ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS TO AID PUBLIC COMMENT

In the Matter of Amneal Holdings, LLC, Amneal Pharmaceuticals LLC, Impax Laboratories, Inc., and Impax Laboratories, LLC

File No. 181-0017

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 nan4 (e)-10 (r)-1 [illegible]
fluocinonide-E cream; (6) generic methylphenidate hydro
olopatadine hydrochloride nasal spray. The proposed Con
alleged violations by preserving the competition that other
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 A

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

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 FTCs 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 (opa)y t t frsed2 (e)4 ((e)0 (t)-4 (t)-2 (s)-1 (i)-2

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

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 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.