

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2007-D-0369]

**Product-Specific Guidance for Tiotropium Bromide; Draft Guidance for Industry; Availability**

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry, entitled “Draft Guidance for Tiotropium Bromide.” The draft guidance, when finalized, will provide product-specific recommendations on, among other things, the information and data needed to demonstrate bioequivalence (BE) to support abbreviated new drug applications (ANDAs) for tiotropium bromide inhalation spray.

**DATES:** Submit either electronic or written comments on the draft guidance by January 19, 2021 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments as follows:

*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-2007-D-0369 for “Draft Guidance for Tiotropium Bromide.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” will be publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **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.govinfo.gov/content/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, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

**FOR FURTHER INFORMATION CONTACT:** Mara Miller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4709C, Silver Spring, MD 20993-0002, 301-796-0683.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products,” which explained the process that would be used to make product-specific guidances available to the public on FDA’s website at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>.

As described in that guidance, FDA adopted this process to develop and disseminate product-specific guidances and to provide a meaningful opportunity for the public to consider and comment on the guidances. This notice announces the availability of a draft guidance on a generic tiotropium bromide inhalation spray.

FDA initially approved new drug application 21936 for SPIRIVA RESPIMAT (tiotropium bromide inhalation spray) in September 2015. We are now issuing draft guidance for industry on BE recommendations for generic tiotropium bromide inhalation spray (“Draft Guidance for Tiotropium Bromide”).

In October 2012, Boehringer Ingelheim, manufacturer of the reference listed drug SPIRIVA HANDIHALER, new drug application 21395, submitted a citizen petition requesting, among other things, that FDA adopt and apply certain requirements in its review of any

proposed generic and follow-on versions of SPIRIVA HANDIHALER or any other Boehringer Ingelheim oral inhalation product containing the active ingredient tiotropium bromide under section 505(j) and (b)(2), respectively, of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j) and (b)(2)) (Docket No. FDA-2012-P-1072). FDA is reviewing the issues raised in the petition and will consider any comments on the draft guidance entitled "Draft Guidance for Tiotropium Bromide" before responding to Boehringer's citizen petition.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the information and data to demonstrate BE to support ANDAs for tiotropium bromide inhalation spray. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: November 12, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2020-25412 Filed 11-17-20; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-N-5843]

#### Pharmacia and Upjohn Co., et al.; Withdrawal of Approval of 19 New Drug Applications; Correction

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

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on January 8, 2020. The document announced the withdrawal of approval of 19 new drug applications (NDAs) from multiple applicants, withdrawn as of February 7, 2020. The document indicated that FDA was withdrawing approval of NDA 202342,

Esomeprazole Strontium Delayed-Release Capsules, Equivalent to (EQ) 20 milligrams (mg) base and EQ 40 mg base, after receiving a withdrawal request from R2 Pharma, LLC, 11550 North Meridian St., Suite 290, Carmel, IN 46032-5505 (R2 Pharma). Because of clerical errors in the Agency's processing of communications regarding this application, FDA has determined that NDA 202342 remains approved. Accordingly, FDA's approval of NDA 202342 remains in effect. There are no changes with respect to the other 18 NDA withdrawals announced in the January 8, 2020 **Federal Register** notice.

#### 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, [Kimberly.Lehrfeld@fda.hhs.gov](mailto:Kimberly.Lehrfeld@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### Correction

In the **Federal Register** of Wednesday, January 8, 2020 (85 FR 915), appearing on page 916 in FR Doc. 2020-00075, the following correction is made:

On page 916, in the table, the entry for NDA 202342 is removed.

Dated: November 12, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2020-25413 Filed 11-17-20; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-1429]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act and Associated Fees

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by December 18, 2020.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0776. Also include the FDA docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act and Associated Fees

*OMB Control Number 0910-0776—Revision*

This information collection helps to support implementation of section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Drug Quality and Security Act (DQSA).

##### A. Registration

Under section 503B of the FD&C Act (21 U.S.C. 353b), added by DQSA, a facility that compounds drugs may elect to register with FDA as an outsourcing facility. Drug products compounded in a registered outsourcing facility can qualify for exemptions from the FDA-approval requirements in section 505 of the FD&C Act (21 U.S.C. 355), the requirement to label products with adequate directions for use under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)), and the requirements for drug supply chain security in section 582 of the FD&C Act (21 U.S.C. 360eee-1) if the requirements in section 503B of the FD&C Act have been met.

After the initial registration, under section 503B(b) of the FD&C Act, a facility that elects to register with FDA as an outsourcing facility must also do so annually between October 1 and