FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board’s Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)). The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board’s Freedom of Information Office at https://www.federalreserve.gov/foia/request.htm. Interested persons may express their views in writing on the standards enumerated in the paragraph 7 of the Act. Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551–0001, not later than August 31, 2021.

1. The CAOS Family Irrevocable Trust, Bradley D. Simington, individually and as co-trustees with Teresa J. Simington, all of Milford, Iowa; to form the CAOS Family Irrevocable Trust control group, a group acting in concert, to retain voting shares of Fostoria Bankshares, Inc., and thereby indirectly retain voting shares of Farm Savings Bank, both of Postoria, Iowa.

Board of Governors of the Federal Reserve System, August 11, 2021.
Ann Misback,
Secretary of the Board.

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 et seq.) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board’s Freedom of Information Office at https://www.federalreserve.gov/foia/request.htm. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551–0001, not later than September 15, 2021.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:


Board of Governors of the Federal Reserve System, August 11, 2021.
Ann Misback,
Secretary of the Board.

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special review process. In addition, the Federal Travel Regulation (FTR) allows for actual expense reimbursement as provided in §§301–1.300 through 301–11.306.

For FY 2022, all current non-standard area (NSA) maximum lodging allowance rates will remain at FY 2021 levels. The standard lodging rate will also remain unchanged at $96. The M&E reimbursement rates were revised for FY 2022; they were last revised in FY 2019. The M&E NSA tiers are revised from $56–$76 to $59–$79, and the standard M&E rate is revised from $55 to $59.

Notices published periodically in the Federal Register now constitute the only notification of revisions in CONUS per diem reimbursement rates to agencies, other than the changes posted on the GSA website.

Krystal J. Brumfield, Associate Administrator, Office of Government-wide Policy.

[FR Doc. 2021–17491 Filed 8–13–21; 8:45 am]
BILLING CODE 5820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Needs and Challenges in Personal Protective Equipment (PPE) Use for Underserved User Populations; Extension of Comment Period

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Extension of comment period.

SUMMARY: On June 24, 2021, NIOSH opened a notice to request information on the Needs and Challenges in Personal Protective Equipment (PPE) Use for Underserved User Populations. Written comments were to be received by August 23, 2021. NIOSH is extending the public comment period to October 15, 2021.

DATES: The comment period for the document published on June 24, 2021 (86 FR 33296), is extended. Comments must be received by October 15, 2021.

ADDRESSES: Interested parties should submit information to: NIOSH, Attn: Sherri Diana, National Institute for Occupational Safety and Health, NIOSH Docket Office, 1080 Tusculum Avenue, MS C–34, Cincinnati, Ohio 45226–1998, Email address: ppeconcerns@cdc.gov.

FOR FURTHER INFORMATION CONTACT: N. Katherine Yoon, Ph.D., National Institute for Occupational Safety and Health Centers for Disease Control and Prevention Email Address: NYoon@cdc.gov, Phone number: 412–386–6752 [non-toll-free number].

SUPPLEMENTARY INFORMATION: NIOSH published a notice and request for information in the Federal Register on June 24, 2021 (86 FR 33296) regarding the Needs and Challenges in Personal Protective Equipment (PPE) Use for Underserved User Populations. This notice announces the extension of the comment period until October 15, 2021.

Frank J. Hearl, Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2021–17485 Filed 8–13–21; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. FDA–2021–N–0709

Prescription Drug User Fee Rates for Fiscal Year 2022

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 2022. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2017 (PDUFA VI), authorizes FDA to collect application fees for certain applications for the review of human drug and biological products, and prescription drug program fees for certain approved products. This notice establishes the fee rates for FY 2022.


SUPPLEMENTARY INFORMATION:

I. Background

Sections 735 and 736 of the FD&C Act (21 U.S.C. 379g and 379h, respectively) establish two different kinds of user fees. Fees are assessed as follows: (1) Application fees are assessed on certain types of applications for the review of human drug and biological products and (2) prescription drug program fees are assessed on certain approved products (section 736(a) of the FD&C Act). When specific conditions are met, FDA may waive or reduce fees (section 736(d) of the FD&C Act) or exempt certain prescription drug products from fees (section 736(k) of the FD&C Act).

For FY 2018 through FY 2022, the base revenue amount for the total revenues from all PDUFA fees are established by PDUFA VI. The base fee revenue amount for FY 2022 is $1,098,077,960. The FY 2022 base revenue amount is adjusted for inflation and for the resource capacity needs for the process for the review of human drug applications (the capacity planning adjustment (CPA)). An additional dollar amount specified in the statute (see section 736(b)(1)(F) of the FD&C Act) is then added to provide for additional full-time equivalent (FTE) positions to support PDUFA VI initiatives. The FY 2022 revenue amount may be adjusted further, if necessary, to provide for sufficient operating reserves of carryover user fees. Finally, the amount is adjusted to provide for additional direct costs to fund PDUFA VI initiatives. Fee amounts are to be established each year so that revenues from application fees provide 20 percent of the total revenue, and prescription drug program fees provide 80 percent of the total revenue.

This document provides fee rates for FY 2022 for an application requiring clinical data ($3,117,218), for an application not requiring clinical data ($1,558,609), and for the prescription drug program fee ($369,413). These fees are effective on October 1, 2021, and will remain in effect through September 30, 2022. For applications that are submitted on or after October 1, 2021, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2022

The base revenue amount for FY 2022 is $1,098,077,960 prior to adjustments for inflation, capacity planning, additional FTE, operating reserve, and additional direct costs (see section 736(b)(1) of the FD&C Act).

A. FY 2022 Statutory Fee Revenue Adjustments for Inflation

PDUFA VI specifies that the $1,098,077,960 is to be adjusted for inflation increases for FY 2022 using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 736(c)(1) of the FD&C Act).

The component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all PC&B paid per FTE positions at FDA for the first 3 of the