

voucher. FDA has determined that an efficacy supplement for DESCOVY (emtricitabine and tenofovir alafenamide) approved October 3, 2019, meets the redemption criteria.

**FOR FURTHER INFORMATION CONTACT:**

Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4061, Fax: 301-796-9858, email: [althea.cuff@fda.hhs.gov](mailto:althea.cuff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that an efficacy supplement for DESCOVY (emtricitabine and tenofovir alafenamide) approved October 3, 2019, meets the redemption criteria.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about DESCOVY (emtricitabine and tenofovir alafenamide) efficacy supplement approved October 3, 2019, go to the “*Drugs@FDA*” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: October 21, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA 2013-N-0719]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Planning for the Effects of High Absenteeism To Ensure Availability of Medically Necessary Drug Products

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency.

Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection for the guidance on planning for the effects of high absenteeism to ensure availability of medically necessary drug products.

**DATES:** Submit either electronic or written comments on the collection of information by December 24, 2019.

**ADDRESSES:** 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 24, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 24, 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 a 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-2013-N-0719 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket 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 CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://>

[www.regulations.gov](http://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.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information,

including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Planning for the Effects of High Absenteeism To Ensure Availability of Medically Necessary Drug Products**

OMB Control Number 0910–0675—Extension

This information collection supports recommendations found in Agency guidance. Specifically, we have developed guidance intended to encourage manufacturers of drug and therapeutic biological products, and any raw materials and components used in those products, to develop a written Emergency Plan (Plan) for maintaining an adequate supply of medically necessary drug products (MNPs) during an emergency that results in high employee absenteeism. The guidance document entitled, "Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products," discusses the elements that should be covered by such a Plan, and is available from our website at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/planning-effects-high-absenteeism-ensure-availability-medically-necessary-drug-products>.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Activate/deactivate Plan as recommended in the guidance .....	2	1	2	16	32

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
Develop initial Plan as recommended in the guidance .....	70	1	70	250	17,500

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

As explained in the guidance, we provide recommendations for developing and implementing a written Plan, including: (1) Identifying a person or position title (as well as two designated alternates) with the authority to activate and deactivate the Plan and make decisions during the emergency; (2) prioritizing the manufacturer's drug products based on medical necessity; (3) identifying actions that should be taken prior to an anticipated period of high absenteeism; (4) identifying criteria for activating the Plan; (5) performing quality risk assessments to determine

which manufacturing activities may be reduced to enable the company to meet a demand for MNPs; (6) returning to normal operations and conducting a post-execution assessment of the execution outcomes; and (7) testing the Plan.

The guidance also encourages manufacturers to include and document procedures in the Plan for notifying the FDA Center for Drug Evaluation and Research (CDER) when the Plan is activated and when returning to normal operations. The guidance recommends that these notifications occur within 1

day of a Plan's activation and within 1 day of a Plan's deactivation. The guidance identifies the information that should be included in these notifications, such as which drug products will be manufactured under altered procedures, which products' manufacturing will be temporarily delayed, and any anticipated or potential drug shortages. We assume two notifications (for purposes of this analysis, we consider an activation and a deactivation notification to equal one notification) will be submitted to CDER

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.  
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**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. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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