

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>—Continued

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
111.570, Records regarding product complaints .....	240	600	144,000	0.5 (30 minutes)	72,000
Total .....					929,140

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

The average burden per recordkeeping estimates in Table 1 of this document are based on those in the June 25, 2007, final rule, which were based on our institutional experience with other CGMP requirements and on data provided by Research Triangle Institute in the “Survey of Manufacturing Practices in the Dietary Supplement Industry” cited in that rule.

The estimates in table 1 of the number of firms affected by each provision of part 111 are based on the percentage of manufacturers, packagers, labelers, holders, distributors, and warehouseers that reported in the survey that they have not established written SOPs or do not maintain records that were later required by the June 25, 2007, final rule. Because we do not have survey results for general warehouses, we entered the approximate number of facilities in that category for those provisions covering general facilities. For the dietary supplement industry, the survey estimated that 1,460 firms would be covered by the final rule, including manufacturers, packagers, labelers, holders, distributors, and warehouseers. The time estimates include the burden involved in documenting that certain requirements are performed and in recordkeeping. We used an estimated annual batch production of 1,408 batches per year to estimate the burden of requirements that are related to the number of batches produced annually, such as § 111.260, “What must the batch production record include?” The estimate of 1,408 batches per year is near the midpoint of the number of annual batches reported by survey firms.

The length of time that CGMP records must be maintained is set forth in § 111.605. Table 1 of this document reflects the estimated burdens for written procedures, record maintenance, periodically reviewing records to determine if they may be discarded, and for any associated documentation for that activity for records that are required under part 111. We have not included a separate estimate of burden for those sections that require maintaining records in accordance with § 111.605, but have included those burdens under

specific provisions for keeping records. For example, § 111.255(a) requires that the batch production records be prepared every time a batch is manufactured, and § 111.255(d) requires that batch production records be kept in accordance with § 111.605. The estimated burdens for both § 111.255(a) and (d) are included under § 111.260, what the batch record must include.

Dated: September 23, 2016.  
**Leslie Kux**,  
*Associate Commissioner for Policy.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2015–N–3326]

**Biosimilar User Fee Act; Public Meeting; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration is correcting a notice entitled “Biosimilar User Fee Act; Public Meeting” that appeared in the **Federal Register** of September 19, 2016 (81 FR 64171). The document announced a public meeting to discuss proposed recommendations for the reauthorization of the Biosimilar User Fee Act (BsUFA) for fiscal years (FYs) 2018 through 2022. The document was published with the incorrect date of the closure of the docket and incorrect transcript information. This document corrects those errors.

**FOR FURTHER INFORMATION CONTACT:** Lisa Granger, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–9115, *lisa.granger@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of Monday, September 19, 2016, in FR Doc. 2016–22442, the following corrections are made:

1. On page 64172, in the first column, in the third sentence of the **DATES**

section, “October 19, 2016” is corrected to read “October 28, 2016.”

2. On page 64175, in the third column, the section “*Transcripts: As soon as a transcript is available, FDA will post it at <http://www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/ucm461774.htm>.” is corrected to read “*Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov> and <http://www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/ucm461774.htm>. It may be viewed at the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency’s Web site at <http://www.fda.gov>.”**

Dated: September 23, 2016.  
**Leslie Kux**,  
*Associate Commissioner for Policy.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources And Services Administration**

**National Vaccine Injury Compensation Program; List of Petitions Received**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of HHS (the Secretary) is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute