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21 U.S. Code § 379h-2

Reauthorization; reporting requirements

(a) Performance report

(1) In general

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—

(A) the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 101(b) [1] of the Prescription Drug User Fee Amendments of 2022 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals, including the status of the independent assessment described in such letters; and

(B) the progress of the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research in achieving the goals, and future plans for meeting the goals, including, for each review division—

(i) the number of original standard new drug applications and biologics license applications filed per fiscal year for each review division;

(ii) the number of original priority new drug applications and biologics license applications filed per fiscal year for each review division;

(iii) the number of standard efficacy supplements filed per fiscal year for each review division;

(iv) the number of priority efficacy supplements filed per fiscal year for each review division;

(v) the number of applications filed for review under accelerated approval per fiscal year for each review division;

(vi) the number of applications filed for review as fast track products per fiscal year for each review division;

(vii) the number of applications filed for orphan-designated products per fiscal year for each review division;

(viii) the number of breakthrough designations for a fiscal year for each review division; and

(ix) the number of investigational new drug applications submitted per fiscal year, including for each review division.

Nothing in subparagraph (B) shall be construed to authorize the disclosure of information that is prohibited from disclosure under section 331(j) of this title or section 1905 of title 18 or that is subject to withholding under section 552(b)(4) of title 5.

(2) Inclusion

The report under this subsection for a fiscal year shall include information on all previous cohorts for

which the Secretary has not given a complete response on all human drug applications and supplements in the cohort.

(3) 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 for such quarter and on a cumulative basis for such fiscal year, and may remove duplicative data from the annual performance 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 the process for the review of human drug applications, and whether such guidances were issued as required by statute or pursuant to a commitment under the letters described in section 101(b) [1] of the Prescription Drug User Fee Amendments of 2022.

(ii) The number and titles of public meetings held on topics related to the process for the review of human drug applications, and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 101(b) [1] of the Prescription Drug User Fee Amendments of 2022.

(iii) The number of new drug applications and biological licensing applications approved.

(iv) The number of new drug applications and biological licensing applications filed.

(v) For fiscal years 2023 and 2024, of the meeting requests from sponsors for which the Secretary has determined that a face-to-face meeting is appropriate, the number of face-to-face meetings requested by sponsors to be conducted in person (in such manner as the Secretary shall prescribe on the website of the Food and Drug Administration), and the number of such in-person meetings granted by the Secretary, with both such numbers disaggregated by the relevant agency center.