52.247–64 a statement on vouchers involving such transportation. The contracting officer uses the information furnished in the statement to determine whether adequate justification exists for the contractor's use of other than a U.S.-flag air carrier.

B. Annual Reporting Burden

Respondents: 150.
Responses Per Respondent: 2.
Annual Responses: 300.
Hours per Response: .25.
Total Burden Hours: 75.

C. Public Comments

A notice was published in the **Federal Register** at 83 FR 12949 on March 26, 2018. No comments were received. Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street, NW, Washington, DC, 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0054, U.S.-Flag Air Carriers Statement, in all correspondence.

Dated: June 29, 2018.

William F. Clark,

Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2018–14409 Filed 7–3–18; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organizations, Functions, and Delegations of Authority

AGENCY: Office of Foods and Veterinary Medicine, Center for Food Safety and Applied Nutrition, Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: Statement of Organizations, Functions, and Delegations of Authority.

The Food and Drug Administration (FDA) is announcing that it has reorganized the Office of Foods and Veterinary Medicine (OFVM), Center for Food Safety and Applied Nutrition (CFSAN) by establishing the new Office of Executive Programs (OEP); realigning OFVM's Office of Coordinated Outbreak Response and Evaluation (CORE) Network along with its Prevention Staff and Response Staff under CFSAN; and retitling the Office of Regulations, Policy, and Social Science (ORPSS) to the Office of Regulations and Policy (ORP). With the retitling to ORP, the Regulations and Special Government Employee Management Staff was retitled to the Regulations Development Staff, and the Government Information Staff was established. This reorganization resulted in the abolishment of OFVM's Executive Secretariat Staff, CFSAN's Office of the Center Director's (OCD) Executive Operations Staff, and the Division of Social Sciences under the former ORPSS. This new organizational structure was approved by the Acting Secretary of Health and Human Services and applicable on December 7, 2017.

FOR FUTHER INFORMATION CONTACT: Jeffrey Domanski, Associate Director for Management, Center for Food Safety and Applied Nutrition, Office of Foods and Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, 240–402–2471.

I. Part D, Chapter D–B, (Food and Drug Administration), the Statement of Organizations, Functions, and Delegations of Authority for the Department of Health Human Services (35 FR 3685, February 25, 1970; 60 FR 56605, November 9, 1995; 64 FR 36361, July 6, 1999; 72 FR 50112, August 30, 2007; 74 FR 41713, August 18, 2009; and 76 FR 45270, July 28, 2011) is amended to reflect the realigning of functions and personnel from OFVM's abolished Executive Secretariat Staff and CFSAN OCD's Executive Operations Staff to the newly established OEP, which will strengthen OFVM's capacity to coordinate across the various components of the Foods and Veterinary Medicine Program and better meet the day-to-day needs of its senior leadership. CORE is now reflected under CFSAN to facilitate greater collaboration, coordination, and leveraging of resources. ORP formalizes previous informal programs clarifying staff allocation, management, and leadership for internal and external stakeholders. This reorganization is explained in Staff Manual Guides 1160.1, 1230A.1, 1231.10, 1231.19, 1231.22, 1231.23, and 1241.1.

FDA, OFVM and CFSAN have been restructured as follows:

DJJ Organization. OFVM is headed by the Deputy Commissioner for Foods and Veterinary Medicine and includes the following organizational units:

Office of Foods and Veterinary Medicine (DJJ)
Communications and Public Engagement Staff (DJJ1)
Office of Resource Planning and Strategic Management (DJJA)
Center for Food Safety and Applied Nutrition (DJJH) Center for Veterinary Medicine (DJJV)

DJJH Organization. CFSAN is headed by the Center Director and includes the following organizational units:

Center for Food Safety and Applied Nutrition (DJJH)
Office of the Center Director (DJJHA)
Office of Management (DJJHB)
Office of Analytics and Outreach (DJJHC)
Office of Food Safety (DJJHD)
Office of Cosmetics and Colors (DJJHE)
Office of Regulatory Science (DJJHF)
Office of Food Additive Safety (DJJHG)
Office of Compliance (DJJHH)
Office of Applied Research and Safety Assessment (DJJHI)
Office of Regulations and Policy (DJJHJ)
Office of Nutrition and Food Labeling (DJJHK)
Office of Dietary Supplement Programs (DJJHL)
Office of Executive Programs (DJJHM)
Office of Coordinated Outbreak Response and Evaluation Network (DJJHN)

DJJHJ Organization. ORP is headed by the Office Director and includes the following organizational units:

Office of Regulations and Policy (DJJHJ)
Regulations Development Staff (DJJHJ1)
Government Information Staff (DJJHJ2)

DJJHM Organization. OEP is headed by the Office Director and includes the following organizational unit:

Office of Executive Programs (DJJHM)

DJJHN Organization. CORE is headed by the Office Director and includes the following organizational units:

Office of Coordinated Outbreak Response and Evaluation Network (DJJHN)
Prevention Staff (DJJHN1)
Response Staff (DJJHN2)

I. *Delegations of Authority.* Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations

of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

II. *Electronic Access.* Persons interested in seeing the completed Staff Manual Guide can find it on FDA's Webs site at: *http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.*

(Authority: 44 U.S.C. § 3101.)

Dated: June 28, 2018.

Alex M. Azar II,

Secretary.

[FR Doc. 2018–14375 Filed 7–3–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5670]

Abbreviated New Drug Application Submissions—Amendments to Abbreviated New Drug Applications Under the Generic Drug User Fee Act; 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 final guidance for industry entitled ''ANDA Submissions—Amendments to Abbreviated New Drug Applications Under GDUFA.'' This guidance finalizes the October 2017 draft guidance for industry ''ANDA Submissions—Amendments to Abbreviated New Drug Applications Under GDUFA.'' This guidance is intended to explain to applicants how the review goals established as part of the Generic Drug User Fee Amendments Reauthorization of 2017 (GDUFA II) apply to amendments to either abbreviated new drug applications (ANDAs) or prior approval supplements (PASs) submitted to FDA under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance describes amendment classifications and categories and explains how amendment submissions may affect an application's review goal dates. The guidance also describes how FDA will review amendments submitted to ANDAs and PASs received prior to October 1, 2017, the effective date to implement the GDUFA II review goals.

DATES: The announcement of the guidance is published in the **Federal Register** on July 5, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2017–D–5670 for ''ANDA Submissions—Amendments to Abbreviated New Drug Applications Under GDUFA.'' 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 Dockets Management Staff 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 Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1670, Silver Spring, MD 20993–0002, 240–