(74 FR 47804). After consideration of comments received in response to the draft guidance, the guidance was restructured to describe general approaches to microbiology data collection in the body of the guidance and to provide more specific recommendations in appendixes (*e.g.,* the format for microbiology data presentation and an example for sections of labeling that pertain to microbiology).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the development, analysis, and presentation of microbiology data for systemic antibacterial drugs. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This 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).

1. This guidance provides recommendations on the type of information to include in submissions of the clinical microbiology section of investigational new drug applications (INDs) and new drug applications (NDAs) for systemic antibacterial drugs. The microbiology section of an NDA is required under 21 CFR 314.50(d)(4) and this information collection is approved under OMB control number 0910–0001. For INDs, this information is required under 21 CFR 312.23(a) and approved under OMB control number 0910–0014.

2. This guidance also recommends the types of data that should be submitted in a labeling supplement to update the microbiology information in approved labeling if an application holder chooses to update this information without relying on a standard recognized by FDA. The submission of labeling supplements is required under 21 CFR 314.70(b)(2)(v) and 201.56(a)(2) and this information collection is approved under OMB control numbers 0910–0001 and 0910–0572, respectively.

3. Appendix D of this guidance describes the content of the Microbiology subsection of labeling. This labeling is covered under 21 CFR 201.57(c)(13)(i) and the information collection is approved under OMB control number 0910–0572.

4. This guidance also references the guidance for industry entitled ''Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices'' for updating labeling information. The information collection in this guidance has been approved under OMB control number 0910–0638.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: August 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–20473 Filed 8–25–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2496]

Agency Information Collection Activities; Proposed Collection; Comment Request; User Account Management Function for the Import Trade Auxiliary Communication System

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, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information required to implement user account management function in FDA's Import Trade Auxiliary Communication System (ITACS). Secure user accounts will allow import trade users to receive Notices of FDA Action and requests for specific information via email or via download within ITACS.

DATES: Submit either electronic or written comments on the collection of information by October 25, 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–2016–N–2496 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; User Account Management Function for the Import Trade Auxiliary Communication System.'' 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, 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 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.

Account Management Function for the Import Trade Auxiliary Communication System—OMB Control Number 0910–NEW

ITACS currently provides the import trade community with four functions: The ability to check the status of FDA-regulated entries and lines, the ability to submit entry documentation electronically, the ability to electronically submit the location of goods for those lines targeted for FDA physical examination, and the ability to check estimated laboratory analysis completion dates. No user login accounts are currently necessary to access these functions; all that is necessary is a valid customs entry number that has been successfully transmitted to FDA.

FDA has developed ITACS user account management functionality. Implementation of this functionality would allow members of the import trade community to create and manage secure user accounts in ITACS, which would enable FDA to distribute Notices of FDA Action to users electronically via email (rather than regular mail), enable users to download Notices of FDA Action from within ITACS, and allow users to view in ITACS the details of specific information requests which are currently delivered via hard copy Notices of FDA Action. ITACS user account management functionality would also allow for potential future ITACS enhancements, requested by the import trade community, that require user authentication.

To create a secure user account for ITACS via the user account management function, a person would have to enter basic information such as the person's name, their employer's name, a contact email address, an account password, etc., into ITACS via the user account management function interface.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Creation of ITACS account	5,000	1	5,000	0.5 (30 minutes)	2,500

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

Dated: August 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–20472 Filed 8–25–16; 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, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (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 Health and Human Services 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 with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place NW., Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, MD 20857; (301) 443–6593, or visit our Web site at: *http://www.hrsa.gov/vaccinecompensation/index.html.*

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that ''[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**.'' Set forth below is a list of petitions received by HRSA on July 1, 2016, through July 31, 2016. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master ''shall afford all interested persons an opportunity to submit relevant, written information'' relating to the following:

1. The existence of evidence ''that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,'' and

2. Any allegation in a petition that the petitioner either:

a. ''[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by'' one of the vaccines referred to in the Table, or

b. ''[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine'' referred to in the Table.

In accordance with Section 2112(b)(2), all interested persons may submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the U.S. Court of Federal Claims at the address listed above (under the heading ''For Further Information Contact''), with a copy to HRSA addressed to Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, 5600 Fishers Lane, 08N146B, Rockville, Maryland 20857. The Court's caption (Petitioner's Name v. Secretary of Health and Human Services) and the docket number assigned to the petition should be used as the caption for the written submission. Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

Dated: August 18, 2016.

James Macrae,

Acting Administrator.

List of Petitions Filed

1. Joel Flores, San Antonio, Texas, Court of Federal Claims No: 16–0788V.
2. Katie Tambouris, Manchester, New Hampshire, Court of Federal Claims No: 16–0790V.
3. Cassie Keener, Fort Worth, Texas, Court of Federal Claims No: 16–0791V.
4. Manya Cetlin-Salter, Exeter, New Hampshire, Court of Federal Claims No: 16–0792V.
5. Gabrielle Salomone, Philadelphia, Pennsylvania, Court of Federal Claims No: 16–0795V.
6. Tara Hurley, Pawtucket, Rhode Island, Court of Federal Claims No: 16–0797V.
7. Malka Nussbaum on behalf of S. N., Queens, New York, Court of Federal Claims No: 16–0799V.
8. Donna Deaton, Gibsonville, North Carolina, Court of Federal Claims No: 16–0802V.
9. Fredric C. Thompson, Gray, Maine, Court of Federal Claims No: 16–0803V.
10. Sharlee Funai, Wailuku, Hawaii, Court of Federal Claims No: 16–0807V.
11. Dolores Soltero Arias, Auburn, Washington, Court of Federal Claims No: 16–0808V.
12. Luisa Gomes, Dorchester, Massachusetts, Court of Federal Claims No: 16–0809V.
13. Linda Saucedo, Indialantic, Florida, Court of Federal Claims No: 16–0810V.
14. Tasha Loyd on behalf of C. L., Tampa, Florida, Court of Federal Claims No: 16–0811V.
15. Rebekah R. Codde on behalf of I. R. H., Sacramento, California, Court of Federal Claims No: 16–0812V.
16. Maureen Revaitis and Chris Revaitis on behalf of J. R. Marlton, New Jersey, Court of Federal Claims No: 16–0813V.
17. Mary Butler, San Mateo, California, Court of Federal Claims No: 16–0814V.
18. David Palmieri, Galloway, New Jersey, Court of Federal Claims No: 16–0818V.
19. Connor Toes, Phoenix, Arizona, Court of