U.S. FOOD & DRUG ADMINISTRATION

DEC 3 1 2019

Navneet Malpani
Regulatory Affairs (Formulation)
Harman Finochem Limited
107-A Vinay Bhavya Complex, 159 A, CST Road
Kalina Santacruz (East) Mumbai, INDIA 400098

Ushma Patel
Senior Consultant
Navitas Life Sciences
502 Carnegie Center, Suite 102
Princeton, NJ 08540

Re: Docket No. FDA-2019-P-3877

Dear Navneet Malpani and Ushma Patel:

This letter responds to your citizen petition dated August 17, 2019, requesting that the Food and Drug Administration (FDA) confirm that Glucophage (metformin hydrochloride) oral tablets (new drug application (NDA) 020357) were not withdrawn from sale for safety or effectiveness reasons.

FDA has reviewed its records and determined that Glucophage (metformin hydrochloride) oral tablets, 500 milligrams (mg), 850 mg, and 1 gram (g) (NDA 020357), were not withdrawn from sale for reasons of safety or effectiveness. In addition, FDA has determined that Glucophage XR (metformin hydrochloride) oral extended-release tablets, 500 mg and 750 mg (NDA 021202), were not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Glucophage (metformin hydrochloride) oral tablets, 500 mg, 850 mg, and 1 g (NDA 020357), and Glucophage XR (metformin hydrochloride) oral extended-release tablets, 500 mg and 750 mg (NDA 021202), in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 796-3702.

Sincerely,

Stacy Kane
Office of Regulatory Policy
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

- What types of regulatory trends or information should be analyzed to benefit the regulatory process?
- What technologies or policies could assist with sharing of data or interoperability of regulatory management systems across the Federal government?
- What are the challenges and opportunities for third party service providers to use regulatory information alone or in combination with other data to deliver commercial services or analysis?
- What technologies or policies could assist with increasing public access to data for or through commercial applications?

In-Person Attendance

Interested parties are invited to attend the public meetings to be held at GSA Headquarters, located at 1800 F St. NW, Washington, DC 20006. While walk-ins will be allowed if there is seating capacity, the public is encouraged to pre-register prior to the scheduled date due to seating limitations. Pre-register for the January 30, 2020, meeting at *https://regulationsmanagement.eventbrite.com. Pre-register for the March 25, 2020, meeting at https://regulationsmanagement2.eventbrite.com.* Check for additional information regarding meeting logistics on *regulations.gov,* Docket No. 2019–0002; Sequence No. 35 as dates approach. Questions may be directed to *eRulemaking@gsa.gov.*

Registration check-in will begin at 1:00 p.m. (ET), and each meeting will start promptly at 2:00 p.m. (ET). Depending on levels of attendance for registered attendees, walk-in registration may or may not be available. Updates on whether registration has reached capacity will be posted on *regulations.gov,* Docket No. 2019–0002; Sequence No. 35. Walk-ins may be admitted if registered attendees do not show. Attendees must present government-issued photo identification.

Virtual Attendance

Interested parties may also attend virtually through GSA's virtual meeting platform, hosted by Adobe Connect. Further details on the virtual meeting will be made available via GSA Interact at *https://interact.gsa.gov/group/commercial-platform-initiative.*

Meeting Accommodations

The public meeting is physically accessible to people with disabilities. Sign language interpretation and auxiliary aids will be available at the meetings and online. Any specific requests for accommodations and auxiliary aids must be directed to *eRulemaking@gsa.gov* no later than 10 working days prior to the scheduled meetings.

Panel Presentations

GSA intends to conduct two town-hall/panel style discussions, with each event focused on the respective topics outlined above. Each meeting is expected to consist of two panels with three to five participants per panel. Each panel is expected to run 50 minutes, with 45 minutes of panel discussion and 10 minutes of audience questions.

Subject matter experts interested in serving on a panel at one or both public meetings must submit their proposals, to include a resume, an indication of the selected meeting or meetings, and a synopsis of their proposed topics and key points of no more than 250 words, no later than the following dates:

For the January 30, 2020, meeting, proposals are due midnight January 10, 2020.

For the March 25, 2020, meeting, proposals are due midnight March 2, 2020.

Submissions are to be emailed to *eRulemaking@gsa.gov.* GSA will select the panelists and will formally notify and coordinate with them in advance of the respective meeting. In selecting panelists, GSA will seek an array of perspectives, backgrounds, and experiences.

Dated: December 24, 2019.

Tobias Q. Schroeder,

Director, eRulemaking Program Management Office, Office of Regulation Management, Office of Government-wide Policy, General Services Administration.

[FR Doc. 2019–28242 Filed 12–30–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–P–3877]

Determination That GLUCOPHAGE (Metformin Hydrochloride) Oral Tablets, 500 Milligrams, 850 Milligrams, and 1 Gram, and GLUCOPHAGE XR (Metformin Hydrochloride) Oral Extended-Release Tablets, 500 Milligrams and 750 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that, GLUCOPHAGE (metformin hydrochloride) oral tablets, 500 milligrams (mg), 850 mg, and 1 gram (g), and GLUCOPHAGE XR (metformin hydrochloride) oral extended-release tablets, 500 mg and 750 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to these products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Carlarease Hunter, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993–0002, 301–796–3702, *Carlarease.Hunter@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn

from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

GLUCOPHAGE (metformin hydrochloride) oral tablets, 500 mg, 850 mg, and 1 g, are the subject of NDA 020357, held by EMD Serono Inc. and initially approved on March 3, 1995. GLUCOPHAGE is indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus. GLUCOPHAGE (metformin hydrochloride) oral tablets, 500 mg, 850 mg, and 1 g, are currently listed in the "Discontinued Drug Product List" section of the Orange Book.

GLUCOPHAGE XR (metformin hydrochloride) oral extended-release tablets, 500 mg and 750 mg, are the subject of NDA 021202, held by EMD Serono Inc. and initially approved on October 13, 2000. GLUCOPHAGE XR is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. GLUCOPHAGE XR (metformin hydrochloride) oral extended-release tablets, 500 mg and 750 mg, are currently listed in the "Discontinued Drug Product List" section of the Orange Book.

Harman Finochem Ltd. submitted a citizen petition dated August 17, 2019 (Docket No. FDA–2019–P–3877), under 21 CFR 10.30, requesting that FDA confirm that GLUCOPHAGE (metformin hydrochloride) oral tablets were not withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the GLUCOPHAGE XR (metformin hydrochloride) oral extended-release tablets, 500 mg and 750 mg, those products have also been discontinued. On our own initiative, we have also determined whether those products were withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that GLUCOPHAGE (metformin hydrochloride) oral tablets, 500 mg, 850 mg, and 1 g, and GLUCOPHAGE XR (metformin hydrochloride) oral extended-release tablets, 500 mg and 750 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that GLUCOPHAGE (metformin hydrochloride) oral tablets were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of GLUCOPHAGE (metformin hydrochloride) oral tablets, 500 mg, 850 mg, and 1 g, and GLUCOPHAGE XR (metformin hydrochloride) oral extended-release tablets, 500 mg and 750 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list GLUCOPHAGE (metformin hydrochloride) oral tablets, 500 mg, 850 mg, and 1 g, and GLUCOPHAGE XR (metformin hydrochloride) oral extended-release tablets, 500 mg and 750 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to these drug products. Additional ANDAs for these drug products may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: December 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–28270 Filed 12–30–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–N–0134; FDA–2011–N–0902; FDA–2013–N–0662; FDA–2013–N–0242; FDA–2019–N–1517; FDA–2019–N–0549; FDA–2019–N–0305; FDA–2012–N–0477; FDA–2016–D–2565, and FDA–2018–N–4839]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *http://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Mammography Quality Standards Act Requirements	0910–0309	10/31/2022
Prescription Drug Product Labeling; Medication Guide Requirements	0910–0393	10/31/2022
Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed	0910–0513	10/31/2022
Current Good Manufacturing Practice for Positron Emission	0910–0667	10/31/2022