

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Maureen K. Ohlhausen, Acting Chairman
 Terrell McSweeney

In the Matter of)
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)
 AMNEAL HOLDINGS, LLC,)
 a limited liability company;)
)
 AMNEAL PHARMACEUTICALS LLC,)
 a limited liability company;)
)
 IMPAX LABORATORIES, INC.,)
 a corporation;)
)
 and)
)
 IMPAX LABORATORIES, LLC,)
 a limited liability company.)

Docket No. C-4650

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Amneal Holdings, LLC, and Respondent Amneal Pharmaceuticals LLC (collectively, “Amneal”), corporations subject to the jurisdiction of the Commission, have agreed

- d. aspirin and dipyridamole extended release (“ER”) capsules;
- e. azelastine nasal spray;
- f. diclofenac sodium and misoprostol delayed release (“DR”) tablets;
- g.

10. Aspirin and dipyridamole is an antiplatelet therapy used to reduce the risk of stroke. Only Amneal currently sells generic aspirin and dipyridamole ER capsules in the United States. Impax is one of only a limited number of suppliers capable of entering the market for generic aspirin and dipyridamole ER capsules in the near future.
11. Azelastine nasal spray is used to treat seasonal allergies. Three companies currently sell generic azelastine nasal spray: Impax, partnered with Perrigo Company plc (“Perrigo”); Wallace; and Apotex Inc. (“Apotex”). Amneal is one of a limited number of suppliers capable of entering the market in the near future.

16. Olopatadine hydrochloride nasal spray is used to treat seasonal allergies. Three companies currently sell generic olopatadine hydrochloride nasal spray in the United States: Impax, partnered with Perrigo; Sandoz; and Apotex. Amneal is one of only a few suppliers capable of entering the market for generic olopatadine hydrochloride nasal spray in the near future.

V. ENTRY CONDITIONS

17. Entry into the relevant markets described in Paragraphs 7-16 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. De novo entry would not take place in a timely manner because the combination of drug development times and FDA approval requirements would be lengthy. In addition, no other entry is likely to occur such that it would be timely and sufficient to deter or counteract the competitive harm likely to result from the Acquisition.

VI. EFFECTS OF THE ACQUISITION

18. The effects of the Acquisition, if consummated, may be to substantially lessen competition in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:
 - a. by eliminating actual, direct, and substantial competition between Amneal and Impax and reducing the number of independent significant competitors in the markets for (1) generic desipramine hydrochloride tablets; (2) generic ezetimibe and simvastatin IR tablets; and (3) generic felbamate tablets, thereby increasing the likelihood that: (a) Amneal would be able to unilaterally exercise market power in these markets; (b) the remaining competitors would engage in coordinated interaction between or among each other; and (c) customers would be forced to pay higher prices; and
 - b.

methylphenidate hydrochloride ER tablets; and (7) generic olopatadine hydrochloride nasal spray, thereby (a) increasing the likelihood that the combined entity would forego or delay the launch of each product, and (b) increasing the likelihood that the combined entity would delay, eliminate, or otherwise reduce the substantial additional price competition that would have resulted from an additional supplier of each product.

VII. VIOLATIONS CHARGED

19. The Acquisition described in Paragraph 4 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.
20. The Acquisition described in Paragraph 4, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-seventh day of April, 2018, issues its Complaint against said Respondents.

By the Commission.

Donald S. Clark
Secretary

SEAL: