paragraph VI.A. for appointment of the initial Divestiture Trustee.
- 10. In the event that the Divestiture Trustee determines that he or she is unable to divest the relevant assets required to be divested in a manner that preserves their marketability, viability and competitiveness and ensures their continued use in the research, development, manufacture, distribution, marketing, promotion, sale, or after-sales support of Propofol, the Divestiture Trustee may divest such additional assets of Respondents and effect such arrangements as are necessary to satisfy the requirements of this Order.
- 11. 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 required by this Order.
- 12. The Divestiture Trustee shall have no obligation or authority to operate or maintain the assets required to be divested by this Order.
- 13. The Divestiture Trustee shall report in writing to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.

VII.

- A. Within thirty (30) days after the date this Order becomes final, and every sixty (60) days thereafter until Respondents have fully complied with Paragraphs II. through IV., Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order. Respondents shall submit at the same time a copy of their report concerning compliance with this Order to the Monitor, if any Monitor has been appointed. Respondents shall include in their reports, among other things that are required from time to time, a full description of the efforts being made to comply with Paragraphs II. through IV. of the Order, including a description of all substantive contacts or negotiations related to the divestiture of the Propofol Assets and the identity of all parties contacted. Respondents shall include in their reports copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning completing the obligations.
- B. One (1) year from the date this Order becomes final, annually for the next nine (9) years on the anniversary of the date this Order becomes final, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which they have complied and are complying with this Order.

#### VIII.

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

#### IX.

**IT IS FURTHER ORDERED** that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to all facilities and access to inspect and copy all non-privileged books, ledgers, accounts, correspondence, memoranda, and other records and documents in the possession or under the control of Respondents relating to any matter contained in this Order; and
- B. Upon five (5) days' notice to Respondents and without restraint or interference from them, to interview Respondents' officers, directors, or employees, who may have counsel present,

regarding any such matters.

X.

**IT IS FURTHER ORDERED** that this Order will terminate ten (10) years from the date on which the Order becomes final.

By the Commission.

Donald S. Clark Secretary

SEAL ISSUED:

# APPENDIX I (non-public) Faulding Divestiture Agreement

### APPENDIX II (non-public) Propofol Employees