Summary of Draft Recommended Changes to Statutory Language for MDUFA IV

DRAFT October 25, 2016

Impact of MDUFA IV Enhancements on User Fee Revenue

To implement the proposed enhancements for MDUFA IV, new funding is proposed to be phased in over the course of MDUFA IV. The new funding will be phased in over each fiscal year (FY) as follows:

- $47,419,400 for FY 2018
- $54,849,400 for FY 2019 ($7,430,000 above the FY 2018 level)
- $64,339,400 for FY 2020 ($9,490,000 above the FY 2019 level)
- $76,563,400 for FY 2021 ($12,224,000 above the FY 2020 level)
- $77,313,400 for FY 2022 ($7,500,000 above the FY 2021 level)

These amounts will be adjusted for inflation each year, as described below.

Proposed Statutory Changes

To implement the proposed MDUFA IV enhancements, the draft recommendations include the following proposed changes to applicable sections of the Federal Food Drug and Cosmetic Act:

- Amend the premarket notification submission fee from 2 percent of the premarket application fee to 3.4 percent of the premarket application fee.

- Amend the provision allowing small businesses to pay a reduced fee for a premarket notification submission, reducing the fee from 50 percent of the standard fee to 25 percent of the standard fee.
- Amend to establish a fee to be collected for de novo classification requests equal to 30 percent of the premarket application fee.
- Amend to reflect that de novo classification requests submitted by a small business are eligible for a reduced fee.
- Amend to reflect that the reduced fee for a de novo classification request may be paid at 25 percent of the standard fee.
- Specify the base fee amounts as:
    - For Premarket Applications:
        - $294,000 in FY 2018
        - $300,000 in FY 2019
        - $310,000 in FY 2020
        - $328,000 in FY 2021
        - $329,000 in FY 2022
    - For Establishment Registration:
        - $4,375 in FY 2018
        - $4,548 in FY 2019
        - $4,760 in FY 2020
        - $4,975 in FY 2021
        - $4,978 in FY 2022

- Specify the total revenue amounts as:
    - $183,280,756 for FY 2018
    - $190,654,875 for FY 2019
    - $200,132,014 for FY 2020
    - $211,748,789 for FY 2021
    - $213,687,660 for FY 2022
- Amend to apply inflation adjustments to the above specified fees starting with FY 2016. The proposed statutory total revenue amounts and base fee amounts are specified in FY2015 dollars such that annual inflation adjustments, based on actual rates of inflation as described in the annual Federal Register Notice for setting fees, will be used to inflate FY2015 dollars to the appropriate amounts for each fiscal year in MDUFA IV.
- Amend the fee setting process to reflect the negotiated agreement, which allows FDA to collect inflation-adjusted base fee amounts without any reduction in fees in the event that submission or registration volumes are higher than planned. Any further adjustments beyond inflation would only be necessary if projected submission volumes decrease or registrations fall below projections such that base fee amounts would need to be increased in order to generate the authorized total fee revenue in a given year.
- Update the appropriations trigger to $320,825,000 (the FY 2014 Enacted level of Budget Authority appropriations for the Devices and Radiological Health program) to provide assurance that user fees will be additive to Budget Authority appropriations.
- Eliminate the fifth-year fee offset provision because the negotiated fee setting structure allows FDA to collect and use inflation-adjusted base fee amounts each year without any

reduction in fees due to increased submission or registration volume. Deleting the fee offset provision is necessary to implement the negotiated fee setting structure.

- Add a subsection to the provision on Performance Standards to provide authority for FDA to establish a conformity assessment program and to specify the requirements for establishing such program.
- Amend the provision on Accredited Persons to provide FDA authority to tailor the scope of the third party review program per the agreements made during the user fee reauthorization negotiations with regulated industry.
- Amend the provision on Electronic Format for Submissions to provide FDA the authority to develop and implement electronic submissions per the agreements made during the user fee reauthorization negotiations with regulated industry.