Respondents and the Bureau of Competition executed an agreement ("Agreement Containing Consent Orders" or "Consent Agreement") containing (1) an admission by Respondents of all the jurisdictional facts set forth in the Draft Complaint, (2) a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in the Draft Complaint, or that the facts as alleged in the Draft Complaint, other than jurisdictional facts, are true, (3) waivers and other provisions as required by the Commission's Rules, and (4) a proposed Decision and Order and Order to Maintain Assets.

The Commission considered the matter and 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. The Commission accepted the Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments; at the same time, it issued and served its Complaint and Order to Maintain Assets. The Commission duly considered any comments received from interested persons pursuant to Commission Rule 2.34,()-2 (s)I2(i)-2 (m

ORDER

I.

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

A. "Amneal" means: Amneal Holdings, LLC; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Amneal Holdings, LLC (including, without limitation, Amneal Pharmaceuticals LLC), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. Amneal also means: Amneal Pharmaceuticals, Inc.; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Amneal Pharmaceuticals, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Amneal will include Impax.

B. "Impax" means: Impax Laboratories, Inc.; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Impax Laboratories, Inc. (including, without limitation, Impax Laboratories, LLC), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

C. "Commission" means the Federal Trade Commission.

D. "Respondent(s)" means Amneal and Impax, individually and collectively.

E. "Acquirer(s)" means the following:

1. a Person specified by name in this Order to acquire particular assets or rights that a Respondent is required to assign, (t)-2 (n]TJ 0 Tw [(;)-2 (i)-2 (t)-2 (d)-1 (ri

H. "Acquisition Date" means the earlier of the following dates: (i) the date on which Respondent Amneal acquires fifty percent (50%) or more of the voting securities of Impax; or (ii) the date on which Respondent Amneal acquires any ownership interest in the assets of Impax pursuant to the Acquisition Agreement.

I.

Assets related to the Aspirin/Dipyridamole ER Products.

O. "Azelastine Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Impax or its co-development partner, Perrigo, pursuant to the following Application: ANDA No. 202743, and any supplements, amendments, or revisions to this ANDA. These Products are nasally administered metered sprays containing, as the active pharmaceutical ingredient, azelastine, at the following strength: eq 0.1876mg/spray.

P. "Azelastine Product Assets" means all rights, title, and interest in and to all assets related to the Business related to the Azelastine Products to the extent that such rights are owned, controlled, or held - opond, (eel

that is not Product Shared Intellectual Property;

6. all Product Marketing Materials related to the specified Divestiture Product;
7. all Product Scientific and Regulatory Material related to the specified Divestiture Product;
8.

11. all Product Development Reports related to the specified Divestiture Product;

12. at the option of the Acquirer of the specified Divestiture Product, all Product Contracts related to the specified Divestiture Product;

13. all patient registries related to the specified Divestiture Product, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data, and identification information required to be maintained by the FDA to facilitate the investigation of adverse effects related to the specified Divestiture Product (including, without limitation, any Risk Evaluation Mitigation Strategy as defined by the FDA);

14. for each specified Divestiture Product that has been marketed or sold by a Respondent prior to the Closing Date:

    a. a list of all customers for the specified Divestiture Product and a listing of the net sales (in either units or dollars) of the specified Divestiture Product to such customers during the one (1) year period immediately prior to the Closing Date, stated on either an annual, quarterly, or monthly basis, including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the name of the employee(s) for each High Volume Account that is or has been responsible for the purchase of the specified Divestiture Product on behalf of the High Volume Account and his or her business contact information;

    b. for each High Volume Account, a list by either SKU or NDC Number containing the following: (i) the net price per SFr NDC Nu - osg7136 0 Td (,)Tj /2T0 1

only in those instances wherein a Respondent is (i) the holder of the Application for that Retained Product and (ii) the Application is not subject to an exclusive license to a Third Party;

16. a list of each specified Divestiture Product that has had any finished product batch or lot determined to be out-of-specification during the three (3) year period immediately preceding the Closing Date, and, for each such Divesture Product: (i) a detailed description of the deficiencies or defects (*e.g.*, impurity content, incorrect levels of the active pharmaceutical ingredient, stability failure) with respect to any out-of-specification batch or lot; (ii) the corrective actions taken to remediate the cGMP deficiencies in the Divestiture Product; uct pituct pi .33 0mtucec

related to the Retained Products; (v) any real estate and the buildings and other permanent structures located on such real estate; and (vi) all Product Shared Intellectual Property;

provided further, however, that in cases in which documents or other materials included in the assets to be divested contain information: (i) that relates both to the specified Divestiture Product and to Retained Products or Businesses of the specified Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the specified Divestiture Product; or (ii) for which any Respondent has a legal obligation to retain the original copies, that Respondent shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Acquirer of the specified Divestiture Product, the Respondents shall provide that Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this provision is to ensure that the Respondents provide the Acquirer with the above-described information without requiring a Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

is provided to an Acquirer by a Respondent

1. the Acquirer for the assets related to a particular Divestiture Product;
2. any Person controlled by or under common control with that Acquirer; and
3. any Manufacturing Designee(s), licensees, sublicensees, manufacturers, suppliers, distributors, and customers of that Acquirer, or of such Acquirer-affiliated entities.

KK. "Divestiture Trustee" means the trustee appointed by the Commission pursuant to Paragraph IV of this Order.

LL. "Domain Name" means the domain name(s) (uniform resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration; *provided, however*, "Domain Name" shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.

MM. "Drug Master File(s)" means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.

NN. "Erythromycin Product(s)" means the Products manufactured or in Development owned or controlled by Impax (ANDA not filed as of the date of the Consent Agreement) that are being developed as oral tablets that contain, as the active pharmaceutical ingredient, erythromycin at the following strengths: 250mg and 500mg.

OO. "Erythromycin Product Assets" means all rights, title, and interest in and to all assets related to the Business of Impax related to each of the Erythromycin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Erythromycin Products.

PP. "Ezetimibe/Simvastatin Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Impax pursuant to the following Application: ANDA No. 201890, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as the active pharmaceutical ingredients, ezetimibe and simvastatin, at the following strengths: 10mg ezetimibe/10mg simvastatin; 10mg ezetimibe/20mg simvastatin;

transferable, including, without limitation, the Categorized Assets related to the Felbamate Products.

TT. "Fluocinonide Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Impax pursuant to the following Application: ANDA No. 074204, and any supplements, amendments, or revisions to this ANDA. These Products are topically administered emulsified creams containing, as the active pharmaceutical ingredient, fluocinonide, at the following strength: 0.05%.

UU. "Fluocinonide Product Assets" means all rights, title, and interest in and to all assets related to the Business related to the Fluocinonide Products to the extent that such rights are owned, controlled, or held by Impax under and by virtue of the *Assignment and Assumption Agreement* between Actavis Pharma, Inc., Actavis Mid Atlantic LLC, and Impax Laboratories, Inc. dated August 3, 2016. This agreement was submitted to the Commission by Respondents and is contained in Non-Public Appendix II.B.

VV. "Fluocinonide Product Divestiture Agreement(s)" means the following:

1. *Termination Agreement* by and between Impax Laboratories, Inc. and G&W Laboratories, Inc., dated [insert], 2018; and
2. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the foregoing listed agreement(s), including without limitation, Appendix I, *Seller NDC Number Transition Services*.

The Fluocinonide Product Divestiture Agreements are contained in Non-Public Appendix II.C. The Fluocinonide Product Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective are Remedial Agreements.

WW. "G&W" means G&W Laboratories, a corporation organized, existing, and doing business under and by virtue of the laws of the State of New Jersey with its principal executive offices located at 111 Coolidge Street, South Plainfield, New Jersey 07080-3895. G&W includes any subsidiaries of G&W Laboratories.

XX. "Government Entity" means any Federal, state, local, or non-U.S. government; any court, legislature, government agency, or government commission; or any judicial or regulatory authority of any government.

YY. "Group A Product(s)" means the following Divestiture Products, individually and collectively:

1. Aspirin/Dipyridamole ER Products;
2. Desipramine Products;
3. Diclofenac/Misoprostol Products;
4. Erythromycin Products;
5. Ezetimibe/Simvastatin Products;

6. Felbamate Products; and

7. Methylphenidate Products.

ZZ. "Group A Product Assets" means the following Divestiture Product Assets, individually and collectively:

1. Aspirin/Dipyridamole ER Product Assets;

2. Desipramine Product Assets;

3. Diclofenac/Misoprostol Product Assets;

4. Erythromycin Product Assets;

5. Ezetimibe/Simvastatin Product Assets;

6. Felbamate Product Assets; and

7. Methylphenidate Product Assets.

AAA. "Group A Product Divestiture Agreement(s)" means the following:

1. the *Asset Purchase Agreement* by and between ANI Pharmaceuticals, Inc. and Impax Laboratories, Inc. dated as of April 23, 2018;

2. the letter agreement from Amneal Pharmaceuticals LLC to ANI Pharmaceuticals, Inc. to provide consulting services through certain named employees of Respondents to ANI Pharmaceuticals, Inc. with respect to the Aspirin/Dipyridamole Products, to be executed on or before the Closing Date for the Group A Product Assets;

3. the *Supply Agreement* by and between ANI Pharmaceuticals, Inc. and Impax Laboratories, Inc. to be executed on or before the Closing Date for the Group A Product Assets (for the supply of the Contract Manufacture Products);

4. the letter agreement from Impax Laboratories, Inc. to ANI Pharmaceuticals, Inc. to be executed on or before the Closing Date for the Group A Product Assets (regarding the labeling of certain products);

5. the *Agreement for the Exchange of Drug Safety Information* between Amneal Pharmaceuticals LLC & ANI Pharmaceuticals, Inc. to be executed on or before the Closing Date for the Group A Product Assets;

6. the *Supply Agreement* by and between ANI Pharmaceuticals, Inc. and Amneal Pharmaceuticals LLC to be executed on or before the Closing Date for the Group A Product Assets (for supply of Amneal Aspirin/Dipyridamole ER Products);

7. the *Quality Agreement* by and between Amneal Pharmaceuticals LLC & ANI Pharmaceuticals, Inc. to be executed on or before the Closing Date for the Group A Product Assets; and

8. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the foregoing listed agreements.

The Group A Product Divestiture Agreements are contained in Non-Public Appendix II.A. The Group A Product Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective are Remedial Agreements.

BBB. "High Volume Account(s)" means any retailer, w (r)-72(pl)-2(pl)-lesaler

Development, marketed, sold, owned, or controlled by Impax or its co-development partner, Perrigo, pursuant to the following Application: ANDA No. 202853, and any supplements, amendments, or revisions to this ANDA. These Products are nasally administered metered sprays containing, as the active pharmaceutical ingredient, olopatadine, at the following strength: 0.665mg/spray.

KKK.

distribution, finishing, packaging, marketing, sale, storage, or transport of a Product within the United States, and includes, without limitation, all approvals, registrations, licenses, or authorizations granted in connection with any Application related to that Product.

TTT. "Product Contracts" means all contracts or agreements:

1. that make specific reference to the specified Divestiture Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the specified Divestiture Product from a Respondent *unless* such contract applies generally to a Respondent's sales of Products to that Third Party;
2. pursuant to which a Respondent had or has as of the Closing Date the ability to independently purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s), or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) from any Third Party, for use in connection with the manufacture of the specified Divestiture Product;
3. relating to any Clinical Trials involving the specified Divestiture Product;
4. with universities or other research institutions for the use of the specified Divestiture Product in scientific research;
5. relating to the specific marketing of the specified Divestiture Product or educational matters relating solely to the specified Divestiture Product(s);
6. pursuant to which a Third Party manufactures or plans to manufacture the specified Divestiture Product as a finished dosage form Product on behalf of a Respondent;
7. pursuant to which a Third Party provides or plans to provide any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of the specified Divestiture Product on behalf of a Respondent;
8. pursuant to which a Third Party provides the Product Manufacturing Technology related to the specified Divestiture Product to a Respondent;
9. pursuant to which a Third Party is licensed by a Respondent to use the Product Manufacturing Technology related to the specified Divestiture Product;
10. constituting confidentiality agreements involving the specified Divestiture Product;
11. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the specified Divestiture Product;
12. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture, or distribution of the specified Divestiture Product to a Respondent including, but not limited to, consultation arrangements; and/or
13. pursuant to which any Third Party collaborates with a Respondent in the

performance of research, Development, marketing, distribution, or selling of the specified Divestiture Product or the Business related to such Divestiture Product;

provided, however, that where any such contract or agreement also relates to a Retained Product(s), a Respondent shall, at the Acquirer's option, assign or otherwise make available to the Acquirer all such rights under the contract or agreement as are related to the specified Divestiture Product, but concurrently may retain similar rights for the purposes of the Retained Product(s).

UUU. "Product Copyrights" means rights to all original works of authorship of any kind

other filings made to, received from, or otherwise conducted with the FDA relating to the Application(s) related to the specified Divestiture Product;

5. annual and periodic reports related to the above-described Application(s), including

Employee, as and to the extent permitted by Law:

1. a complete and accurate list containing the name of each Divestiture Product Core Employee (including former employees who were employed by a Respondent within ninety (90) days of the execution date of any Remedial Agreement); and
2. with respect to each such employee, the following information:
    a. direct contact information for the employee, including telephone number;
    b. the date of hire and effective service date;
    c. job title or position held;
    d. a specific description of the employee's responsibilities related to the relevant Divestiture Product; *provided, however*, in lieu of this description, a Respondent may provide the employee's most recent performance appraisal;
    e. the base salary or current wages;
    f. the most recent bonus paid, aggregate annual compensation for the relevant Respondent's last fiscal year, and current target or guaranteed bonus, if any;
    g. employment status (*i.e.*, active or on leave or disability; full-time or part-time);
    h. all other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and
3. at the Acquirer's option or the Proposed Acquirer'

thereof; or the corporate names or corporate trade dress of any other corporations or

reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchase information to be provided on the basis of dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, advertising and display materials, speaker lists, promotional and marketing materials, Website content, artwork for the production of packaging components, television masters, and other similar materials related to the specified Divestiture Product.

BBBB. "Product Research and Development Employees" means all salaried employees of

JJJJ. "Right of Reference or Use" means the authority to rely upon, and otherwise use all of the following:

1. an investigation of the quality, safety, or efficacy of a Product (including any or all such investigations conducted *in vitro, in vivo,* or *in silico* and any and all Clinical Trials);
2. Product Development Reports; or
3. Product Scientific and Regulatory Material;

for the purpose of obtaining approval of an Application or to defend an Application, including the ability to make available the underlying raw data from the investigation, Product Development Reports, or Product Scientific and Regulatory Material for FDA audit, if necessary.

KKKK. "SKU" means stock keeping unit.

LLLL. "Supply Cost" means a cost not to exceed any of the following: (i) a Respondent's average direct cost per SKU or NDC Number in United States dollars of manufacturing the specified Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date, or (ii) a Respondent's lowest net price (*i.e.*, the final price per SKU or NDC Number charged by a Respondent net of all discounts, rebates, or promotions) of the relevant Divestiture Product to any of a Respondent's top 5 High Volume Accounts (as measured in units of the Divestiture Product purchased by those customers) for the relevant Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date. "Supply Cost" shall expressly exclude any intracompany business transfer profit and any allocation or absorption of costs for excess or idle capacity; *provided, however*, that in each instance where: (i) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, "Supply Cost" means the cost as specified in such Remedial Agreement for that Divestiture Product, but only if the "Supply Cost" specified in such Remedial Agreement during the first twelve (12) month period of a Respondent supplying the Contract Manufacture Product does not exceed a Respondent's lowest net price (*i.e.*, the final price per SKU or NDC Number charged by a Respondent net of all discounts, rebates, or promotions) of the relevant Divestiture Product to any of a Respondent's top 5 High Volume Accounts (as measured in units of the Divestiture Product purchased by those customers)

owned by Third Parties and other Product Intellectual Property not owned by a Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that a Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Products.

II.

IT IS FURTHER ORDERED that:

A. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Group A Product Assets and grant the Divestiture Product License related to the Group A Products, absolutely and in good faith, to ANI Pharmaceuticals pursuant to, and in accordNoNotu(sre6TRP0.004Tw[(A)-3(N)1.6(I)-42(O)-30(A)d0.cal Mivend/TT6(1 n(e2)(c4(0).20(t)-2(2)

construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Perrigo or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Azelastine Product Assets or the Olopatadine Product Assets is incorporated by reference into this Order and made a part hereof;

provided however, that if Respondents have divested the Azelastine Product Assets or the Olopatadine Product Assets to Perrigo prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Azelastine Product Assets or the Olopatadine Product Assets (whichever is relevant) to Perrigo (including, but not limited to, entering into additional agreements or arrangements) as the Commission may

provided, however

the Divestiture Products; and

7. not provide, disclose or otherwise make available, directly or indirectly, any

provide that Acquirer with the actual price paid by Respondents for each active pharmaceutical ingredient(s), component(s), and excipient(s), respectively, used to manufacture that Contract Manufacture Product;

8. for each Contract Manufacturer Product for which Respondents are the source of the active pharmaceutical ingredient(s), component(s), or excipient(s), not charge the Acquirer any intracompany transfer profit for such active pharmaceutical ingredient(s), component(s) or excipient(s) in calculating the total price for the final finished Contract Manufacture Product to the Acquirer, but such charges shall only reflect Respondents' actual cost;

9. during the term of any agreement to Contract Manufacture, take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Product(s);

10. in the event Respondents become (i) unable to supply or produce a Contract Manufacture Product from the facility or facilities originally contemplated under a Remedial Agreement with an Acquirer and (ii) that Product is the subject of an

4. agree to hold harmless and indemnify the Acquirer for any liabilities or loss of

Product(s) acquired by that Acquirer, into, from, or within the United States. The provisions of this Paragraph do not apply to any Patent owned by, acquired by, or licensed to or from a Respondent that claims inventions conceived by and reduced to practice after the Acquisition Date.

R. Upon reasonable written notice and request from an Acquirer to Respondents, Respondents shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondents to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to any of the Divestiture Product(s) acquired by that Acquirer, if such litigation would have the potential to interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of such Divestiture Product(s); or (ii) the import, export, use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer, into, from, or within the United States.

S. For any patent infringement suit filed prior to the Closing Date in which a Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that a Respondent has prepared or is preparing to defend against as of the Closing Date, and where such a suit would have the potential directly to limit or interfere with the Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of such Divestiture Product(s); or (ii) the import, export, use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer, into, from, or within the United States, that Respondent shall:

1. cooperate with that Acquirer and provide any and all necessary technical and legal assistance, documentation, and witnesse(a)4 (n caw [(R)-3 .)]TJ -2 (s4 (d)-4((a)4 (w(cu)-4 (m)-6 (

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sell that Divestiture Product and is able to manufacture the finished dosage form Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents;

b. the date the Acquirer of that Divestiture Product notifies the Commission and Respondents of its intention to abandon its efforts to manufacture that Divestiture Product; or

c. the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture that Divestiture Product;

provided, however, that the Monitor's service shall not extend more than five (5) years after the Order Date *unless* the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

E. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to each Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to that Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Each Respondent shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor that Respondent's compliance with the Orders.

F. The Monitor shall serve, without bond or other security, at the expense of Respondents,

Commission concerning performance by a Respondent of its obligations under the Order; *provided, however*, beginning ninety (90) days after Respondents have filed their final report pursuant to Paragraph VII.C., and ninety (90) days thereafter, the Monitor shall report in writing to the Commission concerning progress by the Acquirer or the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents.

I. Each Respondent may require the Monitor and each of the 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 Monitor from providing any information to the Commission.

J. The Commission may, among other things, require the Monitor and each of the 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 Monitor's duties.

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

L. 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 the Order.

M. The 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 the Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Product Assets as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets in a manner that satisfies the requirements of this Order. 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 assign, grant, license, divest, transfer, deliver, or otherwise convey these 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 a Respondent 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 Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent 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 this 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 assign, grant, license, divest, transfer, deliver, or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, 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 the Commission believes that the divestiture(s) can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *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(s). Any delays in divestiture caused by a Respondent 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.

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

E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee'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 Divestiture Trustee's duties.

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

G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture(s) required by this Order.

V.

IT IS FURTHER ORDERED that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, each Respondent shall assure that its own counsel (including its own in-house counsel under appropriate confidentiality

deemed to have violated this requirement if that Acquirer withholds such

A. any proposed dissolution of Amneal Holdings, LLC, Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals, Inc., Impax Laboratories, Inc., or Impax Laboratories LLC;

B. any proposed acquisition, merger, or consolidation of Amneal Holdings, LLC, Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals, Inc., Impax Laboratories, Inc., or Impax Laboratories LLC; or

C. any other change in a Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Orsusharh

ISSUED:

NON-PUBLIC APPENDIX II.A
AGREEMENTS RELATED TO THE
GROUP A PRODUCTS REMEDY
[Cover Page]

NON-PUBLIC APPENDIX II.B.
AGREEMENTS RELATED TO THE
AZELASTINE PRODUCT AND OLOZ0fSw 6wUCT AN/Type o--0 0o14(Z)51D A. TO THE