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; 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) 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: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0777. 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, 10A-12M, 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.

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

This information collection supports the above captioned Agency guidance. A facility that compounds drugs may elect to register with FDA as an outsourcing facility under section 503B of the Federal Food, Drug, and Cosmetic Act (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 of the FD&C Act 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 and phone number. 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.

In the *Federal Register* of June 20, 2017 (82 FR 28076), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We therefore estimate the burden associated with the information collection as follows:

Table 1.--Estimated Annual Reporting Burden[1]

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

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

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).

Dated: October 10, 2017.

Anna K. Abram,

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

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