click on the Device Registration and Listing Module (DRLM) of FURLS button. New establishments will need to register and existing establishments will update their annual registration using choices on the DRLM menu. When you choose to register or update your annual registration, the system will prompt you through the entry of information about your establishment and your devices. If you have any problems with this process, email: reglist@cdrh.fda.gov or call 301–796–7400 for assistance. (Note: This email address and this telephone number are for assistance with establishment registration only; they are not to be used for questions related to other aspects of medical device user fees.) Problems with the BER system should be directed to https://www.accessdata.fda.gov/scripts/email/cber/blendregcontact.cfm or call 240–402–8360.

D. Enter Your DFUF Order PIN and PCN

After completing your annual or initial registration and device listing, you will be prompted to enter your DFUF order PIN and PCN, when applicable. This process does not apply to establishments engaged only in the manufacture, preparation, propagation, compounding, or processing of licensed biologic devices. CBER will send invoices for payment of the establishment registration fee to such establishments.

Dated: July 24, 2018.

Leslie Kux,
Associate Commissioner for Policy.

BILLING CODE 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) of the 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).³

³On 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.

By a letter dated April 16, 2018, the Acting Chief Scientist, pursuant to authority delegated by the Commissioner, concluded that the 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).³

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