

B. The Division of Strategy, Policy, and Governance responsibilities include strategy, policy, and IT governance, including performance measurement and innovation. Provides governance and oversight of centralized enterprise-wide IT functions, including enterprise architecture, creation and maintenance of the technology roadmap.

C. The Division of Security, Privacy, and Risk Management provides security, privacy, and risk management, including business continuity, standardization and oversight of business processes, external compliance, and security strategy and management. The OCIO will identify the appropriate continuing education for staff in the domain of records management, IT security and privacy, and incident response protocols.

D. The Division of Infrastructure, Data and Web Services provides service planning and architecture, program and project management, portfolio management, applications management, development and maintenance, and IT infrastructure and operations, including data services, big data analytics, and business intelligence.

III. Under KP, Office of the Deputy Assistant Secretary for Administration, delete KP.00 Mission in its entirety and replace with:

KP.00 MISSION. The Deputy Assistant Secretary for Administration serves as principal advisor to the Assistant Secretary for Children and Families on all aspects of personnel administration and management; financial management activities; grants policy and overseeing the issuance of grants; acquisition advisory services; the ethics program; staff development and training activities; organizational development and organizational analysis; administrative services; and facilities management. The Deputy Assistant Secretary for Administration oversees the Diversity Management and Equal Employment Opportunity program and all administrative special initiative activities for ACF.

IV. Under Chapter KP, Office of the Deputy Assistant Secretary for Administration, delete KP.10 Organization in its entirety and replace with:

KP.10 ORGANIZATION. The Office of the Deputy Assistant Secretary for Administration is headed by the Deputy Assistant Secretary who reports to the Assistant Secretary for Children and Families. The Office is organized as follows:

Immediate Office of the Deputy Assistant Secretary for Administration (KPA)
Office of Financial Services (KPC)

Office of Workforce Planning and Development (KPD)

Office of Grants Management (KPG)
Grants Management Regional Units (KPGDI-X)

Office of Diversity Management and Equal Employment Opportunity (KPH)

V. Under Chapter KP, Office of the Deputy Assistant Secretary for Administration, Delete KP.20 Functions, Paragraph B, Office of Information Systems, in its entirety.

VI. Under Chapter KN, Office of Communications, delete KN.20, Functions, Paragraph C, in its entirety and replace with the following:

Division of Digital Information is responsible for the content of ACF's public-facing digital presence. It also coordinates printing services for ACF. The division conducts preparation and clearance of ACF communications associated with web content, audiovisual products, digital publications and graphic designs, but does not include planning, budgeting, and oversight of the Web site maintenance and support contract. It provides guidance and support to program offices related to web content, social media, print publications, audiovisual materials, and digital information and communication activities.

VII. *Delegation of Authority.* Pending further redelegation, directives, or orders made by the Assistant Secretary for Children and Families or Deputy Assistant Secretary for Administration, 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.

VIII. *Funds, Personnel, and Equipment.* Transfer of organizations and functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies, and other resources.

Dated: July 21, 2016.

Mark H. Greenberg,

Acting Assistant Secretary for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public to attend in person at the FDA White Oak campus in Silver Spring, MD. Members will participate via teleconference.

DATES: The meeting will be held on October 13, 2016, from 1 p.m. to 4:30 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>. For those unable to attend in person, the meeting will also be Webcast and will be available at the following link: <https://collaboration.fda.gov/vrbpac101316/>.

FOR FURTHER INFORMATION CONTACT: Sujata Vijh or Rosanna Harvey, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6128, Silver Spring, MD 20993-0002, at 240-402-7107, sujata.vijh@fda.hhs.gov and 240-402-8072, rosanna.harvey@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting

link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On October 13, 2016, the committee will meet in open session to discuss and make recommendations on the selection of strains to be included in an influenza virus vaccine for the 2017 southern hemisphere influenza season.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 3, 2016. Oral presentations from the public will be scheduled between approximately 2:30 p.m. and 3:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 23, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 26, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Sujata Vijh at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 21, 2016.

Janice M. Soreth,

Acting Associate Commissioner, Special Medical Programs.

[FR Doc. 2016-17729 Filed 7-26-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0007]

Generic Drug User Fee—Abbreviated New Drug Application, Prior Approval Supplement, Drug Master File, Final Dosage Form Facility, and Active Pharmaceutical Ingredient Facility Fee Rates for Fiscal Year 2017

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for abbreviated new drug applications (ANDAs), prior approval supplements to an approved ANDA (PASs), drug master files (DMFs), generic drug active pharmaceutical ingredient (API) facilities, and finished dosage form (FDF) facilities user fees related to the Generic Drug User Fee Program for fiscal year (FY) 2017. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Generic Drug User Fee Amendments of 2012 (GDUFA), authorizes FDA to assess and collect user fees for certain applications and supplements for human generic drug products, on applications in the backlog as of October 1, 2012 (only applicable to FY 2013), on FDF and API facilities, and on type II active pharmaceutical ingredient DMFs to be made available for reference. This document establishes the fee rates for FY 2017.

FOR FURTHER INFORMATION CONTACT:

David Haas, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE-14202I, Silver Spring, MD 20993-0002, 240-402-9845.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744A and 744B of the FD&C Act (21 U.S.C. 379j-41 and 379j-42) establish fees associated with human generic drug products. Fees are assessed on: (1) Certain applications in the backlog as of October 1, 2012 (only applicable to FY 2013); (2) certain types of applications and supplements for human generic drug products; (3) certain facilities where APIs and FDFs are produced; and (4) certain DMFs associated with human generic drug products (see section 744B(a)(1)-(4) of the FD&C Act).

For FY 2017, the generic drug fee rates are: ANDA (\$70,480), PAS (\$35,240), DMF (\$51,140), domestic API facility (\$44,234), foreign API facility (\$59,234), domestic FDF facility (\$258,646), and foreign FDF facility (\$273,646). These fees are effective on October 1, 2016, and will remain in effect through September 30, 2017.

Fees for ANDA and PAS will decrease in FY 2017 compared to the FY 2016 fees due to an increase in the number of submissions estimated to be submitted in FY 2017 compared to the estimated number of submissions to be submitted in FY 2016. Fees for DMFs will increase in FY 2017 compared to the FY 2016 fee due to a decrease in the number of submissions estimated to be submitted in FY 2017 compared to the estimated number of submissions to be submitted in 2016. The fees for all types of facilities will increase in FY 2017 compared to the FY 2016 fees in due to a decrease in the number of facilities that self-identified for FY 2017.

II. Fee Revenue Amount for FY 2017

The base revenue amount for FY 2017 is \$299 million, as set in the statute prior to the inflation and final year adjustments (see section 744B(c)(2) of the FD&C Act). GDUFA directs FDA to use the yearly revenue amount as a starting point to set the fee rates for each fee type. For more information about GDUFA, please refer to the FDA Web site (<http://www.fda.gov/gdufa>). The ANDA, PAS, DMF, API facility, and FDF facility fee calculations for FY 2017 are described in this document.

A. Inflation Adjustment

GDUFA specifies that the \$299 million is to be adjusted for inflation increases for FY 2017 using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 744B(c)(1) of the FD&C Act).

The component of the inflation adjustment for PC&B costs shall be one