

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requested that the Agency determine whether TRINTELLIX (vortioxetine hydrobromide) oral tablet, EQ 15 mg base, was withdrawn from sale for reasons of safety or effectiveness.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Drug Product List" section of the Orange Book, these strengths do not require a determination as to whether they were withdrawn from sale for reasons of safety or effectiveness.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FDA has determined under § 314.161 that TRINTELLIX (vortioxetine hydrobromide) oral tablet, EQ 15 mg base, was not withdrawn for reasons of safety or effectiveness.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no data or other information suggesting that TRINTELLIX (vortioxetine hydrobromide) oral tablet, EQ 15 mg base, was withdrawn for reasons of safety or effectiveness.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 We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.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.*

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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

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> 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: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), 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.

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

OMB Control Number 0910–0569—Extension

Section 201 of the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250) amended section 704 of the Federal Food, Drug, and Cosmetic Act by adding subsection (g) (21 U.S.C. 374(g)). This amendment authorized FDA to establish a voluntary third-party inspection program applicable to manufacturers of class II or class III medical devices who meet certain eligibility criteria. In 2007, the program

was modified by the Food and Drug Administration Amendments Act of 2007 by revising eligibility criteria and by no longer requiring prior approval by FDA. To reflect the revisions, FDA modified the title of the collection of information and on March 2, 2009, issued a guidance entitled “Manufacturer’s Notification of the Intent to Use an Accredited Person Under the Accredited Persons Inspection Program Authorized by Section 228 of the Food and Drug Administration Amendments Act of 2007.” This guidance superseded the Agency’s previous guidance regarding requests for third-party inspection and may be found on the internet at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085187.htm>. The guidance is intended to assist device establishments in determining whether they are eligible to participate in the AP Program and, if so, how to submit notification of their intent to use the program. The AP Program applies to manufacturers who currently market their medical devices in the United States and who also market or plan to market their devices in foreign countries. Such manufacturers may need current inspections of their establishments to operate in global commerce.

There are approximately 8,000 foreign and 10,000 domestic manufacturers of medical devices. Approximately 5,000 of these firms only manufacture class I devices and are, therefore, not eligible for the AP Program. In addition, 40 percent of the domestic firms do not export devices and therefore are not eligible to participate in the AP Program. Further, 10 to 15 percent of the firms are not eligible due to the results of their previous inspection. FDA estimates there are 4,000 domestic manufacturers and 4,000 foreign manufacturers that are eligible for inclusion under the AP Program. Based on communications with industry, FDA estimates that on an annual basis approximately 10 of these manufacturers may use an AP in any given year.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

| Activity/21 U.S.C. Section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Notification regarding use of an accredited person—374(g) | 10 | 1 | 10 | 15 | 150 |

Since the last approval of this information collection, we have updated the estimated number of respondents from 20 to 10 respondents per year, based on the reduced number of notifications received in recent years. This adjustment has resulted in a 150-hour reduction to the total hour burden estimate.

Dated: November 9, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0913]

Agency Information Collection Activities; Proposed Collection; Comment Request; 513(g) Request for Information

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 burden estimate for requests for a written statement from FDA regarding the classification and regulatory requirements that may be applicable to a particular device (513(g) requests).

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

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- 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").

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Instructions: All submissions received must include the Docket No. FDA-2014-N-0913 for "Agency Information Collection Activities; Proposed Collection; Comment Request; 513(g) Request for Information." 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.

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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>.

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