weekly Enforcement Report, which includes a description of the products subject to the recall. The commenter can check the Enforcement Report to view drug products that have been recalled. FDA does not include the name/license number of the supervising pharmacist because section 503B of the FD&C Act does not require facilities to provide this information to FDA when registering. This information is not in SPL format because FDA includes information in this list that is not captured in SPL, such as FDA regulatory actions.

(Issue 3) One commenter requested insight on how FDA intends to communicate with industry those facilities that had previously registered as human drug compounders before the implementation of section 503B and those that are now registering under section 503B of the FD&C Act.

(Response) FDA has made available on the Internet a list of the facilities that have registered under section 503B of the FD&C Act as outsourcing facilities. FDA does not have a list of facilities that had previously registered as human drug compounders before section 503B of the FD&C Act was enacted as there was no category of registered human drug compounder before this. Some human drug compounding facilities may have registered prior to the enactment of section 503B as human drug manufacturers under section 510 of the FD&C Act (21 U.S.C. 360). A list of all firms that are registered as manufacturers under section 510 is available to the public on FDA's Drug Establishments Current Registration Site, which is separate from the list of outsourcing facilities that have registered under section 503B of the FD&C Act.

(Issue 4) Another commenter noted that FDA should define what would constitute an undue burden justifying the granting of a waiver from the submission of registration information electronically.

(Response) Section 503B(b)(3) of the FD&C Act specifies the standard FDA is to use to determine whether a waiver should be granted. FDA may grant a waiver if it finds that ''use of electronic means is not reasonable for the person requesting the waiver.'' FDA does not anticipate many instances in which electronic submission of registration information will not be reasonable for the person requesting the waiver, because the information requested is minimal, and the electronic system for submitting the information is an Internet-based system accessible to all firms seeking to register. 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.

As a result of comments received on the ''Draft Guidance for Industry on Fees for Human Drug Compounding Outsourcing Facilities Under the Federal Food, Drug, and Cosmetic Act,'' FDA has increased its estimates of the number of outsourcing facilities that are subject to each guidance. We now estimate that 50 outsourcing facilities will register and pay establishment fees, and we have adjusted the other estimates in the table (except for the ''average burden per response'') accordingly.

We estimate that 50 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 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 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:

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	50	1	50	4.5	225
Waiver Request From Electronic Submission of Registration Information	1	1	1	1	1
Total					226

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

Dated: August 21, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–20276 Filed 8–26–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0007]

Biosimilar User Fee Rates for Fiscal Year 2015; Correction

AGENCY: Food and Drug Administration, HHS

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''Biosimilar User Fee Rates for Fiscal Year 2015'' that appeared in the **Federal Register** of August 1, 2014 (79 FR 44795). The document announced the rates for biosimilar user fees for fiscal year 2015. The document was published with the incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy, Food and Administration, 10990 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–9115.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Friday, August 1, 2014, in FR Doc. 2014–18112, the following correction is made:

1. On page 44795, in the third column, in the Docket No. heading, ''[Docket No. FDA–2013–N–0007]'' is corrected to read ''[Docket No. FDA–2014–N–0007]''.

Dated: August 21, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

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