



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities: Proposed Collection; Comment Request; Guidance for Industry on Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

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 in the guidance on registration of human drug compounding outsourcing facilities under the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

REGISTER]. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. 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-2013-N 1429 for "Guidance for Industry on Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act." 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 docket, 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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, 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.

Guidance for Industry on Registration of Human Drug Compounding Outsourcing Facilities

Under Section 503B of the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910-0777--Extension

A facility that compounds drugs may elect to register with FDA as an outsourcing facility under section 503B of the FD&C Act (21 U.S.C. 353b), as added by the Drug Quality and Security Act (DQSA). 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 drug supply chain security requirements in section 582 of the FD&C Act (21 U.S.C. 360eee) if the requirements in section 503B are 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 its name, place of

business, a unique facility identifier, and a point of contact email address. The outsourcing facility must also indicate whether it intends to compound, within the next calendar year, a drug that appears on FDA's drug shortage list in effect under section 506E of the FD&C Act (21 U.S.C. 356e), and 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 should submit the following registration information to FDA for each facility:

- Name of the facility;
- Place of business;
- Unique facility identifier;
- Point of contact email address and phone number;
- Whether the facility intends to compound drugs that appear on FDA's drug shortage list in effect under section 506E of the FD&C Act; and
- An indication of whether the facility compounds from bulk drug substances, and if so, whether it compounds sterile or nonsterile drugs from bulk drug substances.

Registration information should be submitted to FDA electronically using the Structured Product Labeling (SPL) format and in accordance with section IV of the FDA guidance entitled "Providing Regulatory Submissions in Electronic Format--Drug Establishment Registration and Drug Listing." Under the final guidance, outsourcing facilities may request a waiver from the SPL electronic submission process by submitting a written request to FDA explaining why the use of electronic means is not reasonable.

This information collection supports the Agency guidance discussed above. We estimate that approximately 62 outsourcing facilities ("number of respondents" and "total annual

responses" in table 1, row 1) will annually submit to FDA registration information using the SPL format as specified in the guidance, and that preparing and submitting this information will take approximately 4.5 hours per registrant ("average burden per response" in table 1, row 1). We expect to receive no more than one waiver request from the electronic submission process annually ("number of respondents" and "total annual responses" in table 1, row 2), and that each request should take approximately 1 hour to prepare and submit to us ("average burden per response" in table 1, row 2).

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

Table 1.--Estimated Annual Reporting Burden¹

Compounding Outsourcing Facility	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Electronic Submission of Registration Information Using SPL Format	62	1	62	4.5	279
Waiver Request From Electronic Submission of Registration Information	1	1	1	1	1
Total					280

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

Dated: June 15, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning Legislation, and Analysis.

[FR Doc. 2017-12838 Filed: 6/19/2017 8:45 am; Publication Date: 6/20/2017]