

million. Part B enrollees who are also enrolled in Medicaid have their monthly Part B premiums paid by Medicaid. The cost to each state Medicaid program from the 2018 premium increase is estimated to be less than the threshold. This notice does not impose mandates that will have a consequential effect of the threshold amount or more on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have determined that this notice does not significantly affect the rights, roles, and responsibilities of states. Accordingly, the requirements of Executive Order 13132 do not apply to this notice.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

V. Waiver of Proposed Notice

The Medicare statute requires the publication of the monthly actuarial rates and the Part B premium amounts in September. We ordinarily use general notices, rather than notice and comment rulemaking procedures, to make such announcements. In doing so, we note that, under the Administrative Procedure Act, interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice are excepted from the requirements of notice and comment rulemaking.

We considered publishing a proposed notice to provide a period for public comment. However, we may waive that procedure if we find, for good cause, that prior notice and comment are impracticable, unnecessary, or contrary to the public interest. The statute establishes the time period for which the premium rates will apply, and delaying publication of the Part B premium rate such that it would not be published before that time would be contrary to the public interest. Moreover, we find that notice and comment are unnecessary because the formulas used to calculate the Part B premiums are statutorily directed. Therefore, we find good cause to waive publication of a proposed notice and solicitation of public comments.

Dated: October 27, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 1, 2017.

Eric D. Hargan,

Acting Secretary, Department of Health and Human Services.

[FR Doc. 2017-24877 Filed 11-17-17; 4:15 pm]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2017-P-3989, FDA-2017-P-4195, FDA-2017-P-5114, FDA-2017-P-5909, FDA-2017-P-5910, and FDA-2017-P-5967]

Determination That TRINTELLIX (Vortioxetine Hydrobromide) Oral Tablet, EQ 15 Milligram Base, Was 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 or Agency) has determined that TRINTELLIX (vortioxetine hydrobromide) oral tablet, equivalent to (EQ) 15 milligram (mg) base, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for vortioxetine hydrobromide oral tablet, 15 mg base, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Meadow W. Platt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993-0002, 301-796-1830.

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.

TRINTELLIX (vortioxetine hydrobromide) oral tablets, EQ 5 mg base, EQ 10 mg base, EQ 15 mg base, and EQ 20 mg base, are the subject of NDA 204447, held by Takeda Pharmaceuticals, USA, Inc., and initially approved on September 30, 2013. TRINTELLIX is indicated for the treatment of major depressive disorder.

TRINTELLIX (vortioxetine hydrobromide) oral tablets, EQ 5 mg base, EQ 10 mg base, and EQ 20 mg base, are listed in the “Prescription Drug Product List” section of the Orange Book, and TRINTELLIX (vortioxetine hydrobromide) oral tablet, EQ 15 mg base, is listed in the “Discontinued Drug Product List” section of the Orange Book. Takeda Pharmaceuticals, USA, Inc., has never marketed TRINTELLIX (vortioxetine hydrobromide) oral tablet, EQ 15 mg base. In previous instances (see, e.g., 72 FR 9763 (March 5, 2007), 61 FR 25497 (May 21, 1996)), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

Lachman Consultant Services, Inc.; INC Research, LLC; Locke Lord, LLP; Goodwin Procter, LLP; Cipla USA Inc.; and Apotex, Inc., submitted citizen petitions dated June 29, 2017; July 12, 2017; August 21, 2017; September 25, 2017; September 25, 2017; and September 27, 2017, respectively (Docket Nos. FDA-2017-P-3989, FDA-

2017-P-4195, FDA-2017-P-5114, FDA 2017-P-5909, FDA-2017-P-5910, and FDA-2017-P-5967) (collectively, "citizen petitions"). Under 21 CFR 10.30, the citizen petitions requested that the Agency determine whether TRINTELLIX (vortioxetine hydrobromide) oral tablet, EQ 15 mg base, was withdrawn from sale for reasons of safety or effectiveness. Lachman Consultant Services, Inc., and INC Research also asked FDA to accept ANDAs for all four strengths of TRINTELLIX (vortioxetine hydrobromide) tablets: EQ 5 mg base, EQ 10 mg base, EQ 15 mg base, and EQ 20 mg base. Because TRINTELLIX (vortioxetine hydrobromide) oral tablets, EQ 5 mg base, EQ 10 mg base, and EQ 20 mg base, are not listed in the "Discontinued Drug Product List" section of the Orange Book, these strengths do not require a determination as to whether they were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petitions and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that TRINTELLIX (vortioxetine hydrobromide) oral tablet, EQ 15 mg base, was not withdrawn for reasons of safety or effectiveness. The petitioners have identified no data or other information suggesting that TRINTELLIX (vortioxetine hydrobromide) oral tablet, EQ 15 mg base, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of TRINTELLIX (vortioxetine hydrobromide) oral tablet, EQ 15 mg base, 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 this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list TRINTELLIX (vortioxetine hydrobromide) oral tablet, EQ 15 mg base, 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. ANDAs that refer to TRINTELLIX (vortioxetine hydrobromide) oral tablet, EQ 15 mg base (as well as those that refer to TRINTELLIX (vortioxetine hydrobromide) oral tablets, EQ 5 mg base, EQ 10 mg base, and EQ 20 mg base), may 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 this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 3, 2017.

Anna K. Abram,
*Deputy Commissioner for Policy, Planning,
Legislation, and Analysis.*

[FR Doc. 2017-25156 Filed 11-20-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6162]

Agency Information Collection Activities; Proposed Collection; Comment Request

Notification of the Intent To Use an Accredited Person Under the Accredited Persons Inspection Program

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 eligibility criteria and the process to be followed by establishments when notifying FDA of a manufacturer's intent to have an accredited third party conduct a quality systems regulation inspection of their establishment instead of FDA, under the Accredited Persons (AP) Inspection Program.

DATES: Submit either electronic or written comments on the collection of information by January 22, 2018.

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 January 22, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time

at the end of January 22, 2018. 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-2017-N-6162 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Notification of the Intent To Use an Accredited Person Under the Accredited Persons Inspection Program." 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