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21 U.S. Code § 379j-1

Reauthorization; reporting requirements

(a) Reports

(1) Performance report

(A) In general

(i) General requirements

Beginning with fiscal year 2023, for each fiscal year for which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives annual reports concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(b) [1] of the Medical Device User Fee Amendments of 2022 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(ii) Additional information

Beginning with fiscal year 2023, the annual report under this subparagraph shall include the progress of the Center for Devices and Radiological Health in achieving the goals, and future plans for meeting the goals, including—

(I) the number of premarket applications filed under section 360e of this title per fiscal year for each review division;

(II) the number of reports submitted under section 360(k) of this title per fiscal year for each review division;

(III) the number of expedited development and priority review designations under section 360e–3 [1] of this title per fiscal year;

(IV) the number of investigational device exemption applications submitted under section 360j(g) of this title per fiscal year, including for each review division; and

(V) the number of expedited development and priority review requests and designations under section 360e–3 of this title per fiscal year, including for each review division.

Nothing in this clause 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.

(iii) Real time reporting

(I) In general

Not later than 30 calendar days after the end of the second quarter of fiscal year 2023, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter, the Secretary shall post the data described in subclause (II) 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 report under this subparagraph.

(II) Data

The Secretary shall post the following data in accordance with subclause (I):

(aa) The number and titles of draft and final guidance on topics related to the process for the review of devices, and whether such guidances were issued as required by statute or pursuant to the letters described in section 201(b) [1] of the Medical Device User Fee Amendments of 2022; and

(bb) The number and titles of public meetings held on topics related to the process for the review of devices, and if such meetings were required by statute or pursuant to a commitment under the letters described in section 201(b) [1] of the Medical Device User Fee Amendments of 2022.

(iv) Rationale for MDUFA program changes

Beginning with fiscal year 2023, the Secretary shall include in the annual report under paragraph (1)—

(I) data, analysis, and discussion of the changes in the number of individuals hired as agreed upon in the letters described in section 2001(b) of the Medical Device 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 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 Devices and Radiological Health, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;

(II) data, analysis, and discussion of the changes in the fee revenue amounts and costs for the process for the review of device applications, including identifying—

(aa) drivers of such changes; and

(bb) changes in the average total cost per full-time equivalent in the medical device review program;

(III) for each of the Center for Devices and Radiological Health, 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

(IV) data, analysis, and discussion of the changes in the average full-time equivalent hours required to complete review of medical device application types.

(v) Analysis

For each fiscal year, the Secretary shall include in the report under clause (i) an analysis of the following:

(I) The difference between the aggregate number of premarket applications filed under section 360e of this title and aggregate reports submitted under section 360(k) of this title and the aggregate number of major deficiency letters, not approvable letters, and denials for such applications issued by the agency, accounting for—

(aa) the number of applications filed and reports submitted during one fiscal year for which a decision is not scheduled to be made until the following fiscal year; and

(bb) the aggregate number of applications for each fiscal year that did not meet the goals as identified by the letters described in section 201(b) [1] of the Medical Device User Fee Amendments of 2022 for the applicable fiscal year.

(II) Relevant data to determine whether the Center for Devices and Radiological Health has met performance enhancement goals identified by the letters described in section 201(b) [1] of the Medical Device User Fee Amendments of 2022 for the applicable fiscal year.

(III) The most common causes and trends for external or other circumstances affecting the ability of the Center for Devices and Radiological Health, the Office of Regulatory Affairs, or the Food and Drug Administration to meet review time and performance enhancement goals identified by the letters described in section 201(b) [1] of the Medical Device User Fee Amendments of 2022.

(B) Publication

With regard to information to be reported by the Food and Drug Administration to industry on a quarterly and annual basis pursuant to the letters described in section 201(b) [1] of the Medical Device User Fee Amendments of 2022, the Secretary shall make such information publicly available on the Internet Web site of the Food and Drug Administration not later than 60 days after the end of each quarter or 120 days after the end of each fiscal year, respectively, to which such information applies. This information shall include the status of the independent assessment identified in the letters described in such section 201(b).

(C) Updates

The Secretary shall include in each report under subparagraph (A) information on all previous cohorts for which the Secretary has not given a complete response on all device premarket applications and reports, supplements, and premarket notifications in the cohort.