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Agency in writing that the drug product was no longer marketed and requested that the approval of the application be withdrawn.

DATES: Approval is withdrawn as of November 25, 2019.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