Today, the U.S. Food and Drug Administration announced the rates for over-the-counter (OTC) monograph drug user fees for fiscal year (FY) 2022 in a Federal Register Notice (FRN) titled "*Over-The-Counter Monograph Drug User Fee Rates for Fiscal Year 2022*." This FRN publishes fees for OTC monograph drug facilities and OTC Monograph Order Requests (OMORs) for FY 2022. The FRN includes information about facility fee calculations, OMOR fee calculations, fee due dates, and fee payment options and procedures. OTC monograph drug facility fees for FY 2022 are due June 1, 2022.

FDA recognizes that the fiscal year (FY) 2022 facility fee rates are an increase of 19 percent in comparison to the FY 2021 facility fee rates. To calculate the facility fee rates, in accordance with our statutory authority, FDA bases its calculation on factors for each fiscal year that include the 1) number of fee-liable facilities, 2) ratio of Monograph Drug Facilities (MDF) to Contract Manufacturing Organizations (CMO), and 3) increases in the total target revenue due to inflation and other adjustments. The FY 2022 increase in facility fee rates is largely attributed to these factors:

- The FY 2022 target revenue set under the statute.
- Number of Facilities: In FY 2022, FDA estimates fewer fee-liable facilities (1,118) in comparison to those estimates from FY 2021 (1,184).
- MDF to CMO Ratio: Based on FY 2021 data and other data provided by firms regarding their operations, FDA determined the MDF to CMO ratio in FY 2022 to be 65:35, an adjustment from the FY 2021 ratio of 90:10.
- Inflation and Operating Reserve adjustments: FY 2022 was the first year for which the inflation adjustment applied. FDA also made an operating reserve adjustment and otherwise reserved sufficient carryover fees to sustain program operations until facility fees for the subsequent fiscal year are due on June 1, 2023.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was signed into law. In addition to the COVID-19 response efforts, the CARES Act includes statutory provisions that reform and modernize the way OTC monograph drugs are regulated in the United States. Section 744M of the Federal Food, Drug, and Cosmetic Act, as added by the CARES Act, establishes an OTC monograph drug user fee program, under which FDA assesses and collects fees from submitters of OMORs as well as facility fees from qualifying manufacturers of OTC monograph drugs, to support the agency's OTC monograph drug activities. As with our other user fee programs, this user fee program provides additional resources to help the agency conduct these important regulatory activities in a timely manner and ultimately helps provide the public with access to innovative OTC monograph drugs.

For more information, please refer to the FRN or FDA's Over-the-Counter Monograph Drug User Fee Program (OMUFA) webpage.