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FEDERAL TRADE COMMISSION

[File No. 181 0017]

Amneal Holdings, LLC, and Impax Laboratories, Inc.; Analysis to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order -- embodied in the consent agreement -- that would settle these allegations.

DATES: Comments must be received on or before May 29, 2018.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write: "In the Matter of Amneal Holdings, LLC, and Impax Laboratories, Inc.; File No. 181 0017" on your comment, and file your comment online at https://ftcpublic.commentworks.com/ftc/amnealimpaxdivest by following the instructions on the web-based form. If you prefer to file your comment on paper, write "In the Matter of Amneal Holdings, LLC, and Impax Laboratories, Inc.; File No. 181 0017" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Kari Wallace (202-326-3085), Bureau of Competition, 600 Pennsylvania Avenue, NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR § 2.34, notice is hereby given that the above-captioned consent agreement containing consent orders to divest and providing for other relief to resolve the allegations in the complaint, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for April 27, 2018), on the World Wide Web, at https://www.ftc.gov/news-events/commission-actions.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before May 29, 2018. Write "In the Matter of Amneal Holdings, LLC, and Impax Laboratories, Inc.; File No. 181 0017" on your comment. Your comment - including your name and your state - will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Website, at https://www.ftc.gov/policy/public-comments.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at https://ftcpublic.commentworks.com/ftc/amnealimpaxdivest by following the instructions on the web-based form. If this Notice appears at http://www.regulations.gov/#!home, you also may file a comment through that website.

If you prefer to file your comment on paper, write "In the Matter of Amneal Holdings, LLC, and Impax Laboratories, Inc.; File No. 181 0017" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC. 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible FTC Website at https://www.ftc.gov, you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential" – as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2) – including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c).

In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC Website – as legally required by FTC Rule 4.9(b) – we cannot redact or remove your comment from the FTC Website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC Website at http://www.ftc.gov to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before May 29, 2018. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see https://www.ftc.gov/site-information/privacy-policy.

Analysis of Agreement Containing Consent Orders to Aid Public Comment

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Amneal Holdings, LLC, Amneal Pharmaceuticals LLC (collectively, "Amneal"), Impax Laboratories, Inc., and Impax Laboratories, LLC (collectively, "Impax") that is designed to remedy the anticompetitive effects resulting from Amneal's acquisition of equity interests of Impax. Under the terms of the proposed Consent Agreement, the parties are required to divest all of Impax's rights and assets related to the following seven products to ANI Pharmaceuticals, Inc. ("ANI"): generic desipramine hydrochloride tablets; generic felbamate tablets; generic aspirin and dipyridamole

extended release ("ER") capsules; generic diclofenac sodium and misoprostol delayed release ("DR") tablets; generic ezetimibe and simvastatin immediate release ("IR") tablets; generic erythromycin tablets; and generic methylphenidate hydrochloride ER tablets. Pursuant to the Consent Agreement, the parties also are required to divest all of Impax's rights and assets related to generic azelastine nasal spray and generic olopatadine hydrochloride nasal spray to Perrigo Company plc ("Perrigo"), and to divest all of Impax's rights and assets related to generic fluocinonide-E cream to G&W Laboratories ("G&W").

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the proposed Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order ("Order").

Pursuant to agreements dated October 17, 2017, Amneal proposes to acquire the equity interests of Impax in a series of transactions valued at approximately $1.45 billion (the "Proposed Acquisition"). The Commission alleges in its Complaint that the Proposed Acquisition, if consummated, would violate 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, by lessening current competition in the following three U.S. markets: (1) generic desipramine hydrochloride tablets; (2) generic ezetimibe and simvastatin IR tablets; and (3) generic felbamate tablets. The Commission also alleges that the Proposed Acquisition would violate the aforementioned statutes by lessening future competition in the following seven U.S. markets: (1) generic aspirin and dipyridamole ER capsules; (2) generic azelastine nasal spray; (3) generic

diclofenac sodium and misoprostol DR tablets; (4) generic erythromycin tablets; (5) generic fluocinonide-E cream; (6) generic methylphenidate hydrochloride ER tablets; and (7) generic olopatadine hydrochloride nasal spray. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the Proposed Acquisition.

I. The Products and Structure of the Markets

In human pharmaceutical markets, price generally decreases as the number of generic competitors increases. Prices continue to decrease incrementally with the entry of the second, third, fourth, and even fifth generic oral pharmaceutical competitor. Accordingly, the reduction in the number of suppliers within each relevant market has a direct and substantial effect on pricing.

The Proposed Acquisition would reduce current competition in the markets for three products: (1) generic desipramine hydrochloride tablets; (2) generic ezetimibe and simvastatin IR tablets; and (3) generic felbamate tablets.

Desipramine hydrochloride, a tricyclic antidepressant, is sold by only three companies, other than Amneal and Impax, in the United States: Heritage Pharmaceuticals, Inc., Sandoz (a subsidiary of Novartis AG), and Teva Pharmaceutical Industries Ltd. ("Teva").

Ezetimibe and simvastatin is used to improve cholesterol and lower triglycerides. Only four companies currently sell generic ezetimibe and simvastatin IR tablets in the United States: Amneal, Impax, Dr. Reddy's Laboratories, and Teva.

Felbamate is an anticonvulsant used in the treatment of epilepsy. For generic felbamate tablets, Alvogen, and Wallace Pharmaceuticals, Inc. ("Wallace") are the only two companies in addition to Amneal and Impax that sell the product in the United States.

The Proposed Acquisition also would reduce future competition in seven markets in which Amneal or Impax is a current competitor and the other is likely to enter the market: (1) generic aspirin and dipyridamole ER capsules; (2) generic azelastine nasal spray; (3) generic diclofenac sodium and misoprostol DR tablets; (4) generic erythromycin tablets; (5) generic fluocinonide-E cream; (6) generic methylphenidate hydrochloride ER tablets; and (7) generic olopatadine hydrochloride nasal spray.

Aspirin and dipyridamole is an antiplatelet therapy used to reduce the risk of stroke. Amneal is the only company currently selling generic aspirin and dipyridamole ER capsules in the United States, and Impax is one of only a limited number of suppliers capable of entering the market in the near future.

Azelastine nasal spray is used to treat seasonal allergies. Impax partners with Perrigo to sell generic azelastine nasal spray. In addition, Wallace and Apotex Inc. also sell the product. Amneal, one of a limited number of suppliers capable of entering the market for generic azelastine nasal spray in the near future, already has tentative approval from the United States Food and Drug Administration ("FDA").

Diclofenac sodium and misoprostol is used to provide pain relief while minimizing gastrointestinal side effects. Four companies—Amneal, Teva, Sandoz, and Exela Pharma Sciences LLC ("Exela")—have approved ANDAs to sell generic diclofenac sodium and misoprostol DR tablets in the United States. In addition, Greenstone LLC, a Pfizer subsidiary, sells an authorized generic version. Sandoz does not sell its product directly to customers and supplies only to a private labeler. The Exela product, marketed by both Eagle Pharmaceuticals, Inc. and Dash Pharmaceuticals LLC, has limited sales. Impax, partnered with Micro Labs

Limited, is one of only a few suppliers capable of entering the market for generic diclofenac sodium and misoprostol DR tablets in the near future.

Erythromycin is an antibiotic that had only one supplier, Arbor Pharmaceuticals, LLC, before the FDA approved Amneal's ANDA for generic erythromycin tablets in March of 2018. Amneal is the only supplier of generic erythromycin tablets in the United States. Impax is one of only a few suppliers capable of entering the market for generic erythromycin in the near future.

Fluocinonide-E cream, a topical corticosteroid used to reduce swelling, redness, itching, and allergic reactions, is sold in generic form by Impax, Alvogen, Sun Pharmaceutical Industries Ltd., and Teva in the United States. Amneal is one of very few suppliers capable of entering the market for generic fluocinonide-E cream in the near future.

Methylphenidate hydrochloride is a central nervous system stimulant used to treat attention-deficit disorder and attention-deficit/hyperactivity disorder. Only four companies currently sell generic methylphenidate hydrochloride ER tablets in the United States: Amneal, Mylan N.V., Teva, and Trigen Labs. Impax is one of only a limited number of suppliers capable of entering the market for generic methylphenidate hydrochloride ER tablets in the near future.

Olopatadine hydrochloride nasal spray is used to treat seasonal allergies. Generic olopatadine hydrochloride nasal spray is sold in the United States by Sandoz, Apotex, and Impax partnered with Perrigo. Amneal is one of very few suppliers capable of entering the market in the near future.

II. Entry

Entry into the ten markets at issue would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed

Acquisition. The combination of drug development times and regulatory requirements, including approval by the FDA, is costly and lengthy.

III. Competitive Effects

The Proposed Acquisition likely would cause significant anticompetitive harm to consumers by eliminating current competition between Amneal and Impax in the markets for generic desipramine hydrochloride tablets, generic ezetimibe and simvastatin IR tablets, and generic felbamate tablets. Generic desipramine hydrochloride tablets, generic ezetimibe and simvastatin IR tablets, and generic felbamate tablets are commodity products, and prices typically are inversely correlated with the number of competitors in each market. As the number of suppliers offering a therapeutically equivalent drug increases, the price for that drug generally decreases due to the direct competition between the existing suppliers and each additional supplier. Customers also raise concerns about their ability to source product at a competitive price if one supplier experiences manufacturing difficulties when there are fewer competitors in the market. The Proposed Acquisition would combine two of the only five companies selling generic desipramine hydrochloride tablets, and would combine two of the only four companies selling generic ezetimibe and simvastatin IR tablets and generic felbamate tablets, likely resulting in higher prices.

But for the proposed Consent Agreement, the Proposed Acquisition also is likely to delay the introduction of beneficial competition, and subsequent price decreases, by eliminating future competition in seven markets in which either Amneal or Impax is a current competitor and the other is likely to enter. Multiple customers expressed concerns about the effect of the proposed merger on the market for generic aspirin and dipyridamole ER capsules, in which Amneal is the only current generic competitor and Impax is approved to enter. Impax is one of only three

competitors providing generic azelastine nasal spray, and the imminent entry of Amneal likely would allow customers to negotiate more competitive prices and secure adequate supply. Impax is one of very few well-positioned entrants in the market for generic diclofenac sodium and misoprostol DR tablets, in which Amneal is one of four current competitors, and customers note that they would benefit from additional entry to negotiate pricing. Amneal is the only generic erythromycin tablet competitor, and Impax is one of a limited number of companies with products in development that upon entry would allow customers to negotiate lower prices. Amneal is the only foreseeable entrant in the market for generic fluocinonide-E cream, in which Impax is one of only three competitors. In the market for generic methylphenidate hydrochloride ER tablets, Amneal is one of four current competitors and Impax is one of few potential entrants. Finally, Amneal is one of only a few entrants poised to enter the market for generic olopatadine hydrochloride nasal spray, in which Impax is one of only three current competitors. Absent a remedy, the Proposed Acquisition likely would cause U.S. consumers to pay higher prices for the aforementioned generic products.

IV. The Consent Agreement

As the Commission explained in its remedy review, *The FTC's Merger Remedies 2006-2012: A Report of the Bureaus of Competition and Economics* (hereafter *"The FTC Merger Remedies Study"*)[1], products made at third-party manufacturing sites are easier to divest and involve less risk than the technology transfer from in-house manufacturing to a new facility, and thus help ensure the success of divestitures. As a result, in most cases, if one of the products is

[1] *See The FTC's Merger Remedies 2006-2012: A Report of the Bureaus of Competition and Economics* (Jan. 2017) at 36-37, https://www.ftc.gov/system/files/documents/reports/ftcs-merger-remedies-2006-2012-report-bureaus-competition-economics/p143100_ftc_merger_remedies_2006-2012.pdf.

developed or manufactured by a third party, the Commission will require divestiture of that product.

Additionally, in mergers involving complex pharmaceutical products that are difficult to manufacture, the Commission generally will require the divestiture of an on-market product over a pipeline product to place the greater risk on the merging parties rather than the public, with exceptions for compelling and fact-specific reasons. When such compelling, fact-specific reasons exist, "The goal of a divestiture is to put the product development effort (including any pending regulatory filings) in the hands of a new firm with the same ability and incentive to bring the pipeline product to market."[2]

The proposed Consent Agreement conforms to this approach and remedies the competitive concerns raised by the Proposed Acquisition in the generic azelastine nasal spray and generic olopatadine hydrochloride nasal spray markets by requiring Impax to return any rights and assets it has to its partner and ANDA-owner for these products, Perrigo. The proposed Consent Agreement remedies the competitive concerns raised by the Proposed Acquisition in the generic fluocinonide-E cream market by requiring Impax to return any rights and assets it has to its partner and ANDA-owner for this product, G&W. The parties must accomplish these divestitures no later than ten days after they consummate the Proposed Acquisition.

The proposed Consent Agreement remedies the competitive concerns raised by the Proposed Acquisition in seven of the markets at issue by requiring Impax to divest all of its rights and assets related to those products to ANI. ANI is a pharmaceutical corporation that develops, manufacturers, sells, and distributes solid oral, liquid, and topical pharmaceutical products in the United States. ANI's track record in developing and bringing to market pipeline

[2] *See The FTC's Merger Remedies Study* at 31.

products suggests that the divested products will be placed in the hands of a firm with the same ability and incentive to bring the products to market. As explained below, the Consent Agreement helps make that outcome more likely.

For two of the products that both Amneal and Impax currently market, generic desipramine hydrochloride tablets and felbamate tablets, Impax will assign its contract manufacturing agreements to ANI. For the third currently-marketed product, Amneal will supply ANI with generic ezetimibe and simvastatin IR tablets for two years with the option to extend for two additional years.

In four overlap markets in which Amneal has an on-market product and Impax has a product in development, Impax will divest its rights and assets to ANI rather than requiring Amneal to divest its on-market, in-house manufactured products. Each of these product markets has specific facts that warrant the divestiture of the Impax rights and assets rather than the Amneal product. Of note, three products—generic aspirin and dipyridamole ER capsules, generic methylphenidate hydrochloride ER tablets, and generic diclofenac sodium and misoprostol DR tablets—are more complicated to manufacture because they have extended or delayed release characteristics.

For generic aspirin and dipyridamole ER capsules, Amneal is the only manufacturer with a product on the market. Amneal manufactures this product in-house. Impax received FDA approval for its ANDA in 2017 and had expected to use a third-party manufacturer to launch its product. That manufacturer experienced some manufacturing difficulties and Impax had begun the process of developing the means to produce the product at its own facilities. With the divestiture, ANI will finalize the manufacturing process and expects to have the Impax drug on the market soon. Nevertheless, should ANI be unable to market its own version of this product

by October 1, 2019, ANI has the option to source generic aspirin and dipyridamole ER capsules from Amneal until ANI obtains the necessary regulatory approvals or through March 1, 2021, whichever date is earlier. This ensures that ANI will be able to market a competing product near the time Impax likely would have had the product on market, and provides the incentive for ANI to manufacture and market its own product. An alternative divestiture of the Amneal product would involve more risk and could jeopardize the only generic product on the market.

The FDA approved Amneal's ANDA for generic methylphenidate hydrochloride ER tablets in February 2018. Impax also has an approved ANDA. Impax's product is contract manufactured, but the contract manufacturer needs to resolve manufacturing issues before it can resume manufacturing the product. It will be less risky for Impax to assign its manufacturing contract to ANI than to affect a technology transfer from Amneal for this complex product, and it will put the product in ANI's hands, which has the same ability and incentive as Impax to bring methylphenidate hydrochloride ER tablets to market. Thus, the proposed Order requires the divestiture of Impax's rights and assets to ANI.

For generic diclofenac sodium and misoprostol DR tablets, Amneal has an on-market in-house manufactured product, and Impax is partnered with Micro Labs to commercialize a competing product. Impax holds only marketing rights to the product; Micro Labs is responsible for development and manufacturing. Impax will transfer its marketing agreement with Micro Labs to ANI, and Micro Labs will manufacture the product for ANI for the current contract term.

For erythromycin tablets, Amneal launched its product in March 2018, and only one other competitor, Arbor Pharmaceuticals, is currently selling erythromycin tablets. Amneal manufactures the erythromycin tablets in-house. Impax is one of a few companies developing the product, and once approved, it plans to outsource the manufacturing. Here, the easier-to-

divest product is the Impax drug in development. Thus, Commission staff considers it prudent to leave the in-house Amneal-manufactured product with the merged firm, an ongoing and viable competitor to Arbor. Further, Impax will transfer all of its assets related to its development of erythromycin tablets to ANI, which has the same ability and incentive to bring a competing third erythromycin tablet to market.

The proposed Order also requires Amneal to provide transitional services to ANI, Perrigo, and G&W to assist them in establishing their manufacturing capabilities and securing all of the necessary FDA approvals. These transitional services include technical assistance to manufacture the ten products at issue in substantially the same manner and quality employed or achieved by Impax. It also includes advice and training from knowledgeable employees of the parties. Under the proposed Consent Agreement, the Commission also will appoint an Interim Monitor.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Acquisition. If the Commission determines that ANI, Perrigo, and/or G&W are not acceptable acquirers, or that the manner of the divestitures is not acceptable, the proposed Order requires the parties to unwind the sale of rights to ANI, Perrigo, and/or G&W and then divest the affected products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark
Secretary.

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