

special review process. In addition, the Federal Travel Regulation (FTR) allows for actual expense reimbursement as provided in §§ 301–11.300 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&IE reimbursement rates were revised for FY 2022; they were last revised in FY 2019. The M&IE NSA tiers are revised from \$56–\$76 to \$59–\$79, and the standard M&IE 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.

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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, 1090 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.

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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.

FOR FURTHER INFORMATION CONTACT: Misbah Tareen, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61077A, Beltsville, MD 20705–4304, 301–796–3997.

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 amounts for the total revenues from all PDUFA fees are established by PDUFA VI. The base 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