DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Comment Request; University Centers for Excellence in Developmental Disabilities Education, Research, and Service—Annual Report

AGENCY: The Administration on Intellectual and Developmental Disabilities (AIDD), Administration for Community Living (ACL), HHS.

ACTION: Notice.

SUMMARY: The Administration on Intellectual and Developmental Disabilities (AIDD), now part of the Administration for Community Living, is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by October 31, 2016.

ADDRESSES: *OIRA_submission@omb.eop.gov* or by fax to 202.395.5806. Attn: OMB Desk Officer for ACL, Office of Information and Regulatory Affairs, OMB.

FOR FURTHER INFORMATION CONTACT: Ophelia McLain at 202–795–7401 *orophelia.mclain@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, the Administration on Intellectual and Developmental Disabilities (now part of the Administration for Community Living) has submitted the following proposed collection of information to OMB for review and clearance.

Section 104 (42 U.S.C. 15004) of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act of 2000) directs the Secretary of Health and Human Services to develop and implement a system of program accountability to monitor the grantees funded under the DD Act of 2000. The program accountability system shall include the National Network of University Centers for Excellence in Developmental Disabilities Education, Research, and Service (UCEDDs) authorized under Part D of the DD Act of 2000. In addition to the accountability system, Section 154 (e) (42 U.S.C. 15064) of the DD Act of 2000 includes requirements for a UCEDD Annual Report.

The proposed data collection tools may be found on the ACL/AIDD Web site at: *http://www.acl.gov/Programs/AIDD/Program_Resource_Search/Results_UCEDD.aspx.* AIDD estimates the burden of this collection of information as 1,412 average burden hours per responses, for 67 UCEDDs,— Total burden is 94,604 hours per year.

Dated: September 22, 2016.

Edwin L. Walker,

Acting Administrator.

[FR Doc. 2016–23488 Filed 9–28–16; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1143]

Use of Nucleic Acid Tests To Reduce the Risk of Transmission of West Nile Virus From Living Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Guidance for Industry; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; correction.

SUMMARY: The Food and Drug Administration (FDA or Agency) is correcting a notice that appeared in the **Federal Register** of Tuesday, September 13, 2016 (81 FR 62910). The document announced the availability of a guidance for industry entitled ''Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Living Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). The document was published with incorrect information of a comment period due date. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Jonathan McKnight, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 13, 2016, in FR Doc. 2016–21969, on page 62910, the following correction is made:

On page 62910, in the first column under the **DATES:** caption, the sentence is corrected to read, ''Submit either electronic or written comments on Agency guidances at any time.''

Dated: September 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–23514 Filed 9–28–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1619]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 invites comments on the information collection provisions of FDA's regulations regarding current good manufacturing practice (CGMP) for dietary supplements.

DATES: Submit either electronic or written comments on the collection of information by November 28, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–1619 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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 dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@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.

Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements—21 CFR Part 111; OMB Control Number 0910–0606—Extension

On October 25, 1994, the Dietary Supplement Health and Education Act (DSHEA) (Pub. L. 103–417) was signed into law. DSHEA, among other things, amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding section 402(g) of the FD&C Act (21 U.S.C. 342(g)). Section 402(g)(2) of the FD&C Act provides, in part, that the Secretary of Health and Human Services may, by regulation, prescribe good manufacturing practices for dietary supplements. Section 402(g) of the FD&C Act also stipulates that such regulations will be modeled after CGMP regulations for food and may not impose standards for which there are no current, and generally available, analytical methodology. Section 402(g)(1) of the FD&C Act states that a dietary supplement is adulterated if ''it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations.'' Under section 701(a) of the FD&C Act (21 U.S.C. 371), FDA may issue regulations necessary for the efficient enforcement of the FD&C Act. In the **Federal Register** of June 25, 2007 (72 FR 34752), (the June 25, 2007, final rule), FDA published a final rule that established, in part 111 (21 CFR part 111), the minimum CGMP necessary for activities related to manufacturing, packaging, labeling, or holding dietary supplements to ensure the quality of the dietary supplement.

Records are an indispensable component of CGMP. The records required by FDA's regulations in part 111 provide the foundation for the planning, control, and improvement processes that constitute a quality control system. Implementation of these processes in a manufacturing operation serves as the backbone to CGMP. The records show what is to be manufactured; what was, in fact, manufactured; and whether the controls that the manufacturer put in place to ensure the identity, purity, strength, and composition and limits on contaminants and to prevent adulteration were effective. Further, records will show whether and what deviations from control processes occurred, facilitate evaluation and corrective action concerning these deviations (including, where necessary, whether associated batches of product should be recalled from the marketplace), and enable a manufacturer to assure that the corrective action was effective. In

addition, by establishing recordkeeping requirements, FDA can ensure that industry follows CGMP during manufacturing, packaging, labeling, or holding operations. The regulations in part 111 establish the minimum manufacturing practices necessary to ensure that dietary supplements are manufactured, packaged, labeled, or held in a manner that will ensure the quality of the dietary supplements during manufacturing, packaging, labeling or holding operations.

The recordkeeping requirements of the regulations include establishing written procedures and maintaining records pertaining to: (1) Personnel; (2) sanitation; (3) calibration of instruments and controls; (4) calibration, inspection, or checks of automated, mechanical, or electronic equipment; (5) maintaining, cleaning, and sanitizing equipment and utensils and other contact surfaces; (6) water used that may become a component of the dietary supplement; (7) production and process controls; (8) quality control; (9) components, packaging, labels and product received for packaging and labeling; (10) master manufacturing and batch production; (11) laboratory operations; (12) manufacturing operations; (13) packaging and labeling operations; (14) holding and distributing operations; (15) returned dietary supplements; and (16) product complaints.

Description of Respondents: Manufacturers, dietary supplement manufacturers, packagers and repackagers, labelers and re-labelers, holders, distributors, warehousers, exporters, importers, large businesses, and small businesses engaged in the dietary supplement industry.

The recordkeeping requirements of the regulations in part 111 are set forth in each subpart. In table 1 of this document, we list the annual burdens associated with recordkeeping, as described in the June 25, 2007, final rule. For some provisions listed in table 1, we did not estimate the number of records per recordkeeper because recordkeeping occasions consist of frequent brief entries of dates, temperatures, monitoring results, or documentation that specific actions were taken. Information might be recorded a few times a day, week, or month. When the records burden involves frequent brief entries, we entered 1 as the default for the number of records per recordkeeper. For example, many of the records listed under § 111.35 in table 1, such as § 111.35(b)(2) (documentation, in individual equipment logs, of the date of the use, maintenance, cleaning, and sanitizing of equipment), involve many short sporadic entries over the course of the year, varying across equipment and plants in the industry. We did not attempt to estimate the actual number of recordkeeping occasions for these provisions, but instead entered an estimate of the average number of hours per year. We entered the default value of 1 as the number of records per recordkeeper for these and similar provisions. For § 111.35, the entry for number of records is 1 as a default representing a large number of brief recordkeeping occasions.

In many rows of table 1 of this document, we list a burden under a single provision that covers the written procedures or records described in several provisions. For example, the burden of the batch production records listed in table 1 under § 111.260 includes the burden for records listed under § 111.255 because the batch production records must include those records. The number of records for batch production records (and other records kept on a batch basis in table 1 of this document) equals the annual number of batches. The estimated burden for records kept by batch includes both records kept for every batch and records kept for some but not all batches. We use the annual number of batches as the number of records that will not necessarily be kept for every batch, such as test results or material review and disposition records, because such records are part of records, if they are necessary, that will be kept for every batch.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
111.14, Records of personnel practices, including documentation of training.	15,000	4	60,000	1	60,000
111.23, Records of physical plant sanitation practices, including pest control and water quality.	15,000	1	15,000	0.2 (12 minutes)	3,000
111.35, Records of equipment and utensils calibration and sanitation practices.	400	1	400	12.5	5,000
111.95, Records of production and process control systems.	250	1	250	45	11,250
111.140, Records that quality control personnel must make and keep.	240	1,163	279,120	1	279,120
111.180, Records associated with components, packaging, labels, and product received for packaging and labeling as a dietary supplement.	240	1,163	279,120	1	279,120
111.210, Requirements for what the master manufacturing record must include.	240	1	240	2.5	600
111.260, Requirements for what the batch record must include.	145	1,408	204,160	1	204,160
111.325, Records that quality control personnel must make and keep for laboratory operations.	120	1	120	15	1,800
111.375, Records of the written procedures established for manufacturing operations.	260	1	260	2	520
111.430, Records of the written procedures for packaging and labeling operations.	50	1	50	12.6	630
111.475, Records of product distribution and procedures for holding and distributing operations.	15,000	1	15,000	0.4 (24 minutes)	6,000
111.535, Records for returned dietary supplements	110	4	440	13.5	5,940

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—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

[1] 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 warehousers 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 warehousers. 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.

[FR Doc. 2016–23521 Filed 9–28–16; 8:45 am]

BILLING CODE 4164–01–P

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.

[FR Doc. 2016–23523 Filed 9–28–16; 8:45 am]

BILLING CODE 4164–01–P

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