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21 U.S. Code § 379j-43

Reauthorization; reporting requirements

(a) Performance report

(1) General requirements

Not later than 120 days after the end of each fiscal year for which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 301(b) [1] of the Generic Drug User Fee Amendments of 2022 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(2) Real time reporting

(A) In general

Not later than 30 calendar days after the end of each quarter of each fiscal year for which fees are collected under this subpart, the Secretary shall post the data described in subparagraph (B) on the internet website of the Food and Drug Administration, and may remove duplicative data from the annual report under this subsection.

(B) Data

The Secretary shall post the following data in accordance with subparagraph (A):

(i) The number and titles of draft and final guidance on topics related to human generic drug activities and whether such guidances were issued as required by statute or pursuant to a commitment under the letters described in section 301(b) [1] of the Generic Drug User Fee Amendments of 2022.

(ii) The number and titles of public meetings held on topics related to human generic drug activities and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 301(b) [1] of the Generic Drug User Fee Amendments of 2022.

(3) Rationale for GDUFA program changes

The Secretary shall include in the annual report under paragraph (1)—

(A) data, analysis, and discussion of the changes in the number of individuals hired as agreed upon in the letters described in section 3001(b) of the Generic Drug User Fee Amendments of 2022 and the number of remaining vacancies, the number of full-time equivalents funded by fees collected pursuant to section 379j–42 of this title, and the number of full time equivalents funded by budget authority at the Food and Drug Administration by each division within the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;

(B) data, analysis, and discussion of the changes in the fee revenue amounts and costs for human generic drug activities, including—

(i) identifying drivers of such changes; and

(ii) changes in the total average cost per full-time equivalent in the generic drug review program;

(C) for each of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner, the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required; and

(D) data, analysis, and discussion of the changes in the average full-time equivalent hours required to complete review of each type of abbreviated new drug application.