Living) has submitted the following proposed collection of information to OMB for review and clearance.

The ''Empowering Older Adults and Adults with Disabilities through Chronic Disease Self-Management Education (CDSME) Programs'' cooperative agreement program is financed through 2012 Prevention and Public Health Funds. The proposed data collection is necessary for monitoring grant program operations and outcomes. AoA proposes to gather information to monitor grantee progress, record location of sites where workshops are held which will allow mapping of the delivery infrastructure, and document participant attendance and demographic and health characteristics. The proposed Participant Survey requests the participants' gender, zip code and birthdate to allow for potential Medicare claims matching and an analysis of changes in health care utilization post participation.

In response to the 60-day **Federal Register** notice related to this proposed data collection and published on July 23, 2013, four sets of comments were received. Concern was expressed about the collection of sensitive personal information. Most of the remaining comments provided suggestions for enhancing the quality and clarity of the information to be collected. The comments resulted in some revisions to the proposed data collection tools. The originally proposed data collection tools, the comments with responses and a revised set of data collection tools may be found on the AoA Web site at: *http://www.aoa.gov/AoARoot/AoA_Programs/Tools_Resources/collection_tools.aspx*.

ACL estimates the burden of this collection of information as 440 hours for State Governments, 1050 hours for local agency staff, and 2,500 hours for individuals—Total burden is 3,990 hours per year.

Dated: March 15, 2013.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2013–06390 Filed 3–19–13; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0242]

Agency Information Collection Activities: Proposed Collection; Comment Request; Current Good Manufacturing Practice for Positron Emission Tomography Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 solicits comments on the information collection contained in FDA's regulations on current good manufacturing practice (CGMP) for positron emission tomography (PET) drugs.

DATES: Submit either electronic or written comments on the collection of information by May 20, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane., Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–7726, *Ila.mizrachi@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 for Positron Emission Tomography Drugs—(OMB Control Number 0910–0667)—Extension

Positron emission tomography is a medical imaging modality involving the use of a unique type of radiopharmaceutical drug product. FDA's CGMP regulations at 21 CFR part 212 are intended to ensure that PET drug products meet the requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) regarding safety, identity, strength, quality, and purity. The CGMP requirements for PET drugs are issued under the provisions of the Food and Drug Administration Modernization Act (FDAMA). These CGMP requirements are designed to take into account the unique characteristics of PET drugs, including their short half-lives and the fact that most PET drugs are produced at locations that are very close to the patients to whom the drugs are administered.

The CGMP regulations are intended to ensure that approved PET drugs meet the requirements of the FD&C Act as to safety, identity, strength, quality, and purity. The regulations address the following matters: Personnel and resources; quality assurance; facilities and equipment; control of components, in-process materials, and finished products; production and process controls; laboratory controls; acceptance

criteria; labeling and packaging controls; distribution controls; complaint handling; and recordkeeping.

The CGMP regulations establish several recordkeeping requirements and a third-party disclosure requirement for the production of PET drugs. In making our estimates of the time spent in complying with these information collection requirements, we relied on communications we have had with PET producers, visits by our staff to PET facilities, and our familiarity with both PET and general pharmaceutical manufacturing practices. The estimated annual recordkeeping and third-party disclosure burden is based on there being approximately 129 PET drug production facilities. Table 1 provides an estimate of the annual recordkeeping burdens. Table 2 provides an estimate of the annual third-party disclosure burdens associated with this collection.

A. Investigational and Research PET Drugs

Section 212.5(b)(2) provides that for investigational PET drugs produced under an investigational new drug (IND) and research PET drugs produced with approval of a Radioactive Drug Research Committee (RDRC), the requirement under the FD&C Act to follow current good manufacturing practice is met by complying with the regulations in part 212 or with USP 32 Chapter 823. We believe that PET production facilities producing drugs under INDs and RDRCs are currently substantially complying with the recordkeeping requirements of USP 32 Chapter 823 (see section 121(b) of the FDAMA), and accordingly, we do not estimate any recordkeeping burden for this provision.

B. Batch Production and Control Records

Sections 212.20(c) through (e), 212.50(a) through (c), and 212.80(c) set forth requirements for batch and production records as well as written control records. We estimate that it would take approximately 20 hours annually for each PET production facility to prepare and maintain written production and control procedures and to create and maintain master batch records for each PET drug produced. We also estimate that there will be a total of approximately 221 PET drugs produced, with a total recordkeeping burden of approximately 4,420 hours. We estimate that it would take a PET production facility an average of 30 minutes to complete a batch record for each of approximately 501 batches. Our estimated burden for completing batch records is approximately 32,315 hours.

C. Equipment and Facilities Records

Sections 212.20(c), 212.30(b), 212.50(d), and 212.60(f) contain requirements for records dealing with equipment and physical facilities. We estimate that it would take approximately 1 hour to establish and maintain these records for each piece of equipment in each PET production facility. We estimate that the total burden for establishing procedures for these records would be approximately 1,935 hours. We estimate that recording maintenance and cleaning information would take approximately 5 minutes a day for each piece of equipment, with a total recordkeeping burden of approximately 40,237 hours.

D. Records of Components, Containers, and Closures

Sections 212.20(c) and 212.40(a), (b), and (e) contain requirements on records regarding receiving and testing of components, containers, and closures. We estimate that the annual burden for establishing these records would be approximately 259 hours. We estimate that each facility would receive approximately 36 shipments annually and would spend approximately 10 minutes per shipment entering records. The annual burden for maintaining these records would be approximately 771 hours.

E. Process Verification

Section 212.50(f)(2) requires that any process verification activities and results be recorded. Because process verification is only required when results of the production of an entire batch are not fully verified through finished-product testing, we believe that process verification will be a very rare occurrence, and we do not estimate any recordkeeping burden for documenting process verification.

F. Laboratory Testing Records

Sections 212.20(c), 212.60(a), (b), and (g), 212.61(a) through (b), and 212.70(a), (b), and (d) set out requirements for documenting laboratory testing and specifications referred to in laboratory testing, including final release testing and stability testing. Each PET drug production facility will need to establish procedures and create forms for the different tests for each product they produce. We estimate that it will take each facility an average of 1 hour to establish procedures and create forms for one test. The estimated annual burden for establishing procedures and creating forms for these records is approximately 3,225 hours, and the annual burden for recording laboratory test results is approximately 10,728 hours.

G. Sterility Test Failure Notices

Section 212.70(e) requires PET drug producers to notify all receiving facilities if a batch fails sterility tests. We believe that sterility test failures might occur in only 0.05 percent of the batches of PET drugs produced each year. Therefore, we have estimated in Table 2 that each PET drug producer will need to provide approximately 0.25 sterility test failure notice per year to receiving facilities. The notice would be provided using email or facsimile transmission and should take no more than 1 hour.

H. Conditional Final Releases

Section 212.70(f) requires PET drug producers to document any conditional final releases of a product. We believe that conditional final releases will be fairly uncommon, but for purposes of the PRA, we estimated that each PET production facility would have one conditional final release a year and would spend approximately 1 hour documenting the release and notifying receiving facilities. The estimate of one conditional final release per year per facility is an appropriate average number because many facilities may have no conditional final releases while others might have only a few.

I. Out-of-Specification Investigations

Sections 212.20(c) and 212.71(a) and (b) require PET drug producers to establish procedures for investigating products that do not conform to specifications and conduct these investigations as needed. We estimate that it will take approximately 1 hour annually to record and update these procedures for each PET production facility. We also estimate, for purposes of the PRA, that 36 out-of-specification investigations would be conducted at each facility each year and that it would take approximately 1 hour to document the investigation, which results in an annual burden of 4,644 hours.

J. Reprocessing Procedures

Sections 212.20(c) and 212.71(d) require PET drug producers to establish and document procedures for reprocessing PET drugs. We estimate that it will take approximately 1 hour a year to document these procedures for each PET production facility. We do not estimate a separate burden for recording the actual reprocessing, both because we believe it would be an uncommon event and because the recordkeeping burden has been included in our estimate for batch production and control records.

K. Distribution Records

Sections 212.20(c) and 212.90(a) require that written procedures regarding distribution of PET drug products be established and maintained. We estimate that it will take approximately 1 hour annually to establish and maintain records of these procedures for each PET production facility. Section 212.90(b) requires that distribution records be maintained. We estimate that it will take approximately 15 minutes to create an actual distribution record for each batch of PET drug products, with a total burden of approximately 16,157 hours for all PET producers.

L. Complaints

Sections 212.20(c) and 212.100 require that PET drug producers establish written procedures for dealing with complaints, as well as document how each complaint is handled. We estimate that establishing and maintaining written procedures for complaints will take approximately 1 hour annually for each PET production facility and that each facility will receive approximately one complaint a year and will spend approximately 30 minutes recording how the complaint was dealt with.

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
212.20(c) and (e); 212.50(a) and (b)	129	1.71	221	20	4,420
212.20(d) and (e); 212.50(c); 212.80(c)	129	501	64,629	.5 (30 min.)	32,315
212.20(c); 212.30(b); 212.50(d), 212.60(f)	129	15	1,935	1	1,935
212.30(b); 212.50(d); 212.60(f)	129	3,758	484,782	.08 (5 min.)	40,237
212.20(c); 212.40(a) and (b)	129	2	258	1	258
212.40(e)	129	36	4,644	.166 (10 min.)	771
212.20(c); 212.60(a) and (b); 212.61(a); 212.70(a), (b), and (d).	129	25	3,225	1	3,225
212.60(g); 212.61(b); 212.70(d)(2) and (d)(3)	129	501	64,629	.16 (10 min.)	10,728
212.70(f)	129	1	129	1	129
212.20(c); 212.71(a)	129	36	4,644	1	4,644
212.71(b)	129	1	129	1	129
212.20(c); 212.71(d)	129	1	129	1	129
212.20(c); 212.90(a)	129	1	129	1	129
212.90(b)	129	501	64,629	.25 (15 min.)	16,157
212.20(c); 212.100(a)	129	1	129	1	129
212.100(b) and (c)	129	1	129	.5 (30 min.)	65
Total					115,400

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

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR Section	Number of respondents	Annual frequency of disclosure	Total annual disclosures	Hours per disclosure	Total hours
212.70(e)	129	.25	32	1	32

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

Dated: March 14, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–06351 Filed 3–19–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1984.

HRSA especially requests comments on: (1) The necessity and utility of the