041 0025

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Timothy J. Muris, Chairman**
Mozelle W. Thompson
Orson Swindle
Thomas B. Leary
Pamela Jones Harbour

In the Matter of	)	
	)	
CEPHALON, INC.,	)	
a corporation;	)	
	)	
and	)	
	)	**Docket No.**
CIMA LABS INC.,	)	**DECISION AND ORDER**
a corporation.	)	**[Public Record Version]**
	)	

The Federal Trade Commission ("Commission") having initiated an investigation of the proposed merger of Respondent Cephalon, Inc. ("Cephalon") and Respondent CIMA LABS INC. ("CIMA"), 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 Order ("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 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 Cephalon is 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 145 Brandywine Parkway, West Chester, Pennsylvania 19380.

2. Respondent CIMA is 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 10000 Valley View Road, Eden Prairie, Minnesota 55344.

3. The Federal Trade Commission has jurisdiction over 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. "Cephalon" means Cephalon, Inc., its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Cephalon, Inc. (including, but not limited to, MergerCo), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Effective Date, the term "Cephalon" shall include CIMA.

B. "CIMA" means CIMA LABS INC., its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by CIMA LABS, INC., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

C. "Respondents" means Cephalon and CIMA, individually and collectively.

D. "Commission" means the Federal Trade Commission.

E. "Barr" means Barr Laboratories, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, having its principal place of business located at Two Quaker Road, P.O. Box 2900, Pomona, New York 10970.

F. "Acquisition" means the acquisition contemplated by the "Agreement and Plan of Merger" dated as of November 3, 2003, by and among Cephalon, CIMA and MergerCo ("Acquisition Agreement"), whereby Cephalon agreed to acquire CIMA.

G. "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 Oral Opioid Fentanyl. The term "Agency" includes, but is not limited to, the United States Food and Drug Administration ("FDA") and the United States Drug Enforcement Administration ("DEA").

H. "Application", "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, and 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.

I. "Approvable Letter" means a letter from the FDA that an Application is basically approvable as described in 21 C.F.R. Part 314.110.

J. "Approval Letter" means a letter from the FDA approving an Application as described in 21 C.F.R. Part 314.105.

K. "Closing Date" means the date on which Respondents (or a Divestiture Trustee) and a Commission-approved Acquirer consummate a transaction to grant, license, deliver or otherwise convey relevant assets pursuant to this Order. (Pursuant to Paragraph II.A. of this Order, the Closing Date is required to occur not later than ten (10) Days after the Effective Date.)

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

1. Barr, if Barr has not been rejected by the Commission pursuant to Paragraph II.A. of this Order; or

2. an entity approved by the Commission to acquire particular assets that the Respondents are required to grant, license, deliver or otherwise convey pursuant to this Order.

M. "Confidential Business Information" means all information owned by, or in the possession or control of, Respondents that is not in the public domain and that is related to the research, Development, manufacture, marketing, importation, exportation, supply, sales, sales support, or use of Oral Opioid Fentanyl.

N. "Contract Manufacture" means the manufacture of Oral Opioid Fentanyl to be supplied by Respondents or a Designee specifically identified in this Order for sale to the Commission-approved Acquirer.

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

P. “Designee” means any entity other than the Respondent(s) that will manufacture Oral Opioid Fentanyl for a Commission-approved Acquirer.

Q. “DD5” means the Product in preclinical development by Respondent Cephalon as of the Effective Date that is a buccal patch formulation comprising Fentanyl and is designated “DD5.”

R. “Development” means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, bioequivalency, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting clinical trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing and sale of a Product (including any governmental price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. “Develop” means to engage in Development.

S. “Direct Cost” means the cost of direct labor and direct material used to provide the relevant assistance or service.

T. “Divestiture Trustee” means a trustee appointed by the Commission pursuant to the relevant provisions of this Order.

U. “Drug Master Files” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.

V. “Effective Date” means the earlier of the following dates:

1. the date the Respondents close on the Acquisition Agreement; or

2. the date the merger contemplated by the Acquisition Agreement becomes effective by filing the certificate of merger with the Secretary of State of the State of Delaware.

W. “Fentanyl” means the chemical substance known by the international non-proprietary name fentanyl citrate and/or all pharmaceutically active derivatives thereof including, without limitation, esters, salts, hydrates, solvates, polymorphs, prodrugs, metabolites and isomers thereof and all hydrates, solvates, polymorphs, prodrugs and isomers of such salts.

X. “Field” means the prevention, treatment, diagnosis, or control of a particular medical condition.

Y. "Final FDA Approval" means approval of a Product by the FDA pursuant the Federal Food, Drug, and Cosmetic Act § 505(b), 21 U.S.C. 355(b).

Z. "Final Finished Form" means a Product packaged in final form and ready for sale by the Commission-approved Acquirer to the Commission-approved Acquirer's ultimate customer (other than for the addition of the Commission-approved Acquirer's specific packaging and/or labeling).

AA. "Generic Entrant Forbearance Date" means the earlier of the following dates:

1. August 3, 2007; or

2. one hundred eighty (180) Days after the Marketing Licensing Date.

BB. "Governmental Entity" means any Federal, state, local or non-U.S. government or any court, legislature, governmental agency or governmental commission or any judicial or regulatory authority of any government.

CC. "Interim Monitor" means a monitor appointed by the Commission pursuant to Paragraph III of this Order.

DD. "Law" means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law by any Governmental Entity.

EE. "Marketing Licensing Date" means the following dates:

1. with respect to Substantially Sugar-Free Formulations of Oral Opioid Fentanyl, the earliest of the following dates:

   a. the date of Final FDA Approval of OVF;

   b. the date of notice of a withdrawal of approval by the FDA of NDA No. 20-747;or

   c. the date of Final FDA Approval of a Substantially Sugar-Free Formulation of Oral Opioid Fentanyl (*unless*, at least sixty (60) Days prior to the occurrence of the Marketing Licensing Date with respect to all other formulations of Oral Opioid Fentanyl (as determined below), the FDA determines such formulation is therapeutically equivalent to other formulations of Oral Opioid Fentanyl already approved by the FDA, *i.e.*, the FDA determines that any actual or potential bioequivalence problems have been resolved with adequate evidence supporting bioequivalence);

provided, however, that should Marketing Licensing Date with respect to Substantially Sugar-Free Formulations of Oral Opioid Fentanyl (as determined above) occur prior to

the occurrence of the Marketing Licensing Date with respect to all other formulations of Oral Opioid Fentanyl (as determined below), then the Marketing Licensing Date for the Sugar-Free Formulations of Oral Opioid Fentanyl shall instead be defined to be the same date as Marketing Licensing Date with respect to all other formulations of Oral Opioid Fentanyl (as determined below); and

2. with respect to all other formulations of Oral Opioid Fentanyl the earliest of the following dates:

   a. the date of Final FDA Approval of OVF;

   b. September 5, 2006, if Respondents are not granted Pediatric Exclusivity with respect to Oral Opioid Fentanyl; or

   c. February 3, 2007, if Respondents are granted Pediatric Exclusivity with respect to Oral Opioid Fentanyl,

provided, however, if Respondents have not obtained Final FDA Approval of a Substantially Sugar-Free Formulation of Oral Opioid Fentanyl on or before the later of the following dates: (1) July 1, 2005; or (2) one hundred eighty (180) Days from the date of an Approvable Letter for a Substantially Sugar-Free Formulation of Oral Opioid Fentanyl issued to the Respondents (but only if such Approvable Letter is issued on or before July 1, 2005), then the Marketing Licensing Date with respect to Substantially Sugar Free Formulations and all other formulations of Oral Opioid Fentanyl shall be no later than September 5, 2006.

FF. "Not Approvable Letter" means a letter from the FDA that an Application may not be approved, as described in 21 C.F.R. Part 314.120.

GG. "Oral Opioid Fentanyl" means all Products that contain the active pharmaceutical ingredient Fentanyl and any dose form, presentation or line extension thereof existing as of the Effective Date. The term "Oral Opioid Fentanyl" also includes all Products marketed or in Development by Respondent Cephalon on or before the Effective Date that contain active pharmaceutical ingredient Fentanyl and are planned to be marketed for use in the Field of pain management. This includes all sugar-free versions of such Products (*except* where this Order specifically differentiates between Substantially Sugar-Free Formulation(s) and other formulations of the Products); *provided, however*, the term "Oral Opioid Fentanyl" does not include the following: (1) Products that were owned or controlled by Respondent CIMA prior to the Effective Date and that were not owned or controlled by Respondent Cephalon prior to such date; and (2) Respondent Cephalon's Product DD5.

HH. "Oral Opioid Fentanyl Assets" means all of Respondent Cephalon's rights in and to all Product Intellectual Property and Product Manufacturing Technology related to Respondent Cephalon's business in the United States related to the Oral Opioid Fentanyl to the extent

legally transferable, including the research, Development, manufacture, distribution, marketing or sale of Oral Opioid Fentanyl, including, without limitation, the following:

1. license(s) to all Product Intellectual Property;

2. Right of Reference or Use to the Drug Master Files including, but not limited to, the pharmacology and toxicology data contained in all Applications, NDAs, ANDAs, SNDAs and MAAs;

3. Rights of Reference or Use (if such rights exist) to information similar to the Drug Master Files submitted to any Agency other than the FDA;

4. copies of all Product Scientific and Regulatory Material;

5. licenses to all Product Manufacturing Technology;

6. copies of all Respondents' books, records and files related to the foregoing, including, but not limited to, the following specified documents:

    a. the Product Registrations;

    b. Drug Master Files, including, but not limited to, the pharmacology and toxicology data contained in all Applications, NDAs, ANDAs, SNDAs and MAAs; all data submitted to and all correspondence with the FDA and other Agencies; all validation documents and data; including, without limitation, clinical data, and quality control histories pertaining to Oral Opioid Fentanyl owned by, or in the possession or control of, Respondents, or to which Respondents have a right of access, in each case such as is in existence as of the Closing Date;

provided, however, the Oral Opioid Fentanyl Assets do not include the following: (1) businesses and assets that were owned or controlled by Respondent CIMA prior to the Effective Date and that were not owned or controlled by Respondent Cephalon prior to such date; and (2) and assets solely related to Respondent Cephalon's Product DD5.

II. "Oral Opioid Fentanyl Core Employees" means Product Manufacturing Employees, and Product Research and Development Employees.

JJ. "Oral Opioid Fentanyl License and Supply Agreement" means the "License and Supply Agreement" by and between Cephalon Inc. and Barr Laboratories, Inc. dated July 7, 2004, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Oral Opioid Fentanyl Assets to be granted, licensed, delivered, or otherwise conveyed, that have been approved by the Commission to accomplish the requirements of this Order. The Oral Opioid Fentanyl License and Supply Agreement is attached to this Order as non-public Appendix I.

KK. "Oral Opioid Fentanyl Releasee(s)" means the Commission-approved Acquirer or any entity controlled by or under common control with the Commission-approved Acquirer, or any licensees, sublicensees, manufacturers, suppliers, distributors, and customers of the Commission-approved Acquirer, or of such Commission-approved Acquirer-affiliated entities.

LL. "Oral Opioid Risk Management Program" means a strategic safety program designed to decrease product risk by using one or more interventions or tools beyond the package insert, which program may be modified or amended from time to time and may be a condition of Final FDA Approval.

MM. "OVF" means the Product, OraVescent® Fentanyl, under development by Respondent CIMA that contains Fentanyl and is formulated with an effervescent agent and is the subject of an IND No. 65,447 or any other IND subsequently filed by Respondents.

NN. "Patents" means all patents, patent applications and statutory invention registrations, in each case existing as of the Effective Date (*except* where this Order specifies a different time), and includes all reissues, divisions, continuations, continuations-in-part, substitutions, reexaminations, restorations, and /or patent term extensions thereof, all inventions disclosed therein, all rights therein provided by international treaties and conventions, and all rights to obtain and file for patents and registrations thereto in the United States, related to a Product of or owned by Respondent Cephalon as of the Effective Date.

OO. "Pediatric Exclusivity" means exclusivity obtained in accordance with the requirements of Federal Food, Drug, and Cosmetic Act § 505a, 21 U.S.C. 355a.

PP. "Product" means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically or genetically active ingredient.

QQ. "Product Employee Information" means the following:

1. a complete and accurate list containing the name of each relevant employee as of the execution date of the related Remedial Agreement. This list shall be organized by the relevant respective employee categories defined in this Order, (*i.e.*, "Product Manufacturing Employees," or "Product Research and Development Employees," as applicable);

2. with respect to each such employee the following information:

    a. job title or position held;

    b. a specific description of the employee's responsibilities related to Oral Opioid Fentanyl; *provided, however*, in lieu of this description, Respondents may provide

the employee's most recent performance appraisal.

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

1. Patents;

2. Product Trademarks;

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

4. rights to obtain and file for Patents and registrations thereof;

provided, however, "Product Intellectual Property" does not include the names "CIMA", "Cephalon," or the names of any other corporations or companies owned by Respondents or related logos to the extent used on other of Respondent CIMA's or Respondent Cephalon's Products;

provided further, however, "Product Intellectual Property" does not include the trade name Actiq®.

SS. "Product Manufacturing Employees" means all salaried employees of Respondent(s) who directly have participated (irrespective of the portion of working time involved) in the manufacture of the Oral Opioid Fentanyl, including, but not limited to, the Senior Director of Commercial Manufacturing, the Associate Director of Production Planning, and the Manager of Commercial Manufacturing, and all those involved in the quality assurance and quality control of the Oral Opioid Fentanyl, within the eighteen (18) month period immediately prior to the Closing Date.

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

clinical trial reports, regulatory communications and labeling and all other information related to the manufacturing process, and supplier lists.

UU. "Product Research and Development Employees" means all employees of Respondent(s) who directly have participated (irrespective of the portion of working time involved) in the research, Development, regulatory approval process, or clinical studies of Oral Opioid Fentanyl within the eighteen (18) month period immediately prior to the Closing Date.

VV. "Product Scientific and Regulatory Material" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and clinical trial materials and information related to Oral Opioid Fentanyl, and full rights to use such materials, in any and all jurisdictions.

WW. "Product Trademark(s)" means the following as related to Oral Opioid Fentanyl:

1. the U.S. Trademark Registration No. 2,622,734 as needed for a single dose entity of any generic version of Oral Opioid Fentanyl;

2. at the Commission-approved Acquirer's option, any trademark or trade dress covering the size, shape and color of a single dose entity of any generic version of Oral Opioid Fentanyl;

3. the Oral Opioid Risk Management Program; and

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

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

YY. "Remedial Agreement" means the following:

1. the Oral Opioid Fentanyl License and Supply Agreement, if such agreement has not been rejected by the Commission pursuant to Paragraph II.A. of this Order; or

2. any agreement between a Respondent(s) and a Commission-approved Acquirer (or between a Divestiture Trustee and a Commission-approved Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, and all

amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets to be granted, licensed, delivered or otherwise conveyed that have been approved by the Commission to accomplish the requirements of this Order.

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

AAA. "Substantially Sugar-Free Formulation(s)" means either of the following:

1. a Product containing less than one-half (0.5) grams of Sugar(s) per dosage; or

2. a Product approved by the FDA for labeling as "Sugar-Free."

BBB. "Sugar(s)" means the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose) as defined in 21 C.F.R. §101.9(c)(6)(ii).

CCC. "Supply Cost" means the manufacturer's average direct per unit cost of manufacturing the Product plus costs of manufacturing the Product that are directly attributable to FDA regulatory, quality control and compliance. "Supply Cost" shall expressly exclude any intracompany business transfer profit.

DDD. "Third Party(ies)" means any private entity other than the following: (1) the Respondents, or (2) the Commission-approved Acquirer.

II.

IT IS FURTHER ORDERED that:

A. Not later than ten (10) Days after the Effective Date, Respondents shall grant irrevocable, perpetual, fully paid-up and royalty-free license(s) in the United States to the Oral Opioid Fentanyl Assets and shall grant, license, deliver or otherwise convey the Oral Opioid Fentanyl Assets, absolutely and in good faith, on a non-exclusive basis to Barr pursuant to and in accordance with the Oral Opioid Fentanyl License and Supply Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Barr or to reduce any obligations of Respondents under such agreement). Such licenses shall be effective as follows:

1. as of the Closing Date, as to Barr's rights to manufacture and Develop Oral Opioid Fentanyl using the Oral Opioid Fentanyl Assets; and

2. not later than the Marketing Licensing Date, as to Barr's rights to distribute, market or

sell Oral Opioid Fentanyl using the Oral Opioid Fentanyl Assets.

If Respondents do not grant, license, deliver or otherwise convey the Oral Opioid Fentanyl Assets to Barr within ten (10) Days after the Effective Date as provided above, the Commission may, pursuant to Paragraph IV of this Order, appoint a Divestiture Trustee to license, grant, deliver and otherwise convey the Oral Opioid Fentanyl Assets;

provided, however, that, if Respondents have granted, licensed, delivered or otherwise conveyed the Oral Opioid Fentanyl Assets to Barr 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 Barr is not an acceptable purchaser of the Oral Opioid Fentanyl Assets, then Respondent shall immediately rescind the transaction with Barr and shall grant, license, deliver or otherwise convey the Oral Opioid Fentanyl Assets within six (6) months from the date the Order becomes final, absolutely and in good faith, at no minimum price, to a Commission-approved Acquirer and only in a manner that receives the prior approval of the Commission;

provided further, however, that if the Respondents have granted, licensed, delivered or otherwise conveyed the Oral Opioid Fentanyl Assets to Barr prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies the Respondents that the manner in which the grant, license, delivery or conveyance was accomplished is not acceptable, the Commission may direct the Respondents, or appoint a Divestiture Trustee, pursuant to Paragraph IV of this Order, to effect such modifications to the manner of granting, licensing, delivery or conveyance of the Oral Opioid Fentanyl Assets to Barr (including, but not limited to, entering into additional agreements or arrangements) as the Commission may be necessary to satisfy the requirements of this Order.

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

Business Information and facilitating the delivery in a manner consistent with this Order.

C. Respondents shall not enforce any agreement against a Third Party or the Commission-approved Acquirer to the extent that such agreement may limit or otherwise impair the ability of the Commission-approved Acquirer to acquire the Product Manufacturing Technology or related equipment from the Third Party. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to the Product Manufacturing Technology.

D. Not later than ten (10) Days after the Effective Date, Respondents shall grant a release to each Third Party that is subject to an agreement as described in Paragraph II.C. that allows the Third Party to provide the relevant Product Manufacturing Technology or related equipment to the Commission-approved Acquirer. Within five (5) Days of the execution of each such release, Respondents shall provide a copy of the release to the Commission-approved Acquirer.

E. Any Remedial Agreement that has been approved by the Commission between Respondents (or a Divestiture Trustee) and a Commission-approved Acquirer of the Oral Opioid Fentanyl Assets shall be deemed incorporated into this Order, and any failure by Respondents to comply with any term of such Remedial Agreement related to the Oral Opioid Fentanyl Assets shall constitute a failure to comply with this Order.

F. Respondents shall include in any Remedial Agreement related to the Oral Opioid Fentanyl Assets the following provisions:

1. At the Commission-approved Acquirer's Option, Respondents shall Contract Manufacture and deliver to the Commission-approved Acquirer, in a timely manner and under reasonable terms and conditions, a supply of Oral Opioid Fentanyl, including such Product in Final Finished Form, at Respondents' Supply Cost, for a period of time sufficient to allow the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) to obtain all FDA approvals necessary to manufacture Oral Opioid Fentanyl independently of Respondents; *provided, however*, Respondents' obligation to Contract Manufacture shall not exceed six (6) years from the Closing Date.

2. After the Closing Date and continuing for the term of the Contract Manufacture related to Oral Opioid Fentanyl, Respondents will make inventory of Oral Opioid Fentanyl available for sale or resale only to the Commission-approved Acquirer (other than for use in Respondents' own business related to Oral Opioid Fentanyl).

3. The Respondents' obligation to supply Oral Opioid Fentanyl to the Commission-approved Acquirer shall take priority over the manufacture and supply of Oral Opioid Fentanyl for Respondents' own use or sale.

4. Respondents shall make representations and warranties to the Commission-approved

Acquirer that the Oral Opioid Fentanyl supplied through Contract Manufacture pursuant to the Remedial Agreement meets current good manufacturing practices of the FDA, as set forth in 21 C.F.R. Parts 210 and 211. 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 Oral Opioid Fentanyl supplied to the Commission-approved Acquirer pursuant to the Remedial Agreement by the Respondents to meet such specifications. This obligation shall be contingent upon the Commission-approved Acquirer giving Respondents prompt, adequate notice of such claim and cooperating fully in the defense of such claim. The Remedial Agreement shall be consistent with the obligations assumed by Respondents under this Order; *provided, however*, Respondents may reserve the right to control the defense of any such litigation, including the right to settle the litigation, so long as such settlement is consistent with the Respondents' responsibilities to supply Oral Opioid Fentanyl in the manner required by this Order; *provided further, however*, 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.

5. Respondents shall make representations and warranties to the Commission-approved Acquirer that Respondents will hold harmless and indemnify the Commission-approved Acquirer for any liabilities including, but not limited to, indirect damages, special damages, consequential damages, lost profits, legal fees and costs resulting from the failure by Respondents to deliver Oral Opioid Fentanyl in a timely manner as required by the Remedial 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.

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

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

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

b. assistance to the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) to manufacture Oral Opioid Fentanyl in substantially the same manner and quality employed or achieved by Respondent Cephalon; 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 of the Commission-approved Acquirer) obtains all FDA approvals necessary to manufacture Oral Opioid Fentanyl independently of the Respondents and sufficient to satisfy management of the Commission-approved Acquirer that its personnel (or the Designee's personnel) are adequately trained in the manufacture of Oral Opioid Fentanyl.

8. Upon reasonable notice and request from the Commission-approved Acquirer to the Respondents, after the Marketing Licensing Date, Respondent shall provide in a timely manner, at no greater than Direct Cost, assistance with knowledgeable employees of the relevant Respondent to assist the Commission-approved Acquirer to defend against, respond to, or otherwise participate in any litigation related to the Product Intellectual Property related to Oral Opioid Fentanyl.

9. Respondents shall covenant to the Commission-approved Acquirer that, after the Marketing Licensing Date (*except* for the manufacture and Development of Oral Opioid Fentanyl, in which case, the covenant shall begin as of the Closing Date), Respondents shall not join, or file, prosecute or maintain any suit, in Law or equity, against the Commission-approved Acquirer or the Oral Opioid Fentanyl Releasee(s) for the research, Development, manufacture, use, import, distribution, or sale of Oral Opioid Fentanyl (but only as to those Products that are commercialized or in Development as of the Closing Date) under Patents that:

   a. are owned or licensed by Respondent Cephalon as of immediately prior to the closing on the acquisition of CIMA; or

   b. may be assigned, granted, licensed, or otherwise conveyed to Respondents after the Effective Date, if such suit would have the potential to interfere with the Commission-approved Acquirer's freedom to practice in the research, Development, manufacture, use, import, sale, marketing or distribution of Oral Opioid Fentanyl (but only as to those Products that are commercialized or in Development as of the Closing Date) in the Field of pain management.

10. Respondents shall covenant to the Commission-approved Acquirer that, after the Marketing Licensing Date (*except* for the manufacture and Development of Oral Opioid Fentanyl, in which case, the covenant shall begin as of the Closing Date):

a. any Third Party assignee or licensee of the above-described Patents shall agree to provide a covenant not to sue the Oral Opioid Fentanyl Releasees, at least as protective as those extended pursuant to the preceding Paragraph II.F.9, as a condition of such assignment or license; and

b. with respect to any Third Party rights licensed to Respondents as of or after the Effective Date, and as to which Respondents do not control the right of prosecution of any suit, legal or other action, Respondents shall not actively induce, assist or participate in any suit, legal or other action or proceeding relating to the Oral Opioid Fentanyl Products (but only as to those Products that are commercialized or in Development as of the Closing Date) against the Oral Opioid Releasees, unless required by Law or contract (such contract not to be solicited or entered into for the purpose of circumventing any of the requirements of this Order).

provided, however, that if the Oral Opioid Fentanyl License and Supply Agreement is the Remedial Agreement for the Oral Opioid Fentanyl Assets, then Respondents shall be deemed to have complied with any of the Supply Cost and Direct Cost requirements described in this Paragraph II.F. by complying with the such cost provisions as provided in the Oral Opioid Fentanyl License and Supply Agreement.

G. For a period from the Closing Date until August 3, 2007, ("the Oral Opioid Fentanyl Access Period"), Respondents shall provide the Commission-approved Acquirer with the opportunity to enter into employment contracts with the Oral Opioid Fentanyl Core Employees. Respondents shall remove any impediments within the control of Respondents 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 of those individuals to be employed by the Commission-approved Acquirer.

H. Not later than the earlier of the following dates: (1) ten (10) Days after notice by staff of the Commission to the Respondents to provide the Product Employee Information; or (2) ten (10) Days after the Closing Date, Respondents shall provide the Commission-approved Acquirer or the Proposed Acquirer the Product Employee Information related to the Oral Opioid Fentanyl Core Employees. Failure by Respondents to provide the Product Employee Information for any relevant employee within the time provided herein shall extend the Oral Opioid Fentanyl Access Period with respect to that employee in an amount equal to the delay.

I. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary for the licensing of the Oral Opioid Fentanyl Assets to the Commission-approved Acquirer, or for the continued research, Development, manufacture, use, import, sale, marketing or distribution of Oral Opioid Fentanyl by the Commission-approved Acquirer.

J. Upon reasonable notice and request from the Commission-approved Acquirer to the Respondents, Respondents shall provide (in a timely manner and at no greater than Direct Cost) to the Commission-approved Acquirer consultation with, assistance, training, and advice from, knowledgeable employees of Respondents with respect to the Development and manufacture of Oral Opiod Fentanyl, that the Commission-approved Acquirer might reasonably need in order to receive and use the Oral Opioid Fentanyl Assets in a manner consistent with this Order, and shall continue providing such consultation, assistance, training and advice, at the request of the Commission-approved Acquirer, until the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) is fully validated, qualified, and approved by the FDA, and able to manufacture Oral Opioid Fentanyl independently of the Respondents.

K. Pending the granting, licensing, delivery or conveyance of the Oral Opioid Fentanyl Assets, Respondents shall take such actions as are necessary to maintain the full economic viability, marketability and competitiveness of the business associated with the Oral Opioid Fentanyl Assets, to minimize any risk of loss of competitive potential for the business associated with the Oral Opioid Fentanyl Assets, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Oral Opioid Fentanyl Assets except for ordinary wear and tear.

L. After the Marketing Licensing Date (*except* for the manufacture and Development of Oral Opioid Fentanyl, in which case, this Paragraph shall apply as of the Closing Date), Respondents shall not join, or file, prosecute or maintain any suit, in Law or equity, against the Commission-approved Acquirer or the Oral Opioid Fentanyl Releasee(s) for the research, Development, manufacture, use, import, sale, marketing or distribution of Oral Opioid Fentanyl (but only as to those Products that are commercialized or in Development as of the Closing Date) under the following:

1. any Patents owned or licensed by Respondents as of the Effective Date or acquired after the Effective Date that claim the use of Oral Opioid Fentanyl in the Field of pain management; or

2. that claim any aspect of the research, Development, manufacture, use, import, sale, marketing, or distribution of Oral Opioid Fentanyl other than such Patents that claim inventions conceived by and reduced to practice by Respondents' employees after the Effective Date.

M. Respondents shall maintain manufacturing facilities for the Oral Opioid Fentanyl finished drug product, that are validated, qualified and approved by the FDA, and fully capable of producing Oral Opioid Fentanyl finished drug product and shall Contract Manufacture and supply such finished drug product to 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 Oral Opioid Fentanyl finished drug product in a facility that is independent of Respondents;

provided, however, this obligation shall not exceed six (6) years from the Closing Date;

provided further, however, the Commission may eliminate, or further limit the duration of, the Respondent's obligation under this provision should the Commission determine that the Commission-approved Acquirer is not using commercially reasonable best efforts to secure the FDA approvals necessary to manufacture Oral Opioid Fentanyl finished drug product in a facility that is independent of Respondents.

N. At any time after the Generic Entrant Forbearance Date, Respondents shall not seek to enforce any Patent(s) related to Oral Opioid Fentanyl that is filed pursuant to 21 U.S.C. § 355(b)(1) as a part of the following:

1. the NDA No. 20-747, as supplemented, or amended; or

2. any Application filed by the Respondents for the purposes of obtaining an approval to label a formulation of Oral Opioid Fentanyl as "Sugar-Free" or an equivalent labeling designation,

against any Third Party to the extent that such enforcement might prohibit, limit, or otherwise impair the Third Party's ability to commercialize a Product under an ANDA filed by the Third Party that references such Patent(s) and the Product listed under the above-referenced NDA; *provided, however*, that this Paragraph shall not apply to Patents solely related to Substantially Sugar-Free Formulations of Oral Opioid Fentanyl until Final FDA Approval of OVF.

O. Not later than the Generic Entrant Forbearance Date, Respondents shall make available to the public those patent applications filed by Respondents, not already published, that are related to Oral Opioid Fentanyl.

P. The purpose of the grant, license, delivery and conveyance of the Oral Opioid Fentanyl Assets to a Commission-approved Acquirer is to create an independent, viable and effective competitor in the relevant market in which the Oral Opioid Fentanyl Assets were engaged 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.

III.

IT IS FURTHER ORDERED that:

A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order, and the Remedial Agreements.

B. The Commission shall select the Interim Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If neither Respondent has opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) Days after notice by the staff of the Commission to Respondents of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor.

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

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

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

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

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

   a. the completion by Respondents of the divestiture of all relevant assets required to be granted, licensed, delivered, or otherwise conveyed pursuant to this Order in a manner that fully satisfies the requirements of the Order and notification by the Commission-approved Acquirer to the Interim Monitor that it is fully capable of producing the relevant Product(s) acquired pursuant to a Remedial Agreement independently of Respondents; or

   b. the completion by Respondents of the last obligation under the Order pertaining to the Interim Monitor's service;

   provided, however, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Order.

4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to

Respondents' compliance with their obligations under the Order, including, but not limited to, their obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Order.

5. The Interim 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 Interim Monitor shall have authority to employ, at the expense of the Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.

6. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations 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 Interim Monitor.

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

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

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

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

provided in this Paragraph.

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

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

IV.

IT IS FURTHER ORDERED that:

A. If Respondents have not fully complied with the obligations to grant, license, deliver or otherwise convey relevant assets as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to grant, license, deliver or otherwise convey the assets required to be granted, licensed, delivered or otherwise conveyed pursuant to each of the relevant Paragraphs in a manner that satisfies the requirements of each such Paragraph. In the event that the Commission or the Attorney General brings an action pursuant to § 5(*l*) of the Federal Trade Commission Act, 15 U.S.C. § 45(*l*), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to grant, license, deliver or otherwise convey 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 Respondents to comply with this Order.

B. 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.

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

D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the

Divestiture Trustee's powers, duties, authority, and responsibilities:

1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to grant, license, deliver or otherwise convey the assets that are required by this Order to be granted, licensed, delivered or otherwise conveyed.

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

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and 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. 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.

4. The Divestiture Trustee shall use commercially reasonable 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 expeditiously and at no minimum price. Each divestiture 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) Days after receiving notification of the Commission's approval.

5. 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 of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's 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.

6. 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.

7. In the event that the Divestiture Trustee determines that he or she is unable to grant, license, deliver or otherwise convey the relevant assets required to be granted, licensed, delivered or otherwise conveyed in a manner that preserves their marketability, viability and competitiveness and ensures their continued use in the research, Development, manufacture, import, distribution, marketing, promotion, sale, or after-sales support of the relevant Product, the Divestiture Trustee may assign, grant, license, transfer, divest, deliver or otherwise convey such additional assets of Respondents and effect such arrangements as are necessary to satisfy the purposes and requirements of this Order.

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

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

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

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

F. 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.

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

V.

IT IS FURTHER ORDERED that:

A. Within five (5) Days of the Acquisition, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.

B. Within five (5) Days of the occurrence of each of the following events, Respondent shall notify the Commission, the Commission-approved Acquirer, and the Interim Monitor (if any has been appointed) in writing of the occurrence of such event:

1. the following events related to an Application related to OVF:

    a. filing of an Application;

    b. issuance of an Approvable Letter; and

    c. issuance of an Approval Letter; and

2. the following events related to an Application seeking pediatric exclusivity related to Oral Opioid Fentanyl:

    a. receipt by Respondents of a request from the FDA to submit a pediatric study to the FDA;

    b. submission by the Respondents to the FDA of the protocol related to the pediatric study;

    c. submission by the Respondents of the pediatric study to the FDA; and

    d. receipt by Respondents of grant or denial of Pediatric Exclusivity from the FDA.

3. the following events related to an Application seeking approval of a Substantially Sugar-Free Formulation(s) of Oral Opioid Fentanyl:

    a. filing of an Application;

b. issuance of an Approvable Letter;

c. issuance of a Not Approvable Letter; and

d. issuance of an Approval Letter.

C. 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.A. (*i.e.* has granted, licensed, delivered or otherwise conveyed all relevant assets to the Commission-approved Acquirer in a manner that fully satisfies the requirements of the Order), II.B., II.D., and all its responsibilities to render transitional services to the Commission-approved Acquirer as provided in the Remedial Agreement(s), Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intends to comply, are complying, and have complied with this Order. Respondents shall submit at the same time a copy of its report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondents shall include in their reports, among other things that are required from time to time:

1. a full description of the efforts being made to comply with the relevant Paragraphs of the Order;

2. if Barr is rejected by the Commission pursuant to Paragraph II.A., a description of all substantive contacts or negotiations related to the licensing of the Oral Opioid Fentanyl Assets and the identity of all parties contacted and copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning completing its obligations to license the Oral Opioid Fentanyl Assets;

3. a detailed plan to deliver all Confidential Business Information required to be delivered to the Commission-approved Acquirer pursuant to Paragraph II.B, and agreed upon by the Commission-approved Acquirer and the Interim Monitor (if applicable) and any updates or changes to such plan;

4. a description of all Confidential Business Information delivered to the Commission-approved Acquirer, including the type of information delivered, method of delivery, and date(s) of delivery;

5. a description of the Confidential Business Information currently remaining to be delivered and a projected date(s) of delivery; and

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

D. One (1) year after 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.

VI.

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

VII.

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

A. Access, during office hours of Respondents and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondents related 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.

VIII.

IT IS FURTHER ORDERED that this Order shall terminate twenty (20) years from the date on which the Order becomes final.

By the Commission.

Donald S. Clark
Secretary

SEAL
ISSUED:

APPENDIX I
NON-PUBLIC
ORAL OPIOID FENTANYL LICENSE AND SUPPLY AGREEMENT

[Redacted From Public Record Version But Incorporated By Reference]