115TH CONGRESS
1ST SESSION

S. 1062

To increase reporting transparency and accountability with respect to Food and Drug Administration user fees.

IN THE SENATE OF THE UNITED STATES

MAY 4, 2017

Mr. BURR (for himself and Mr. YOUNG) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To increase reporting transparency and accountability with respect to Food and Drug Administration user fees.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''FDA Reporting Transparency and Accountability Act''.

SEC. 2. STREAMLINING AND IMPROVING CONSISTENCY IN PERFORMANCE REPORTING.

(a) PDUFA.—Section 736B(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2(a)) is amended—

(1) in paragraph (1)(B)—

(A) in each of clauses (i), (ii), and (v), by inserting ''and the number of complete response letters issued for such applications'' before the semicolon;

(B) in each of clauses (iii) and (iv), by inserting ''and the number of complete response letters issued for such supplements'' before the semicolon;

(C) in clause (vi), by inserting ''and the number of designations and denials issued by the agency for such applications'' before the semicolon;

(D) in clause (vii), by striking ''; and'' and inserting ''and the number of designations and denials issued by the agency for such applications;''; and

(E) in clause (viii) by striking the period and inserting ''and the number of designations and denials issued by the agency for such applications;''; and

(2) by inserting after paragraph (2) the following:

''(3) REAL TIME REPORTING.—

''(A) IN GENERAL.—Beginning with fiscal year 2018, every 30 calendar days, the Secretary shall post the data described in subparagraph (B) on the Internet website of the Food and Drug Administration and remove from such website duplicative data from the annual performance report.

''(B) DATA.—The following data is required to be posted in accordance with subparagraph (A):

''(i) The number and titles of draft and final guidance issued by the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research, and the justification for the issuance and finalization of each such guidance.

''(ii) The number and titles of public meetings held by the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research each fiscal year.

''(iii) The list of standard new drug applications and biologics license applications, by fiscal year of receipt.

''(iv) The number of filed applications by each review division.

''(4) CAPACITY PLANNING AND IMPROVED TIME REPORTING.—Beginning with fiscal year 2020, the Secretary shall include in the annual report under paragraph (1)—

''(A) the number of full-time equivalents agreed upon and the number of appropriated full time equivalents 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) identification by name of all time reporting categories that Food and Drug Administration uses for capacity planning and time reporting with respect to 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, pursuant to the 'resource capacity planning and modernized time reporting implementation plan';

''(C) the processes by which 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 require reporting on the amount of an employee's time that is dedicated to the review of human drug applications, including information regarding employees dedicated to such activities on a full-time basis, and employees dedicated to such activities on a part-time basis; and

''(D) 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 described in subparagraph (C) (both full-time equivalents and employees dedicated to such activities on a part-time basis) for whom time reporting is required as described in subparagraph (C), and the number of such employees required to estimate time dedicated to the review of human drug applications.''.

(b) MDUFA.—Section 738A(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–1(a)(1)(A)) is amended—

(1) by striking ''Beginning with'' and inserting the following:

''(i) GENERAL REQUIREMENTS.—Beginning with''; and

(2) by adding at the end the following:

''(ii) ADDITIONAL INFORMATION.—Beginning with fiscal year 2018, 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, for each review division—

''(I) the number of premarket applications filed under section 515 per fiscal year for each review division, and the number of approvable letters, major deficiency letters, not approvable letters, and denials for such applications;

''(II) the number of reports filed under section 510(k) per fiscal year for each review division and the num-

ber of devices cleared or not substantially equivalent for such reports; and

''(III) the number of expedited access pathway designations for a fiscal year for each review division and the number of cleared or approved devices or denials for such applications.

''(iii) REAL TIME REPORTING.—

''(I) IN GENERAL.—Beginning with fiscal year 2018, the Secretary shall, every 30 calendar days, post the data described in subclause (II) on the Internet website of the Food and Drug Administration and remove from such website duplicative data from the annual report under this subparagraph.

''(II) DATA.—The following data is required to be posted in accordance with subclause (I):

''(aa) The number and titles of draft and final guidance issued by the Center for Devices and Radiological Health and the jus-

tification for the issuance and finalization of such guidance.

''(bb) The number and titles of public meetings held by the Center for Devices and Radiological Health each fiscal year.''.

(c) GDUFA.—Section 744C(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–43(a)) is amended—

(1) by striking ''Beginning with'' and inserting the following:

''(1) GENERAL REQUIREMENTS.—Beginning with''; and

(2) by adding at the end the following:

''(2) ADDITIONAL INFORMATION.—Beginning with fiscal year 2018, the report under this subsection shall include the progress of the Office of Generic Drugs in achieving the goals, and future plans for meeting the goals, including—

''(A) the number of original abbreviated new drug applications filed per fiscal year;

''(B) the number of amendments to abbreviated new drug applications filed per fiscal year; and

''(C) the number of actions taken delineated by the type of action, including final approvals, tentative approvals, complete response letters, and the number of 'refuse to receive' letters issued by the Food and Drug Administration per fiscal year.

''(3) REAL TIME REPORTING.—

''(A) IN GENERAL.—Beginning with fiscal year 2018, the Secretary shall, every 30 calendar days, post the data described in subparagraph (B) on the Internet website of the Food and Drug Administration and remove from such website duplicative data from the annual report under this subsection.

''(B) DATA.—The following data is required to be posted in accordance with subparagraph (A):

''(i) The number and titles of draft and final guidance issued by the Office of Generic Drugs and the justification for the issuance and finalization of such guidance.

''(ii) The number and titles of public meetings held by the Office of Generic Drugs each fiscal year.''.

(d) BsUFA.—Section 744I(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–53(a)) is amended—

(1) by striking ''Beginning with'' and inserting the following:

''(1) GENERAL REQUIREMENTS.—Beginning with''; and

(2) by adding at the end the following:

''(2) ADDITIONAL INFORMATION.—Beginning with fiscal year 2018, the report under this subsection shall include the progress of the Center for Biologics Evaluation and Research in achieving the goals, and future plans for meeting the goals, including—

''(A) information on all previous cohorts for which the Secretary has not given a complete response on all biosimilar biological product applications and supplements in the cohort;

''(B) the number of original biosimilar biological product applications filed per fiscal year, and the number of approvals or complete response letters issued by the agency for such applications; and

''(C) the number of resubmitted original biosimilar biological product applications filed

per fiscal year and the number of approvals or complete response letters issued by the agency for such applications.

''(3) REAL TIME REPORTING.—

''(A) IN GENERAL.—Beginning with fiscal year 2018, the Secretary shall, every 30 calendar days, post the data described in subparagraph (B) on the Internet website of the Food and Drug Administration and remove from such website duplicative data from the annual report under this subsection.

''(B) DATA.—The following data is required to be posted in accordance with subparagraph (A):

''(i) The number and titles of draft and final guidance issued by the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research and the justification for the issuance and finalization of such guidance.

''(ii) The number and titles of public meetings held by the Center for Drug Evaluation and Research and the Center for Biologic Evaluation and Research each fiscal year.''.

''(4) CAPACITY PLANNING AND TIME REPORTING.—Beginning with fiscal year 2020, the Secretary shall include in the annual report under this subsection—

''(A) the number of full-time equivalents agreed upon and the number of appropriated full time equivalents 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) identification by name of all time reporting categories that the Food and Drug Administration uses for capacity planning and time reporting under the 'resource capacity planning and modernized time reporting implementation plan' for 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;

''(C) the process by which 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 require reporting on the amount of an employee's time that is dedicated to the review of biosimilar biological product applications, including information regarding both employees dedicated to such activities on a full-time basis, and employees dedicated to such activities on a part-time basis; and

''(D) 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 actual number of employees described in subparagraph (C) (both full-time equivalents and employees dedicated to such activities on a part-time basis) for whom time reporting is required as described in subparagraph (C), and the number of such employees required to estimate time dedicated to the review of biosimilar biological product applications.''.

SEC. 3. FDA ANALYSIS OF USE OF FUNDS.

(a) PDUFA REPORTS.—

(1) ANALYSIS IN PDUFA PERFORMANCE REPORTS.—Section 736B(a) of the Federal Food,

Drug, and Cosmetic Act (21 U.S.C. 379h–2(a)), as amended by section 2(a), is further amended by adding at the end the following:

''(5) ANALYSIS.—For each fiscal year, the Secretary shall include in the report an analysis of the following:

''(A) The difference between the number of human drug applications filed and the number of approvals or complete response letters issued by the agency, accounting for—

''(i) such applications filed during one fiscal year for which a decision is not scheduled to be made until the following fiscal year;

''(ii) such applications pending with the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research that did not meet the goals for the corresponding fiscal year and the future plans of the Food and Drug Administration to meet these goals; and

''(iii) the most common causes within the agency for missing such goals.

''(B) Relevant data to determine whether the Center for Drug Evaluation and Research

and the Center for Biologics Evaluation and Research have met performance enhancement goals for the corresponding fiscal year.

''(C) External or other circumstances impacting the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, or the Food and Drug Administration, that impacted the ability of the agency to meet review time and performance enhancement goals.''.

(2) ISSUANCE OF CORRECTIVE ACTION REPORTS.—Section 736B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2) is amended—

(A) by redesignating subsections (c) and (d) as subsections (e) and (f), respectively; and

(B) inserting after subsection (b) the following:

''(c) CORRECTIVE ACTION REPORT.—Beginning with fiscal year 2018, and for each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit a corrective action report to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate upon submis-

sion of the performance report in subsection (a) for the corresponding fiscal year. The report shall include the following information, as applicable:

''(1) GOALS MET.—For each fiscal year, if the Secretary determines, based on the analysis under subsection (a)(3), that each of the goals for the corresponding fiscal year have been met, the corrective action report shall include a summary of goals met, and recommendations on ways in which the Secretary can improve and streamline the human drug application review process.

''(2) GOALS MISSED.—For each of the goals for the corresponding fiscal year that the Secretary determines to not have been met, the corrective action report shall include a detailed justification for such determination and—

''(A) a detailed description of the circumstances under which each drug application that missed the review goal time was approved during the first cycle review, as applicable;

''(B) aggregate data on the circumstances for all unapproved drug applications for which the review goal time was missed; and

''(C) the performance enhancement goals that were not achieved during the previous fis-

cal year and a detailed description of efforts the agency has put in place for the current fiscal year to improve the ability of the agency to meet each such goal, while maintaining standards of approval, for the current fiscal year.

''(d) ENHANCED COMMUNICATION.—

''(1) COMMUNICATIONS WITH CONGRESS.—Each fiscal year, as applicable, representatives from the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research shall meet with representatives from the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding the contents of the corrective action reports described in subsection (c)(2) and the annual performance reports under subsection (a).

''(2) PARTICIPATION IN CONGRESSIONAL HEARING.—Each fiscal year, as applicable, representatives from the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research shall participate in a public hearing before the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representa-

tives, regarding the reports under this section. Such hearing shall occur not later than 120 days after the end of each fiscal year for which fees are collected under this part.

''(3) PUBLICLY AVAILABLE UPDATES.—The Secretary shall provide an update on progress made for the corrective action report during the following fiscal year on the publicly available Internet website of the Food and Drug Administration every 30 business days.''.

(b) MDUFA REPORTS.—

(1) ANALYSIS IN MDUFA PERFORMANCE REPORTS.—Section 738A(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–1(a)(1)(A)), as amended by section 2(b), is further amended by adding at the end the following:

''(iv) ANALYSIS.—For each fiscal year, the Secretary shall include in the report an analysis of the following:

''(I) The difference between the number of premarket applications filed under section 515 and applications filed under section 510(k) and the number of major deficiency letters, not approvable letters, and deni-

als for such applications issued by the agency, accounting for—

"(aa) such applications filed during one fiscal year for which a decision is not scheduled to be made until the following fiscal year;

"(bb) such applications pending with the Center for Devices and Radiological Health that did not meet the goals for the corresponding fiscal year and the future plans of the Food and Drug Administration to meet these goals; and

"(cc) the most common causes within the agency for missing such goals.

"(II) Relevant data to determine whether the Center Devices and Radiological Health have met performance enhancement goals for the corresponding fiscal year.

"(III) External or other circumstances impacting the Center De-

vices and Radiological Health or the Food and Drug Administration that impacted the ability of the agency to meet review time and performance enhancement goals.''.

(2) ISSUANCE OF CORRECTIVE ACTION REPORTS.—Section 738A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2(a)) is amended—

(A) by redesignating paragraphs (2) and (3) as paragraphs (4) and (5), respectively; and

(B) by inserting after paragraph (1) the following:

''(2) CORRECTIVE ACTION REPORT.—Beginning with fiscal year 2018, and for each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit a corrective action report to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate upon submission of the performance report in paragraph (1)(A) for the corresponding fiscal year. The report shall include the following information, as applicable:

"(A) GOALS MET.—For each fiscal year, if the Secretary determines, based on the analysis under paragraph (1)(A)(iii), that each of the goals for the corresponding fiscal year have been met, the corrective action report shall include a summary of goals met, and recommendations on ways in which the Secretary can improve and streamline the medical device application review process.

"(B) GOALS MISSED.—For each of the goals for the corresponding fiscal year that the Secretary determines to not have been met, the corrective action report shall include a detailed justification for such determination and—

"(i) a detailed description of the circumstances under which each application or report submitted under section 515 or section 510(k) missed the review goal time but was approved during the first cycle review, as applicable;

"(ii) aggregate data on the circumstances for all unapproved medical device applications for which the review goal time was missed; and

''(iii) the performance enhancement goals that were not achieved during the previous fiscal year and a detailed description of efforts the agency has put in place for the current fiscal year to improve the ability of the agency to meet each such goal, while maintaining standards of approval, for the current fiscal year.

''(3) ENHANCED COMMUNICATION.—

''(A) COMMUNICATIONS WITH CONGRESS.—Each fiscal year, as applicable, representatives from the Center for Devices and Radiological Health shall meet with representatives from the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding the contents of the corrective action reports described in paragraph (2) and the annual performance reports under paragraph (1).

''(B) PARTICIPATION IN CONGRESSIONAL HEARING.—Each fiscal year, as applicable, representatives from the Center for Devices and Radiological Health shall participate in a public hearing before the Committee on Health, Edu-

cation, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to report on the contents described in the corrective action reports under paragraph (2). Such hearing shall occur not later than 120 days after the end of each fiscal year for which fees are collected under this part.

''(C) PUBLICLY AVAILABLE UPDATES.—The Secretary shall provide an update on progress made for the corrective action report during the following fiscal year on the publicly available Internet website of the Food and Drug Administration every 30 business days.''.

(c) GDUFA REPORTS.—

(1) ANALYSIS IN GDUFA PERFORMANCE REPORTS.—Section 744C(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–43(a)), as amended by section 2(c) is further amended by adding at the end the following:

''(4) ANALYSIS.—For each fiscal year, the Secretary shall include in the report an analysis of the following:

''(A) The difference between the number of abbreviated new drug applications filed and the

number of approvals or complete response letters issued by the agency, accounting for—

''(i) such applications filed during one fiscal year for which a decision is not scheduled to be made until the following fiscal year;

''(ii) such applications pending with the Office of Generic Drugs that did not meet the goals for the corresponding fiscal year and the future plans of the Food and Drug Administration to meet these goals; and

''(iii) the most common causes within the agency for missing such goals.

''(B) Relevant data to determine whether the Office of Generic Drugs has met the performance enhancement goals for the corresponding fiscal year.

''(C) External or other circumstances impacting the Office of Generic Drugs or the Food and Drug Administration that impacted the ability of the agency to meet review time and performance enhancement goals.''.

(2) ISSUANCE OF CORRECTIVE ACTION REPORTS.—Section 744C of the Federal Food, Drug,

and Cosmetic Act (21 U.S.C. 379j–43) is amended—

(A) by redesignating subsections (c) and (d) as subsections (e) and (f), respectively; and

(B) inserting after subsection (b) the following:

''(c) CORRECTIVE ACTION REPORT.—Beginning with fiscal year 2018, and for each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit a corrective action report to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate upon submission of the performance report in section 744C(a) for the corresponding fiscal year. The report shall include the following information, as applicable:

''(1) GOALS MET.—For each fiscal year, if the Secretary determines, based on the analysis under subsection (a)(4), that each of the goals for the corresponding fiscal year have been met, the corrective action report shall include a summary of goals met, and recommendations on ways in which the Secretary can improve and streamline the abbreviated new drug application review process.

''(2) GOALS MISSED.—For each of the goals for the corresponding fiscal year that the Secretary determines to not have been met, the corrective action report shall include a detailed justification for such determination and—

''(A) a detailed description of the circumstances under which each abbreviated new drug application missed the review goal time but was approved during the first cycle review, as applicable;

''(B) aggregate data on the circumstances for all unapproved abbreviated new drug applications for which the review goal time was missed; and

''(C) the performance enhancement goals that were not achieved during the previous fiscal year and a detailed description of efforts the agency has put in place for the current fiscal year to improve the ability of the agency to meet each such goal for the current fiscal year.

''(d) ENHANCED COMMUNICATION.—

''(1) COMMUNICATIONS WITH CONGRESS.—Each fiscal year, as applicable, representatives from the Office of Generic Drugs shall meet with representatives from the Committee on Health, Edu-

cation, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding the contents of the corrective action reports described in subsection (c)(2) and the annual performance reports under subsection (a).

''(2) PARTICIPATION IN CONGRESSIONAL HEARING.—Each fiscal year, as applicable, representatives from the Center for Drug Evaluation and Research shall participate in a public hearing before the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to report on the contents described in the reports under this section. Such hearing shall occur not later than 120 days after the end of each fiscal year for which fees are collected under this part.

''(3) PUBLICLY AVAILABLE UPDATES.—The Secretary shall provide an update on progress made for the corrective action report during the following fiscal year on the publicly available Internet website of the Food and Drug Administration every 30 business days.''.

(d) BSUFA REPORTS.—

(1) ANALYSIS IN BSUFA PERFORMANCE REPORTS.—Section 744I(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–53(a)) as amended by section 2(d) is further amended by adding at the end the following:

''(5) ANALYSIS.—For each fiscal year, the Secretary shall include in the report an analysis of the following:

''(A) The difference between the number of biosimilar biological product applications and supplements filed and the number of approvals or complete response letters issued by the agency, accounting for—

''(i) such applications filed during one fiscal year for which a decision is not scheduled to be made until the following fiscal year;

''(ii) such applications pending with the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research that did not meet the goals for the corresponding fiscal year and the future plans of the Food and Drug Administration to meet these goals; and

''(iii) the most common causes within the agency for missing such goals.

''(B) Relevant data to determine whether the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research have met the performance enhancement goals for the corresponding fiscal year.

''(C) External or other circumstances impacting the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Food and Drug Administration that impacted the ability of the agency to meet review time and performance enhancement goals.''.

(2) ISSUANCE OF CORRECTIVE ACTION REPORTS.—Section 744I of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–53) is amended—

(A) by redesignating subsections (c), (d), and (e) as subsections (d), (e), and (f), respectively; and

(B) inserting after subsection (a) the following:

''(b) CORRECTIVE ACTION REPORT.—Beginning with fiscal year 2018, and for each fiscal year for which fees

are collected under this part, the Secretary shall prepare and submit a corrective action report to the Committee on Energy and Commerce and Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and Committee on Appropriations of the Senate upon submission of the performance report in section 744I(a) for the corresponding fiscal year. The report shall include the following information, as applicable:

''(1) GOALS MET.—For each fiscal year, if the Secretary determines, based on the analysis under subsection (a)(5), that each of the goals for the corresponding fiscal year have been met, the corrective action report shall include a summary of goals met, and recommendations on ways in which the Secretary can improve and streamline the biosimilar biological product application review process.

''(2) GOALS MISSED.—For each of the goals for the corresponding fiscal year that the Secretary determines to not have been met, the corrective action report shall include a detailed justification for such determination and—

''(A) a detailed description of the circumstances under which each biosimilar biological product application missed the review goal

time but was approved during the first cycle review, as applicable;

''(B) aggregate data on the circumstances for all biosimilar biological product applications for which the review goal time was missed; and

''(C) the performance enhancement goals that were not achieved during the previous fiscal year and a detailed description of efforts the agency has put in place for the current fiscal year to improve the ability of the agency to meet each such goal for the current fiscal year.

''(c) ENHANCED COMMUNICATION.—

''(1) COMMUNICATIONS WITH CONGRESS.—Each fiscal year, as applicable, representatives from the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research shall meet with representatives from the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding the contents of the corrective action reports described in subsection (b) and the annual performance reports under subsection (a).

''(2) PARTICIPATION IN CONGRESSIONAL HEARING.—Each fiscal year, as applicable, representatives

from the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research shall participate in a public hearing before the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to report on the contents described in the reports under this section. Such hearing shall occur not later than 120 days after the end of each fiscal year for which fees are collected under this part.

''(3) PUBLICLY AVAILABLE UPDATES.—The Secretary shall provide an update on progress made for the corrective action report during the following fiscal year on the publicly available Internet website of the Food and Drug Administration every 30 business days.''.

SEC. 4. PROHIBITING USE OF FUNDS FOR FACILITY MAINTENANCE.

(a) PDUFA.—Section 735(7)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(7)(C)) is amended by striking ''renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies'' and inserting ''and necessary scientific equipment''.

(b) MDUFA.—Section 737(9)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i(9)) is amended by striking ''renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies'' and inserting ''and necessary scientific equipment''.

(c) GDUFA.—Section 744A(11)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–41(11)(C)) is amended by striking ''renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies'' and inserting ''and necessary scientific equipment''.

(d) BsUFA.—Section 744G(9)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51(9)(C)) is amended by striking ''renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies'' and inserting ''and necessary scientific equipment''.

SEC. 5. INFORMATION ON IT CONTRACTING.

Section 736B(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 378h–2(b)) is amended—

(1) by striking ''report on the'' and inserting ''report on—

''(1) the'';

(2) by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(2) the amount of the fees collected that are invested in the information technology infrastructure of the Food and Drug Administration, the entities receiving contracts to develop such infrastructure, the length of such contracts (including renewals), and the progress such entities have made toward meeting the goals described in such contracts.''.

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