grantees have asked about this element on the current PPR and currently do not have a place to report that information. This is information that most grantees are already collecting. Adding this field will allow grantees to provide this information in a consistent format and allow OCS to more accurately reflect the total number of jobs created through the CED program. Since grantees are already familiar with the current format and elements, and all questions on the PPR will remain the same (with one added question based on grantee feedback), there will be no additional burden on grantees.

Respondents: Current CED grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Questionnaire for current OCS—CED grantees	170	2	1.50	510

Estimated Total Annual Burden Hours: 510.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov*.

OMB Comment:

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2017–00202 Filed 1–9–17; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0008]

Agency Information Collection Activities: Proposed Collection; Comment Request; Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act

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 in the guidance on citizen petitions and petitions for stay of action subject to section 505(q) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the collection of information by March 13, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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–2009–D–0008 for ''Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://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 *https://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 *https://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 10A12M, 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.

Guidance for Industry on Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act, OMB Control Number 0910–0679—Extension

FDA's guidance for industry entitled ''Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act'' provides information regarding FDA's current thinking on interpreting section 914 of Title IX of the Food and Drug Administration Amendments Act (FDAAA) (Pub. L. 110–85). Section 914 of FDAAA added new section 505(q) to the FD&C Act (21 U.S.C. 355(q)) and governs certain citizen petitions and petitions for stay of Agency action that request that FDA take any form of action related to a pending application submitted under section 505(b)(2) or 505(j) (21 U.S.C. 355(b)(2) or 21 U.S.C. 355(j)) of the FD&C Act. The guidance describes FDA's interpretation of section 505(q) of the FD&C Act regarding how the Agency will determine if: (1) The provisions of section 505(q) addressing the treatment of citizen petitions and petitions for stay of Agency action (collectively, petitions) apply to a particular petition and (2) a petition would delay approval of a pending abbreviated new drug application (ANDA) or a 505(b)(2) application. The guidance also describes how FDA will interpret the provisions of section 505(q) requiring that: (1) A petition includes a certification and (2) supplemental information or comments to a petition include a verification. Finally, the guidance addresses the relationship between the review of petitions and pending ANDAs and 505(b)(2) applications for which the Agency has not yet made a decision on approvability.

The Food and Drug Administration Safety and Innovation Act (FDASIA) was signed into law on July 9, 2012 (Pub. L. 112–144). Section 1135 of FDASIA amended section 505(q) of the FD&C Act in two ways. First, it shortened FDA's deadline from 180 days to 150 days for responding to petitions subject to section 505(q) of the FD&C Act. Second, it expanded the scope of section 505(q) of the FD&C Act to include certain petitions concerning applications submitted under section 351(k) of the Public Health Service (PHS) Act (42 U.S.C. 262), the abbreviated pathway for the approval of biosimilar biological products. Accordingly, we are now including submissions pertaining to biosimilar biological product applications in the information collection burden estimates in this document.

Section 505(q)(1)(H) of the FD&C Act requires that citizen petitions and petitions for stay of Agency action that are subject to section 505(q) include a certification to be considered for review by FDA. Section 505(q)(1)(I) of the FD&C Act requires that supplemental information or comments to such citizen petitions and petitions for stay of Agency action include a verification to be accepted for review by FDA. The guidance sets forth the criteria the Agency will use in determining if the provisions of section 505(q) of the FD&C Act apply to a particular citizen petition or petition for stay of Agency action. The guidance states that one of the criteria for a citizen petition or petition for stay of Agency action to be subject to section 505(q) of the FD&C Act is that a related ANDA or 505(b)(2) application is pending at the time the citizen petition or petition for stay is submitted. Because petitioners or commenters may not be aware of the existence of a pending ANDA or 505(b)(2) application, the guidance recommends that all petitioners challenging the approvability of a possible ANDA or 505(b)(2) application include the certification required in section 505(q)(1)(H) of the FD&C Act and that petitioners and commenters submitting supplements or comments, respectively, to a citizen petition or petition for stay of action challenging the approvability of a possible ANDA or 505(b)(2) application include the verification required in section 505(q)(1)(I) of the FD&C Act. The guidance also recommends that if a petitioner submits a citizen petition or petition for stay of Agency action that is missing the required certification but is otherwise within the scope of section 505(q) of the FD&C Act, and the petitioner would like FDA to review the citizen petition or petition for stay of Agency action, the petitioner should submit a letter withdrawing the deficient petition and submit a new petition that contains the required certification.

FDA currently has OMB approval for the collection of information entitled ''General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions'' (OMB control

number 0910–0191). This collection of information includes, among other things: (1) The format and procedures by which an interested person may submit to FDA, in accordance with § 10.20 (21 CFR 10.20), a citizen petition requesting the Commissioner of Food and Drugs (Commissioner) to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action (§ 10.30(b) (21 CFR 10.30(b))); (2) the submission of written comments on a filed citizen petition (§ 10.30(d)); (3) the submission of a supplement or amendment to or a letter to withdraw a filed citizen petition (§ 10.30(g)); (4) the format and procedures by which an interested person may request, in accordance with § 10.20, the Commissioner to stay the effective date of any administrative action (§ 10.35(b) (21 CFR 10.35(b))); and (5) the submission of written comments on a filed petition for administrative stay of action (§ 10.35(c)). This information collection includes citizen petitions, petitions for administrative stay of action, comments to petitions, supplements to citizen petitions, and letters to withdraw a citizen petition, as described previously in this document, which are subject to section 505(q) of the FD&C Act and described in the guidance.

We are requesting OMB approval for the following collection of information submitted to FDA under section 505(q) of the FD&C Act and the guidance:

- The certification required under section 505(q)(1)(H) of the FD&C Act for citizen petitions that are subject to section 505(q) and/or that are challenging the approvability of a possible ANDA, 505(b)(2) application, or biosimilar biological product application. Although the submission of a certification for citizen petitions is approved under OMB control number 0910–0191, the certification would be broadened under section 505(q) of the FD&C Act and the guidance.
- The certification required under section 505(q)(1)(H) of the FD&C Act for petitions for stay of Agency action that are subject to section 505(q) and/or that are challenging the approvability of a possible ANDA, 505(b)(2) application, or biosimilar biological product application.
- The verification required under section 505(q)(1)(I) of the FD&C Act for comments to citizen petitions.
- The verification required under section 505(q)(1)(I) of the FD&C Act for comments to petitions for stay of Agency action.
- The verification required under section 505(q)(1)(I) of the FD&C Act for supplements to citizen petitions.
- Supplements to petitions for stay of Agency action.
- The verification required under section 505(q)(1)(I) of the FD&C Act for supplements to petitions for stay of Agency action.
- The letter submitted by a petitioner withdrawing a deficient petition for stay of Agency action that is missing the required certification but is otherwise within the scope of section 505(q) of the FD&C Act.

Section 505(q)(1)(B) and (C) of the FD&C Act and the guidance state that if FDA determines that a delay in approval of an ANDA, 505(b)(2) application, or biosimilar biological product application is necessary based on a petition subject to section 505(q), the applicant may submit to the petition docket clarifications or additional data to allow FDA to review the petition promptly. This information collection is not included in this analysis because it is currently approved under OMB control number 0910–0001 (21 CFR 314.54, 314.94, and 314.102).

Based on FDA's knowledge of citizen petitions and petitions for stay of Agency action subject to section 505(q) of the FD&C Act that have been submitted to FDA, as well as the Agency's familiarity with the time needed to prepare a supplement, a certification, and a verification, FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C Act section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Certification for citizen petitions (505(q)(1)(H))	38	1.37	52	0.5 (30 minutes)	26
Certification for petitions for stay of Agency action (505(q)(1)(H)).	3	1	3	0.5 (30 minutes)	1.5
Verification for comments to citizen petitions (505(q)(1)(I)).	12	1.66	20	0.5 (30 minutes)	10
Verification for comments to petitions for stay of Agency action (505(q)(1)(I)).	1	1	1	0.5 (30 minutes)	.5
Verification for supplements to citizen petitions (505(q)(1)(I)).	7	2.29	16	0.5 (30 minutes)	8
Supplements to petitions for stay of Agency action	1	1	1	6	6
Verification for supplements to petitions for stay of Agency action (505(q)(1)(I)).	1	1	1	0.5 (30 minutes)	0.5
Letter withdrawing a petition for stay of Agency action.	3	1	3	0.5 (30 minutes)	1.5
Total hours					54

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

Dated: January 3, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00193 Filed 1–9–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–2175]

Recommendations for Assessment of Blood Donor Eligibility, Donor Deferral and Blood Product Management in Response to Ebola Virus; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled ''Recommendations for Assessment of Blood Donor Eligibility, Donor Deferral and Blood Product Management in Response to Ebola Virus; Guidance for Industry.'' The guidance document notifies blood establishments that FDA has determined Ebola virus to be a transfusion-transmitted infection (TTI) and provides blood establishments that collect blood and blood components for transfusion or further manufacture, including Source Plasma, with FDA recommendations for assessing blood donor eligibility, donor deferral, and blood product management in the event that an outbreak of Ebola virus disease (EVD) with widespread transmission is declared in at least one country. The guidance document applies to Ebola virus (species *Zaire ebolavirus*). The recommendations apply to routine collection of blood and blood components for transfusion or further manufacture, including Source Plasma. The guidance announced in this notice finalizes the draft guidance of the same title dated December 2015.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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–2175 for ''Recommendations for Assessment of Blood Donor Eligibility, Donor Deferral and Blood Product Management in Response to Ebola Virus; Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://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 *https://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 *https://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.

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jessica T. Walker, 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:

I. Background

FDA is announcing the availability of a document entitled ''Recommendations for Assessment of Blood Donor Eligibility, Donor Deferral and Blood Product Management in Response to Ebola Virus; Guidance for Industry.'' The guidance document notifies blood establishments that FDA has determined Ebola virus to be a TTI under 21 CFR