

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 FDA is reviewing the issues raised in the petition and will consider any comments on the draft guidance entitled "Draft Guidance for Tiotropium Bromide" before responding to Boehringer's citizen petition.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the information and data to demonstrate BE to support ANDAs for tiotropium bromide inhalation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Persons with access to the internet may obtain the draft guidance at either 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 The document announced the withdrawal of approval of 19 new drug applications (NDAs) from multiple applicants, withdrawn as of February 7, 2020.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.

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.

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