4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0549]

Prescription Polyethylene Glycol 3350; Denial of a Hearing and Order Withdrawing Approval of Abbreviated New Drug Applications; Temporary Stay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that the effective date of an April 2, 2018, order denying requests for a hearing and withdrawing approval of abbreviated new drug applications (ANDAs) for certain prescription laxatives with the active ingredient polyethylene glycol 3350 (PEG 3350) is stayed until November 2, 2018.

DATES: FDA is staying the effective date of the April 2, 2018, order withdrawing approval of ANDAs for certain prescription laxatives with the active ingredient PEG 3350 until November 2, 2018.

ADDRESSES: For access to the docket, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Julie Finegan, Office of Scientific Integrity, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4218, Silver Spring, MD 20993-0002, 301-796-8618.

SUPPLEMENTARY INFORMATION:

In the *Federal Register* of April 2, 2018 (83 FR 13994), FDA denied requests for hearing and issued an order withdrawing approval of ANDAs for certain prescription laxatives with the active ingredient PEG 3350. The effective date of the order was May 2, 2018. Between April 6, 2018, and April 13, 2018, FDA received petitions for stay under § 10.35 (21 CFR 10.35) on behalf of four ANDA holders: Breckenridge Pharmaceutical, Inc. and Nexgen Pharma, Inc. (hereafter Breckenridge/Nexgen) who submitted a joint petition; Lannett Company, Inc.; and Paddock Laboratories, Inc. (collectively the ANDA holders). Breckenridge/Nexgen, Lannett, and Paddock petitioned FDA to stay its order withdrawing the approval of their ANDAs for prescription PEG 3350 and argued that all four criteria for a mandatory stay under § 10.35(e) were met. Bayer Healthcare, LLC, (Bayer) which holds an approved New Drug Application for MiraLAX, an over-the-counter laxative containing PEG 3350, responded. Bayer argued that the petitioners failed to meet any of the factors in § 10.35(e).[1]

By a letter dated April 16, 2018, the Acting Chief Scientist, pursuant to authority delegated by the Commissioner, concluded that the ANDA holders had not met the criteria for a mandatory stay under § 10.35(e). The Acting Chief Scientist granted a temporary, discretionary stay of the effective date of the order until November 2, 2018. As described in the April 16, 2018, letter, based upon information submitted by the ANDA holders and not disputed by Bayer, it would likely be difficult for manufacturers of OTC PEG 3350 products to compensate for the

[1] On April 30, 2018, Bayer filed a submission titled "Request for Clarification of FDA Granting of a Petition for Stay of Action." Bayer requested that FDA clarify that the stay allowed new manufacturing only until May 2, 2018, with shipment of product permitted until November 2, 2018. Breckenridge/Nexgen responded to Bayer's request for clarification and argued that Bayer's submission should have been a petition for reconsideration and that it failed to meet the standards required for reconsideration. Regardless of whether Bayer's submission should have been a petition for reconsideration, FDA's letter granting the stay provides that the order is stayed until November 2, 2018, without the limitations Bayer now requests.

removal of prescription PEG 3350 products within 30 days. The letter explained that public health interests would not be served should the 30-day effective date negatively impact the availability of PEG 3350, particularly given that the basis of the withdrawal of the ANDA products is not an issue of safety or efficacy. The April 16, 2018, letter additionally noted that FDA has provided lengthier time frames to phase out manufacturing and distribution of affected products in other cases. While the Acting Chief Scientist rejected the petitioners' arguments that financial hardship and harm to reputation resulting from the withdrawal order rise to the level of irreparable injury necessary for a mandatory stay under § 10.35(e), she agreed that there may some validity to the petitioner's concerns of harm to their business interests as a result of the 30-day effective date. The Acting Chief Scientist concluded that it is in the public interest and in the interest of justice to stay the effective date of the April 2, 2018, order until November 2, 2018.

The parties' submissions and the Agency's orders are available at https://www.regulations.gov and with the Dockets Management Staff (see ADDRESSES).

FDA is providing notice of the decision to grant a temporary stay in accordance with § 10.35(f).

Dated: July 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-16148 Filed: 7/27/2018 8:45 am; Publication Date: 7/30/2018]