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 FDA is reviewing the issues raised in the petition and will consider any comments on the draft guidance entitled ''Draft Guidance for Tiotropium Bromide'' before responding to Boehringer's citizen petition.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the information and data to demonstrate BE to support ANDAs for tiotropium bromide inhalation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Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*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 The document announced the withdrawal of approval of 19 new drug applications (NDAs) from multiple applicants, withdrawn as of February 7, 2020.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

December 31. Upon registration, the outsourcing facility must provide specific information including its name, place of business, a unique facility identifier, and a point of contact's email address and phone number. The outsourcing facility must also indicate: (1) Whether it intends to compound, within the next calendar year, a drug that appears on our drug shortage list in effect under section 506E of the FD&C Act (21 U.S.C. 356e); and (2) whether it compounds from bulk drug substances and, if so, whether it compounds sterile or non-sterile drugs from bulk drug substances.

Outsourcing facilities that elect to register submit registration information for each facility electronically using a Structured Product Labeling (SPL) format in accordance with the FDA guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing (May 2009).'' The guidance is available from our website at: *https://www.fda.gov/media/71146/download.* Respondents unable to use electronic means to register may submit a written request for a waiver from the requirement.

B. Registration Fees

Upon registration, and in accordance with section 503B and 744K of the FD&C Act, facilities are assessed an establishment fee and receive an annual invoice from FDA with instructions for remitting payment. Until payment is made for each given fiscal year (FY), an establishment is not considered to be registered as an outsourcing facility.

In accordance with section 744K of the FD&C Act (21 U.S.C. 379j–62), certain outsourcing facilities may qualify for a small business reduction in the amount of the annual establishment fee. To qualify for this reduction, an outsourcing facility must submit a written request to FDA certifying that the entity meets the requirements for the reduction. For each FY a firm seeks to qualify as a small business and receive the fee reduction, it must submit to FDA a written request by April 30 of the preceding FY. For example, an outsourcing facility must have submitted a written request for the small business reduction by April 30, 2020, to qualify for a reduction in the fiscal year 2021 annual establishment fee.

Section 744K also requires an outsourcing facility to submit written requests for a small business reduction in a specified format: Form FDA 3908 entitled ''Outsourcing Facilities for Human Drug Compounding: Small Business Establishment Fee Reduction Request.'' Form FDA 3908 is available from our website at: *https://www.fda.gov/media/90740/download.* In response to the submission of a small business reduction request, FDA will send a notification letter of its decision and recommends that applicants retain the notification.

C. Reinspection Fees

In accordance with section 503B of the FD&C Act, outsourcing facilities are subject to inspection and, in accordance with section 744K, subject to reinspection fees. A reinspection fee will be incurred for each reinspection and is intended to reimburse FDA when a particular outsourcing facility requires reinspection because of noncompliance identified during a previous inspection. After a reinspection is conducted, FDA will send an invoice to the email address indicated in the facility's registration file. The invoice contains instructions for remitting the reinspection fee.

D. Dispute Resolution

Agency regulations under § 10.75 (21 CFR 10.75) provide for internal Agency review of decisions. Accordingly, an outsourcing facility may request reconsideration of an FDA decision related to the fee provisions of section 744K of the FD&C Act. Requests for reconsideration should include the facility's rationale for its position that FDA's decision was in error and include any additional information that is relevant to the outsourcing facility's assertion. The denial of a request for reconsideration may be appealed by submitting a written request to FDA, consistent with § 10.75.

To assist respondents with the information collection provisions, we have developed Agency guidance. The guidance document entitled ''Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act (November 2014)'' describes the process for electronic submission of establishment registration information for outsourcing facilities and provides information on how to obtain a waiver from submitting registration information electronically. The guidance document entitled ''Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act (November 2014)'' describes the types and amounts of fees that outsourcing facilities must pay, the adjustments to fees required by law, how outsourcing facilities can submit payment to FDA, the consequences of outsourcing facilities' failure to pay fees, and how an outsourcing facility can qualify as a small business to obtain a reduction in fees. The guidance documents were issued consistent with our good guidance practice regulations (21 CFR 10.115), which provide for public comment at any time, and are available on our website at *https://www.fda.gov/media/87570/download* and *https://www.fda.gov/media/136683/download*, respectively.

In the **Federal Register** of August 20, 2020 (85 FR 51442), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Electronic Submission of Registration Information Using the SPL Format.	70	1	70	4.5	315
Waiver Request From Electronic Submission of Registration Information.	1	1	1	1	1
Subtotal.					
Remission of Annual Establishment Fee From FDA Invoice.	70	1	70	0.5 (30 minutes)	35
Request for Small Business Reduction (Form FDA 3908).	15	1	15	25	375
Reinspection Fees	14	1	14	0.5 (30 minutes)	7

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Reconsideration Requests	3	1	1	1	3
Appeal of Reconsideration Denials	1	1	1	1	1
Total			101		421

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We estimate 70 respondents annually will submit outsourcing facility registrations using the SPL format as specified in Agency guidance and assume each registration will require 4.5 hours to prepare and complete. We expect no more than one waiver request from the electronic submission requirement annually and assume each waiver request will require 1 hour to prepare and submit. We estimate each of the 70 registrants will remit annual establishment fees and assume this task requires 30 minutes per respondent. We estimate that 15 of those respondents will request a small business reduction in the amount of the annual establishment fee using Form FDA 3908.

We estimate 14 outsourcing facilities annually will remit reinspection fees and assume this will require 30 minutes. We also estimate that we will receive three requests for reconsideration and one appeal of a denial of a request for reconsideration and assume 1 hour per respondent for this activity.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Retention of small business designation notification letter.	15	1	15	0.5 (30 minutes)	7.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We estimate that annually 15 outsourcing facilities will maintain a copy of their small business designation letter and that maintaining each record will require 0.5 hour (30 minutes).

These estimates reflect a slight increase in the number of annual registrations, but a decrease in reinspection fee submissions.

Dated: November 12, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–25411 Filed 11–17–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–D–1137 and FDA–2020–D–1138]

Guidance Documents Related to Coronavirus Disease 2019; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of FDA guidance documents related to the Coronavirus Disease 2019 (COVID–19) public health emergency (PHE). This notice of availability (NOA) is pursuant to the process that FDA announced, in the **Federal Register** of March 25, 2020, for making available to the public COVID–19-related guidances. The guidances identified in this notice address issues related to the COVID–19 PHE and have been issued in accordance with the process announced in the March 25, 2020, notice. The guidances have been implemented without prior comment, but they remain subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidances is published in the **Federal Register** on November 18, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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 name of the guidance