

C. Notice Upon Completion of Evaluation

Upon completion of our evaluation, including evaluation of public comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

IV. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of

this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Dated: July 20, 2018.

Seema Verma,
Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018-15951 Filed 7-23-18; 4:15 pm]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: National Youth in Transition Database (NYTD) and Youth Outcomes Survey.

OMB No.: 0970-0340.

Description: The John H. Chafee Foster Care Program for Successful Transition to Adulthood (42 U.S.C. 677,

as amended by Pub. L. 115-123, the Family First Prevention Services Act within Division E, Title VII of the Bipartisan Budget Act of 2018) requires State child welfare agencies to collect and report to the Administration for Children and Families (ACF) data on the characteristics of youth receiving independent living services and information regarding their outcomes. The regulation implementing the National Youth in Transition Database (NYTD), listed in 45 CFR 1356.80, contains standard data collection and reporting requirements for States to meet the law's requirements. ACF uses the information collected under the regulation to track independent living services, assess the collective outcomes of youth, and assess performance with regard to those outcomes, consistent with the law's mandate.

Respondents: State agencies (including agencies of the District of Columbia, Puerto Rico and the U.S. Virgin Islands) that administer the John H. Chafee Foster Care Program for Successful Transition to Adulthood.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Youth Outcome Survey	21,064	1	0.50	10,529
Data File	53	2	1,849	195,994

Estimated Total Annual Burden Hours: 206,253.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chap 35), the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the

proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,
Reports Clearance Officer.

[FR Doc. 2018-15989 Filed 7-25-18; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1011]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Permanent Discontinuation or Interruption in Manufacturing of Certain Drug and Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 27, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0759. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Permanent Discontinuation or Interruption in Manufacturing of Certain Drug and Biological Products—21 CFR 310.306, 314.81(b)(3)(iii), and 600.82

OMB Control Number 0910-0759—Extension

Sections 310.306, 314.81(b)(3)(iii), and 600.82 (21 CFR 310.306, 314.81(b)(3)(iii), and 600.82) were modified to implement sections 506C and 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c and 356e) as amended by the Food and Drug Administration Safety and Innovation Act. Under these sections, applicants with an approved new drug application (NDA) or abbreviated new drug application (ANDA) for a covered drug product marketed without an approved application, and applicants with an approved biologics license application (BLA) for a covered biological product (including certain applications of blood or blood components) must notify FDA in writing of a permanent discontinuance of the manufacture of the drug or biological product, or an interruption in

manufacturing of the drug or biological product, that is likely to lead to a meaningful disruption in the applicant's supply (or a significant disruption for blood or blood components) of that product. The notification is required if the drug or biological product is life supporting, life sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition, including use in emergency medical care or during surgery, and if the drug or biological product is not a radiopharmaceutical drug product.

The regulations also require that the notification include the following information: (1) The name of the drug or biological product subject to the notification, including the National Drug Code Directory (NDC) (or, for a biological product that does not have an NDC, an alternative standard for identification and labeling that has been recognized as acceptable by the Center Director); (2) the name of each applicant of the drug or biological product; (3) whether the notification relates to a permanent discontinuance of the drug or biological product or an interruption in manufacturing of the product; (4) a description of the reason for the permanent discontinuance or interruption in manufacturing; and (5) the estimated duration of the interruption in manufacturing. The notification must be submitted to FDA electronically at least 6 months prior to the date of the permanent discontinuance or interruption in manufacturing. If 6 months' advance notice is not possible because the permanent discontinuance or interruption in manufacturing was unanticipated 6 months in advance, the applicant must notify FDA as soon as practicable, but in no case later than 5 business days after the permanent discontinuance or interruption in manufacturing occurs.

If an applicant fails to submit the required notification, FDA will issue a letter informing the applicant or manufacturer of its noncompliance. The applicant must submit to FDA, not later than 30 calendar days after FDA issues the letter, a written response setting

forth the basis for noncompliance and providing the required notification.

Description of Respondents: Applicants of prescription drugs and biological products subject to an approved NDA, ANDA, or BLA, and manufacturers of prescription drug products marketed without an approved ANDA or NDA, if the product is life supporting, life sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition, including use in emergency medical care or during surgery, or is not a radiopharmaceutical product. If the BLA applicant is a manufacturer of blood or blood components, it is only subject to these regulations if it manufactures a significant percentage of the nation's blood supply.

Burden Estimates: Based on the number of drug and biological product shortage related notifications we have seen in the past 12 months, we estimate that annually a total of approximately 75 respondents ("No. of Respondents" in table 1) will notify us of a permanent discontinuance of the manufacture of a drug or biological product or an interruption in manufacturing of a drug or biological product that is likely to lead to a meaningful disruption in the respondent's supply of that product. We estimate that these respondents will submit annually a total of approximately 352.5 notifications as required under §§ 310.306, 314.81(b)(3)(iii), and 600.82. We estimate 4.7 notifications per respondent, because a respondent may experience multiple discontinuances or interruptions in manufacturing in a year that requires notification ("No. of Responses per Respondent" in table 1). We also estimate that preparing and submitting these notifications to FDA will take approximately 2 hours per respondent ("Average Burden per Response" in table 1).

In the **Federal Register** of April 13, 2018, (83 FR 16108), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED REPORTING BURDEN¹

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notifications required under §§ 310.306 (unapproved drugs), 314.81(b)(3)(iii) (products approved under an NDA or ANDA), and 600.82 (products approved under a BLA)	75	4.7	352.5	2	705

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

The estimated burden for this information collection has changed since the previous OMB approval. The current burden is based on the number of actual new notifications received including notifications that were counted previously under the OMB approval for the interim final rule entitled "Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products" (80 FR 38915, July 8, 2015) (OMB control number 0910-0699).

Dated: July 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-15948 Filed 7-25-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Charter Renewal for the Advisory Commission on Childhood Vaccines

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of charter renewal.

SUMMARY: HHS is hereby giving notice that the Advisory Commission on Childhood Vaccines (ACCV) has been rechartered. The effective date of the renewed charter is July 20, 2018.

FOR FURTHER INFORMATION CONTACT: Narayan Nair, MD, MPH, Executive Secretary, Advisory Commission on Childhood Vaccines, Health Resources and Services Administration, Department of Health and Human Services, Room 08N146B, 5600 Fishers Lane, Rockville, MD 20857; phone: (301) 443-6593; fax: (301) 443-8196; email: nnair@hrsa.gov.

SUPPLEMENTARY INFORMATION: The ACCV was established by section 2119 of the Public Health Service Act (the Act) (42 U.S.C. 300aa-19), as enacted by Public Law (Pub. L.) 99-660, and as subsequently amended, and advises the Secretary of Health and Human Services (the Secretary) on issues related to implementation of the National Vaccine Injury Compensation Program (VICP). Other activities of the ACCV include: Recommending changes in the Vaccine Injury Table at its own initiative or as the result of the filing of a petition; advising the Secretary in implementing section 2127 of the Act regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; surveying federal, state, and local programs and activities related to gathering information on injuries associated with

the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b) of the Act; advising the Secretary on the methods of obtaining, compiling, publishing, and using credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; consulting on the development or revision of Vaccine Information Statements; and recommending to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the VICP.

The charter renewal for ACCV was approved on July 20, 2018, which will also stand as the filing date. Renewal of the ACCV charter gives authorization for the Commission to operate until July 20, 2020.

A copy of the ACCV charter is available on the VICP website at: <https://www.hrsa.gov/advisory-committees/vaccines/index.html>. A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is <http://www.facadatabase.gov/>.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018-15994 Filed 7-25-18; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special

Emphasis Panel; NIAID Resource-Related Research Projects (R24).

Date: August 23, 2018.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Dharmendar Rathore, Ph.D., Senior Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G30, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892-9823, 240-669-5058, rathored@mail.nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Implementation Cooperative Agreement (U01).

Date: August 24, 2018.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Chelsea D. Boyd, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 5601 Fishers Lane, MSC 9823, Rockville, MD 20852-9834, 240-669-2081, chelsea.boyd@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: July 20, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-15953 Filed 7-25-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5976-N-07]

Housing Opportunity Through Modernization Act of 2016: Final Implementation of Public Housing Income Limit

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: The Housing Opportunity Through Modernization Act of 2016 (HOTMA) was signed into law on July 29, 2016. One of the statutory amendments made by HOTMA adds an income limit to the Public Housing program. This notice informs the public of how HUD is setting that income limit and makes the income limit effective, while providing information to public