factor that has increased the costs of the evaluation is that OCSE is using the grants management information system developed for the grantees to monitor their enrollment and service delivery, which requires additional programming and customized reports. Finally, OCSE has asked for an internal memo describing preliminary impact findings which was not included in the FOA.

As a consequences of these unanticipated costs, the $700,000 supplemental grant will be used for the following activities: (1) Conduct the day-to-day operation of the evaluation, including all costs involved in ensuring continued compliance with human subject research requirements; (2) conduct research and analyze information from the multiple implementation sites; (3) conduct the baseline and follow-up surveys; (4) maintain and provide evaluation-related technical assistance to OCSE and the grantees for the grants management information system; and (5) complete an internal memo describing interim impact findings.

Statutory Authority: Section 1115 of the Social Security Act authorizes funds for experimental, pilot, or demonstration projects that are likely to assist in promoting the objectives of Part D of Title IV.

Christopher Beach,

Senior Grants Policy Specialist, Office of Administration.

[FR Doc. 2015–32702 Filed 12–28–15; 8:45 am]

BILLING CODE 4184–42–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Developmental Disabilities Protection and Advocacy Statement of Goals and Priorities

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration on Intellectual and Developmental Disabilities (AIDD), Administration for Community Living (ACL) is announcing an opportunity to comment on the proposed collection of 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 for public comment in response to the notice. This notice collects comments on the information collection requirements relating to an existing collection: Developmental Disabilities Protection and Advocacy Statement of Goals and Priorities (0985–0034).

DATES: Submit written comments on the collection of information by January 28, 2016.

ADDRESSES: Submit written comments on the collection of information by email to *OIRA_submission@omb.eop.gov* Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Clare Barnett, Administration for Community Living, Administration on Intellectual and Developmental Disabilities, Office of Program Support, One Massachusetts Avenue NW., Room 4204, Washington, DC 20201, 202–357–3426.

SUPPLEMENTARY INFORMATION: Federal statute and regulation require each State Protection and Advocacy (P&A) System annually prepare for public comment a Statement of Goals and Priorities (SGP) for the P&A for Developmental Disabilities (PADD) program for each coming fiscal year. Following the required public input for the coming fiscal year, the P&A is required by Federal statute and regulation to submit the final version of the SGP to the Administration on Intellectual and Developmental Disabilities (AIDD). AIDD reviews the SGP for compliance and will aggregate the information in the SGPs into a national profile of programmatic emphasis for P&A Systems in the coming year to provide an overview of program direction, and permit AIDD to track accomplishments against goals and formulate areas of technical assistance and compliance with Federal requirements.

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

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
PADD SGP	57	1	16	912

Estimated Total Annual Burden Hours: 2,508

Dated: December 22, 2015.

Kathy Greenlee,

Administrator & Assistant Secretary for Aging.

[FR Doc. 2015–32667 Filed 12–28–15; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1318]

Electroconvulsive Therapy Devices for Class II Intended Uses: Draft Guidance for Industry, Clinicians, and FDA Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Electroconvulsive Therapy (ECT) Devices for Class II Intended Uses: Draft Guidance for Industry, Clinicians, and FDA Staff.'' The purpose of this guidance is to make recommendations for 510(k) submissions and complying with special controls being proposed to support reclassification of ECT Devices into Class II (special controls) for severe major depressive episode (MDE) associated with Major Depressive Disorder (MDD) or Bipolar Disorder (BPD) in patients 18 years of age and older who are treatment-resistant or who require a rapid response due to the severity of their psychiatric or medical condition. This draft guidance is not final nor is it in effect at this time.

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 of 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 March 28, 2016.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Electroconvulsive Therapy (ECT) Devices for Class II Intended Uses: Draft Guidance for Industry, Clinicians, and FDA Staff'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request. 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–2014–D–1318 for ''Electroconvulsive Therapy (ECT) Devices for Class II Intended Uses: Draft Guidance for Industry, Clinicians and FDA Staff.'' 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: Peter G. Como, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G242, Silver Spring, MD 20993–0002, 301–796–6919.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document provides draft recommendations for 510(k) submissions and complying with special controls being proposed to support reclassification of ECT Devices into Class II (special controls) for severe MDE associated with MDD or BPD in patients 18 years of age and older who are treatment-resistant or who require a rapid response due to the severity of their psychiatric or medical condition. An ECT device is an electrical device used for treating severe psychiatric disturbances by inducing in the patient a major motor seizure by applying a brief intense electrical current to the patient's head. This draft guidance is being issued in conjunction with a **Federal Register** notice announcing the proposal to reclassify this device type for this intended use. This guidance is issued for comment purposes only.

FDA is issuing a proposed administrative order to reclassify ECT devices for the treatment of severe MDE associated with MDD or BPD in patients 18 years of age or older who are treatment-resistant or who require a rapid response due to the severity of their psychiatric or medical condition, which are currently Class III devices, into Class II (special controls) subject to premarket notification. FDA is proposing this reclassification under the Federal Food, Drug and Cosmetic Act (FD&C Act) based on new information pertaining to the device. This guidance is intended to provide recommendations on how to comply with the special controls proposed in 21 CFR 876.5540(b)(1) and indicate what information is suggested for submission to FDA in a 510(k) to demonstrate that the special controls have been met.

II. Significance of Guidance

This 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 ECT devices for Class II intended uses. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Electroconvulsive Therapy (ECT) Devices for Class II Intended Uses: Draft Guidance for Industry, Clinicians, and FDA Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1823 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910–0120; the collection of information in 21 CFR 801 has been approved under OMB control number 0910–0485; and the collection of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

Dated: December 18, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–32591 Filed 12–28–15; 8:45 am]

BILLING CODE 4164–01–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 February 29, 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–0242 for ''Agency Information Collection Activities: Proposed Collection; Comment Request; Current Good Manufacturing Practice for Positron Emission Tomography Drugs.'' 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.