4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Draft Guidance for Industry on Registration for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft guidance for industry entitled "Registration for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act." The draft guidance addresses new provisions in the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Drug Quality and Security Act (DQSA). The draft guidance is intended to assist human drug compounders that choose to register as outsourcing facilities (outsourcing facilities) in registering with FDA. The draft guidance provides information on how an outsourcing facility should submit facility registration information electronically.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, 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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Registration for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act." The draft guidance is being issued to implement new provisions added to the FD&C Act in the DQSA. In the newly enacted legislation, Congress created a new

statutory category of "outsourcing facilities" that compound human drugs. New section 503B of the FD&C Act (21 U.S.C. 353b) allows compounders to register with FDA as outsourcing facilities. The draft guidance discusses the process for registration of outsourcing facilities.

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 Agency's current thinking on registration for outsourcing facilities under section 503B of the FD&C Act. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

Elsewhere in this issue of the Federal Register, the Agency is making available for comment a draft guidance on interim product reporting for human drug compounding outsourcing facilities under section 503B of the FD&C Act.

II. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (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 that 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 for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this document, FDA invites comments on the following topics: (1) Whether the proposed information collected is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimated burden of the proposed information collected, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Under the draft guidance, 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, within the next calendar year, drugs that appear on FDA's drug shortage list in effect under section 506E of the FD&C Act (21 U.S.C. 356e); and
- An indication of whether the facility compounds from bulk drug substances, and if so, whether it compounds sterile drugs from bulk drug substances.

After initial registration, outsourcing facilities should register annually between October 1 and December 31 of each year. 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." FDA is also providing an alternative interim registration mechanism for use after initial passage of the DQSA because registration is a new requirement for those outsourcing facilities that elect to register under section 503B and because FDA wants to encourage registration of outsourcing facilities. This alternative interim registration method relies on email and is only intended for use in the near term while outsourcing facilities unfamiliar with registration familiarize themselves with the SPL format. FDA encourages outsourcing facilities that choose to use this alternative interim method to begin using the SPL format no later than September 30, 2014. In addition, outsourcing facilities may request a waiver from the electronic submission process by submitting a written request to FDA explaining why the use of electronic means is not reasonable.

Because human drug compounders are not currently required to register and report as outsourcing facilities, it is difficult to anticipate the number of outsourcing facilities that will participate in the process.

Estimated reporting burden until September 30, 2014. We estimate that approximately 15 outsourcing facilities ("number of respondents" and "total responses" in table 1 row 1) will submit registration information to FDA using email as specified in the draft guidance, and that preparing and submitting this information will take approximately 15 minutes ("average burden per response" in table 1 row 1). We also estimate that approximately 5 outsourcing facilities ("number of respondents" and "total responses" in table 1, row 2) will submit to FDA registration information using the SPL format as specified in the draft guidance, and that preparing and submitting this information will take approximately 4.5 hours per registrant ("average burden per response" in table 1, row 2). We expect to receive no more than one waiver request from the electronic submission process during this time period ("number of

respondents" and "total responses" in table 1, row 3), and that each request should take approximately 1 hour to prepare and submit to us ("average burden per response" in table 1, row 3).

Estimated annual reporting burden after September 30, 2014. We estimate that approximately 20 outsourcing facilities ("number of respondents" and "total annual responses" in table 2, row 1) will annually submit to FDA registration information using the SPL format as specified in the draft guidance, and that preparing and submitting this information will take approximately 4.5 hours per registrant ("average burden per response" in table 2, 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 2, row 2), and that each request should take approximately 1 hour to prepare and submit to us ("average burden per response" in table 2, row 2).

Table 1 -- Estimated Reporting Burden Until September 30, 2014[1]

Compounding Outsourcing Facility	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response	Total Hours
Alternative Interim Registration Method Using Email	15	1	15	0.25	3.75
Electronic Submission of Registration Information Using SPL Format	5	1	5	4.5	22.50

Waiver Request From Electronic Submission of Registration Information	1	1	1	1	1
Total					27.25

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

Table 2 -- Estimated Annual Reporting Burden After September 30, 2014[1]

Compounding Outsourcing Facility	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Electronic Submission of Registration Information Using SPL Format	20	1	20	4.5	90
Waiver Request From Electronic Submission of Registration Information	1	1	1	1	1
Total					91

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

III. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the

docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: November 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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