annually, and assume each notification requires 16 hours to prepare and submit.

Finally, the guidance recommends developing a Plan for each individual manufacturing facility as well as a broader Plan that addresses multiple sites within the organization. For purposes of this information collection analysis, we consider the Plan for an individual manufacturing facility and the broader Plan to comprise one Plan for each manufacturer. Based on available data on the number of manufacturers that would be covered by the guidance, we previously estimated 70 manufacturers will develop a Plan as recommended by the guidance (*i.e.,* one Plan per manufacturer, to include all manufacturing facilities, sites, and drug products) and that each Plan would take approximately 500 hours to develop. Upon development of the plan, however, we believe fewer hours are necessary to maintain and update it as needed. As FDA issued the guidance in 2011, we now assume that most respondents have developed the recommended plan, and therefore we limit our current burden estimate to updates and maintenance. Accordingly, we have reduced our estimate by half, reasoning that, although it takes fewer hours for updates and maintenance, new respondents may choose to adopt recommendations found in the guidance.

Dated: October 16, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23272 Filed 10–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4310]

Allergan Pharmaceuticals International, LTD; Withdrawal of Approval of a New Drug Application for LO MINASTRIN FE

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of a new drug application (NDA) for LO MINASTRIN FE (ethinyl estradiol tablets, 0.01 milligrams (mg); ethinyl estradiol and norethindrone acetate tablets, 0.01 mg/1mg; and ferrous fumarate tablets, 75 mg), held by Allergan Pharmaceuticals International, LTD, c/o Allergan Sales, LLC, 5 Giralda Farms, Madison, NJ 07940 (Allergan). Allergan notified the Agency in writing that the drug product was no longer marketed and requested that the approval of the application be withdrawn.

DATES: Approval is withdrawn as of November 25, 2019.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137.

SUPPLEMENTARY INFORMATION: Allergan has informed FDA that LO MINASTRIN FE (ethinyl estradiol tablets, 0.01 mg; ethinyl estradiol and norethindrone acetate tablets, 0.01 mg/1 mg; and ferrous fumarate tablets, 75 mg) is no longer marketed and has requested that FDA withdraw approval of NDA 204654 under the process in § 314.150(c) (21 CFR 314.150(c)). Allergan has also, by its request, waived its opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Therefore, approval of NDA 204654, and all amendments and supplements thereto, is hereby withdrawn as of November 25, 2019. Approval of the entire application is withdrawn, including any strengths and dosage forms inadvertently missing from this notice. Introduction or delivery for introduction into interstate commerce of a product without an approved new drug application violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Any Lo Minastrin Fe that is in inventory on November 25, 2019 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: October 21, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23309 Filed 10–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2018–N–3163; FDA–2012–D–0429; FDA–2012–D–0049; FDA–2018–N–3031; FDA–2011–D–0125; FDA–2018–N–4428; FDA–2012–N–0560; FDA–2010–N–0414; FDA–2012–N–1203; and FDA–2019–N–0430]

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 or Agency) 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 (PRA).

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
Physician Interpretation of Information About Prescription Drugs in Scientific Publications Versus Promotional Pieces	0910–0875	9/30/2021
Guidance on Meetings with Industry and Investigators on the Research and Development of Tobacco Products	0910–0731	8/31/2022

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB—Continued

Title of collection	OMB control No.	Date approval expires
Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act	0910–0732	8/31/2022
Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco	0910–0749	8/31/2022
Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007	0910–0775	8/31/2022
Medicated Feed Mill License Application	0910–0337	9/30/2022
Guidance on Informed Consent for In Vitro Diagnostic Studies Using Leftover Human Specimens That Are Not Individually Identifiable	0910–0582	9/30/2022
Manufactured Food Regulatory Program Standards	0910–0601	9/30/2022
Information to Accompany Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements	0910–0661	9/30/2022
Generic Clearance for Quick Turnaround Testing of Communication Effectiveness	0910–0876	9/30/2022

Dated: October 17, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23251 Filed 10–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4560]

Pediatric Stakeholder Meeting; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration's (FDA or the Agency) Office of Pediatric Therapeutics (OPT), the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) are announcing a public meeting seeking input from patient/parent groups, consumer groups, regulated industry, academia, and other interested parties to obtain any recommendations or information relevant to the report to Congress that FDA is required to submit concerning pediatrics, as outlined in section 508 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (see the **SUPPLEMENTARY INFORMATION** section for additional background information).

DATES: The public meeting will be held on November 21, 2019, from 9 a.m. to 3 p.m. Registration to attend the meeting should be received by November 15, 2019. Onsite registration on the day of the meeting will be based on space availability. Submit either electronic or written comments on the public meeting by December 19, 2019. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (1503–A), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For information on parking and security procedures, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 19, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–4560 for ''Pediatric Stakeholder Meeting.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docker and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS