

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

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “FDA Reporting Trans-
5 parency and Accountability Act”.

6 **SEC. 2. STREAMLINING AND IMPROVING CONSISTENCY IN**
7 **PERFORMANCE REPORTING.**

8 (a) PDUFA.—Section 736B(a) of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 379h–2(a)) is amend-
10 ed—

1 (1) in paragraph (1)(B)—

2 (A) in each of clauses (i), (ii), and (v), by
3 inserting “and the number of complete response
4 letters issued for such applications” before the
5 semicolon;

6 (B) in each of clauses (iii) and (iv), by in-
7 serting “and the number of complete response
8 letters issued for such supplements” before the
9 semicolon;

10 (C) in clause (vi), by inserting “and the
11 number of designations and denials issued by
12 the agency for such applications” before the
13 semicolon;

14 (D) in clause (vii), by striking “; and” and
15 inserting “and the number of designations and
16 denials issued by the agency for such applica-
17 tions;”; and

18 (E) in clause (viii) by striking the period
19 and inserting “and the number of designations
20 and denials issued by the agency for such appli-
21 cations;”; and

22 (2) by inserting after paragraph (2) the fol-
23 lowing:

24 “(3) REAL TIME REPORTING.—

1 “(A) IN GENERAL.—Beginning with fiscal
2 year 2018, every 30 calendar days, the Sec-
3 retary shall post the data described in subpara-
4 graph (B) on the Internet website of the Food
5 and Drug Administration and remove from
6 such website duplicative data from the annual
7 performance report.

8 “(B) DATA.—The following data is re-
9 quired to be posted in accordance with subpara-
10 graph (A):

11 “(i) The number and titles of draft
12 and final guidance issued by the Center for
13 Drug Evaluation and Research or the Cen-
14 ter for Biologics Evaluation and Research,
15 and the justification for the issuance and
16 finalization of each such guidance.

17 “(ii) The number and titles of public
18 meetings held by the Center for Drug
19 Evaluation and Research and the Center
20 for Biologics Evaluation and Research
21 each fiscal year.

22 “(iii) The list of standard new drug
23 applications and biologics license applica-
24 tions, by fiscal year of receipt.

1 “(iv) The number of filed applications
2 by each review division.

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

7 “(A) the number of full-time equivalents
8 agreed upon and the number of appropriated
9 full time equivalents at the Food and Drug Ad-
10 ministration by each division within the Center
11 for Drug Evaluation and Research, the Center
12 for Biologics Evaluation and Research, the Of-
13 fice of Regulatory Affairs, and the Office of the
14 Commissioner;

15 “(B) identification by name of all time re-
16 porting categories that Food and Drug Admin-
17 istration uses for capacity planning and time
18 reporting with respect to the Center for Drug
19 Evaluation and Research, the Center for Bio-
20 logics Evaluation and Research, the Office of
21 Regulatory Affairs, and the Office of the Com-
22 missioner, pursuant to the ‘resource capacity
23 planning and modernized time reporting imple-
24 mentation plan’;

1 “(C) the processes by which the Center for
2 Drug Evaluation and Research, the Center for
3 Biologics Evaluation and Research, the Office
4 of Regulatory Affairs, and the Office of the
5 Commissioner require reporting on the amount
6 of an employee’s time that is dedicated to the
7 review of human drug applications, including
8 information regarding employees dedicated to
9 such activities on a full-time basis, and employ-
10 ees dedicated to such activities on a part-time
11 basis; and

12 “(D) for each of the Center for Drug Eval-
13 uation and Research, the Center for Biologics
14 Evaluation and Research, the Office of Regu-
15 latory Affairs, and the Office of the Commis-
16 sioner, the number of employees described in
17 subparagraph (C) (both full-time equivalents
18 and employees dedicated to such activities on a
19 part-time basis) for whom time reporting is re-
20 quired as described in subparagraph (C), and
21 the number of such employees required to esti-
22 mate time dedicated to the review of human
23 drug applications.”.

1 (b) MDUFA.—Section 738A(a)(1)(A) of the Federal
 2 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
 3 1(a)(1)(A)) is amended—

4 (1) by striking “Beginning with” and inserting
 5 the following:

6 “(i) GENERAL REQUIREMENTS.—Be-
 7 ginning with”; and

8 (2) by adding at the end the following:

9 “(ii) ADDITIONAL INFORMATION.—
 10 Beginning with fiscal year 2018, the an-
 11 nual report under this subparagraph shall
 12 include the progress of the Center for De-
 13 vices and Radiological Health in achieving
 14 the goals, and future plans for meeting the
 15 goals, including, for each review division—

16 “(I) the number of premarket ap-
 17 plications filed under section 515 per
 18 fiscal year for each review division,
 19 and the number of approvable letters,
 20 major deficiency letters, not approv-
 21 able letters, and denials for such ap-
 22 plications;

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

1 ber of devices cleared or not substan-
2 tially equivalent for such reports; and

3 “(III) the number of expedited
4 access pathway designations for a fis-
5 cal year for each review division and
6 the number of cleared or approved de-
7 vices or denials for such applications.

8 “(iii) REAL TIME REPORTING.—

9 “(I) IN GENERAL.—Beginning
10 with fiscal year 2018, the Secretary
11 shall, every 30 calendar days, post the
12 data described in subclause (II) on
13 the Internet website of the Food and
14 Drug Administration and remove from
15 such website duplicative data from the
16 annual report under this subpara-
17 graph.

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

21 “(aa) The number and titles
22 of draft and final guidance issued
23 by the Center for Devices and
24 Radiological Health and the jus-

1 tification for the issuance and fi-
2 nalization of such guidance.

3 “(bb) The number and titles
4 of public meetings held by the
5 Center for Devices and Radio-
6 logical Health each fiscal year.”.

7 (c) GDUFA.—Section 744C(a) of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 379j–43(a)) is amend-
9 ed—

10 (1) by striking “Beginning with” and inserting
11 the following:

12 “(1) GENERAL REQUIREMENTS.—Beginning
13 with”; and

14 (2) by adding at the end the following:

15 “(2) ADDITIONAL INFORMATION.—Beginning
16 with fiscal year 2018, the report under this sub-
17 section shall include the progress of the Office of
18 Generic Drugs in achieving the goals, and future
19 plans for meeting the goals, including—

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

22 “(B) the number of amendments to abbrevi-
23 ated new drug applications filed per fiscal
24 year; and

1 “(C) the number of actions taken delin-
2 eated by the type of action, including final ap-
3 provals, tentative approvals, complete response
4 letters, and the number of ‘refuse to receive’
5 letters issued by the Food and Drug Adminis-
6 tration per fiscal year.

7 “(3) REAL TIME REPORTING.—

8 “(A) IN GENERAL.—Beginning with fiscal
9 year 2018, the Secretary shall, every 30 cal-
10 endar days, post the data described in subpara-
11 graph (B) on the Internet website of the Food
12 and Drug Administration and remove from
13 such website duplicative data from the annual
14 report under this subsection.

15 “(B) DATA.—The following data is re-
16 quired to be posted in accordance with subpara-
17 graph (A):

18 “(i) The number and titles of draft
19 and final guidance issued by the Office of
20 Generic Drugs and the justification for the
21 issuance and finalization of such guidance.

22 “(ii) The number and titles of public
23 meetings held by the Office of Generic
24 Drugs each fiscal year.”.

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

4 (1) by striking “Beginning with” and inserting
5 the following:

6 “(1) GENERAL REQUIREMENTS.—Beginning
7 with”; and

8 (2) by adding at the end the following:

9 “(2) ADDITIONAL INFORMATION.—Beginning
10 with fiscal year 2018, the report under this sub-
11 section shall include the progress of the Center for
12 Biologics Evaluation and Research in achieving the
13 goals, and future plans for meeting the goals, includ-
14 ing—

15 “(A) information on all previous cohorts
16 for which the Secretary has not given a com-
17 plete response on all biosimilar biological prod-
18 uct applications and supplements in the cohort;

19 “(B) the number of original biosimilar bio-
20 logical product applications filed per fiscal year,
21 and the number of approvals or complete re-
22 sponse letters issued by the agency for such ap-
23 plications; and

24 “(C) the number of resubmitted original
25 biosimilar biological product applications filed

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

4 “(3) REAL TIME REPORTING.—

5 “(A) IN GENERAL.—Beginning with fiscal
6 year 2018, the Secretary shall, every 30 cal-
7 endar days, post the data described in subpara-
8 graph (B) on the Internet website of the Food
9 and Drug Administration and remove from
10 such website duplicative data from the annual
11 report under this subsection.

12 “(B) DATA.—The following data is re-
13 quired to be posted in accordance with subpara-
14 graph (A):

15 “(i) The number and titles of draft
16 and final guidance issued by the Center for
17 Drug Evaluation and Research and the
18 Center for Biologics Evaluation and Re-
19 search and the justification for the
20 issuance and finalization of such guidance.

21 “(ii) The number and titles of public
22 meetings held by the Center for Drug
23 Evaluation and Research and the Center
24 for Biologic Evaluation and Research each
25 fiscal year.”.

1 “(4) CAPACITY PLANNING AND TIME REPORT-
2 ING.—Beginning with fiscal year 2020, the Sec-
3 retary shall include in the annual report under this
4 subsection—

5 “(A) the number of full-time equivalents
6 agreed upon and the number of appropriated
7 full time equivalents at the Food and Drug Ad-
8 ministration by each division within the Center
9 for Drug Evaluation and Research, the Center
10 for Biologics Evaluation and Research, the Of-
11 fice of Regulatory Affairs, and the Office of the
12 Commissioner;

13 “(B) identification by name of all time re-
14 porting categories that the Food and Drug Ad-
15 ministration uses for capacity planning and
16 time reporting under the ‘resource capacity
17 planning and modernized time reporting imple-
18 mentation plan’ for the Center for Drug Eval-
19 uation and Research, the Center for Biologics
20 Evaluation and Research, the Office of Regu-
21 latory Affairs and the Office of the Commis-
22 sioner;

23 “(C) the process by which the Center for
24 Drug Evaluation and Research, the Center for
25 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,

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

4 “(5) ANALYSIS.—For each fiscal year, the Sec-
5 retary shall include in the report an analysis of the
6 following:

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

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

15 “(ii) such applications pending with
16 the Center for Drug Evaluation and Re-
17 search and the Center for Biologics Eval-
18 uation and Research that did not meet the
19 goals for the corresponding fiscal year and
20 the future plans of the Food and Drug Ad-
21 ministration to meet these goals; and

22 “(iii) the most common causes within
23 the agency for missing such goals.

24 “(B) Relevant data to determine whether
25 the Center for Drug Evaluation and Research

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

4 “(C) External or other circumstances im-
 5 pacting the Center for Drug Evaluation and
 6 Research, the Center for Biologics Evaluation
 7 and Research, or the Food and Drug Adminis-
 8 tration, that impacted the ability of the agency
 9 to meet review time and performance enhance-
 10 ment goals.”.

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

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

16 (B) inserting after subsection (b) the fol-
 17 lowing:

18 “(c) CORRECTIVE ACTION REPORT.—Beginning with
 19 fiscal year 2018, and for each fiscal year for which fees
 20 are collected under this part, the Secretary shall prepare
 21 and submit a corrective action report to the Committee
 22 on Energy and Commerce and the Committee on Appro-
 23 priations of the House of Representatives and the Com-
 24 mittee on Health, Education, Labor, and Pensions and the
 25 Committee on Appropriations of the Senate upon submis-

1 sion of the performance report in subsection (a) for the
 2 corresponding fiscal year. The report shall include the fol-
 3 lowing information, as applicable:

4 “(1) GOALS MET.—For each fiscal year, if the
 5 Secretary determines, based on the analysis under
 6 subsection (a)(3), that each of the goals for the cor-
 7 responding fiscal year have been met, the corrective
 8 action report shall include a summary of goals met,
 9 and recommendations on ways in which the Sec-
 10 retary can improve and streamline the human drug
 11 application review process.

12 “(2) GOALS MISSED.—For each of the goals for
 13 the corresponding fiscal year that the Secretary de-
 14 termines to not have been met, the corrective action
 15 report shall include a detailed justification for such
 16 determination and—

17 “(A) a detailed description of the cir-
 18 cumstances under which each drug application
 19 that missed the review goal time was approved
 20 during the first cycle review, as applicable;

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

24 “(C) the performance enhancement goals
 25 that were not achieved during the previous fis-

1 cal year and a detailed description of efforts the
2 agency has put in place for the current fiscal
3 year to improve the ability of the agency to
4 meet each such goal, while maintaining stand-
5 ards of approval, for the current fiscal year.

6 “(d) ENHANCED COMMUNICATION.—

7 “(1) COMMUNICATIONS WITH CONGRESS.—

8 Each fiscal year, as applicable, representatives from
9 the Center for Drug Evaluation and Research and
10 the Center for Biologics Evaluation and Research
11 shall meet with representatives from the Committee
12 on Health, Education, Labor, and Pensions of the
13 Senate and the Committee on Energy and Com-
14 merce of the House of Representatives regarding the
15 contents of the corrective action reports described in
16 subsection (c)(2) and the annual performance re-
17 ports under subsection (a).

18 “(2) PARTICIPATION IN CONGRESSIONAL HEAR-

19 ING.—Each fiscal year, as applicable, representatives
20 from the Center for Drug Evaluation and Research
21 and the Center for Biologics Evaluation and Re-
22 search shall participate in a public hearing before
23 the Committee on Health, Education, Labor, and
24 Pensions of the Senate and the Committee on En-
25 ergy and Commerce of the House of Representa-

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

5 “(3) PUBLICLY AVAILABLE UPDATES.—The
 6 Secretary shall provide an update on progress made
 7 for the corrective action report during the following
 8 fiscal year on the publicly available Internet website
 9 of the Food and Drug Administration every 30 busi-
 10 ness days.”.

11 (b) MDUFA REPORTS.—

12 (1) ANALYSIS IN MDUFA PERFORMANCE RE-
 13 PORTS.—Section 738A(a)(1)(A) of the Federal
 14 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
 15 1(a)(1)(A)), as amended by section 2(b), is further
 16 amended by adding at the end the following:

17 “(iv) ANALYSIS.—For each fiscal
 18 year, the Secretary shall include in the re-
 19 port an analysis of the following:

20 “(I) The difference between the
 21 number of premarket applications
 22 filed under section 515 and applica-
 23 tions filed under section 510(k) and
 24 the number of major deficiency let-
 25 ters, not approvable letters, and deni-

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

3 “(aa) such applications filed
4 during one fiscal year for which a
5 decision is not scheduled to be
6 made until the following fiscal
7 year;

8 “(bb) such applications
9 pending with the Center for De-
10 vices and Radiological Health
11 that did not meet the goals for
12 the corresponding fiscal year and
13 the future plans of the Food and
14 Drug Administration to meet
15 these goals; and

16 “(cc) the most common
17 causes within the agency for
18 missing such goals.

19 “(II) Relevant data to determine
20 whether the Center Devices and Radi-
21 ological Health have met performance
22 enhancement goals for the cor-
23 responding fiscal year.

24 “(III) External or other cir-
25 cumstances impacting the Center De-

1 vices and Radiological Health or the
 2 Food and Drug Administration that
 3 impacted the ability of the agency to
 4 meet review time and performance en-
 5 hancement goals.”.

6 (2) ISSUANCE OF CORRECTIVE ACTION RE-
 7 PORTS.—Section 738A(a) of the Federal Food,
 8 Drug, and Cosmetic Act (21 U.S.C. 379h–2(a)) is
 9 amended—

10 (A) by redesignating paragraphs (2) and
 11 (3) as paragraphs (4) and (5), respectively; and
 12 (B) by inserting after paragraph (1) the
 13 following:

14 “(2) CORRECTIVE ACTION REPORT.—Beginning
 15 with fiscal year 2018, and for each fiscal year for
 16 which fees are collected under this part, the Sec-
 17 retary shall prepare and submit a corrective action
 18 report to the Committee on Energy and Commerce
 19 and the Committee on Appropriations of the House
 20 of Representatives and the Committee on Health,
 21 Education, Labor, and Pensions and the Committee
 22 on Appropriations of the Senate upon submission of
 23 the performance report in paragraph (1)(A) for the
 24 corresponding fiscal year. The report shall include
 25 the following information, as applicable:

1 “(A) GOALS MET.—For each fiscal year, if
2 the Secretary determines, based on the analysis
3 under paragraph (1)(A)(iii), that each of the
4 goals for the corresponding fiscal year have
5 been met, the corrective action report shall in-
6 clude a summary of goals met, and rec-
7 ommendations on ways in which the Secretary
8 can improve and streamline the medical device
9 application review process.

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

15 “(i) a detailed description of the cir-
16 cumstances under which each application
17 or report submitted under section 515 or
18 section 510(k) missed the review goal time
19 but was approved during the first cycle re-
20 view, as applicable;

21 “(ii) aggregate data on the cir-
22 cumstances for all unapproved medical de-
23 vice applications for which the review goal
24 time was missed; and

1 “(iii) the performance enhancement
2 goals that were not achieved during the
3 previous fiscal year and a detailed descrip-
4 tion of efforts the agency has put in place
5 for the current fiscal year to improve the
6 ability of the agency to meet each such
7 goal, while maintaining standards of ap-
8 proval, for the current fiscal year.

9 “(3) ENHANCED COMMUNICATION.—

10 “(A) COMMUNICATIONS WITH CON-
11 GRESS.—Each fiscal year, as applicable, rep-
12 representatives from the Center for Devices and
13 Radiological Health shall meet with representa-
14 tives from the Committee on Health, Edu-
15 cation, Labor, and Pensions of the Senate and
16 the Committee on Energy and Commerce of the
17 House of Representatives regarding the con-
18 tents of the corrective action reports described
19 in paragraph (2) and the annual performance
20 reports under paragraph (1).

21 “(B) PARTICIPATION IN CONGRESSIONAL
22 HEARING.—Each fiscal year, as applicable, rep-
23 representatives from the Center for Devices and
24 Radiological Health shall participate in a public
25 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

1 number of approvals or complete response let-
2 ters issued by the agency, accounting for—

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

7 “(ii) such applications pending with
8 the Office of Generic Drugs that did not
9 meet the goals for the corresponding fiscal
10 year and the future plans of the Food and
11 Drug Administration to meet these goals;
12 and

13 “(iii) the most common causes within
14 the agency for missing such goals.

15 “(B) Relevant data to determine whether
16 the Office of Generic Drugs has met the per-
17 formance enhancement goals for the cor-
18 responding fiscal year.

19 “(C) External or other circumstances im-
20 pacting the Office of Generic Drugs or the
21 Food and Drug Administration that impacted
22 the ability of the agency to meet review time
23 and performance enhancement goals.”.

24 (2) ISSUANCE OF CORRECTIVE ACTION RE-
25 PORTS.—Section 744C of the Federal Food, Drug,

1 and Cosmetic Act (21 U.S.C. 379j-43) is amend-
2 ed—

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

5 (B) inserting after subsection (b) the fol-
6 lowing:

7 “(c) CORRECTIVE ACTION REPORT.—Beginning with
8 fiscal year 2018, and for each fiscal year for which fees
9 are collected under this part, the Secretary shall prepare
10 and submit a corrective action report to the Committee
11 on Energy and Commerce and the Committee on Appro-
12 priations of the House of Representatives and the Com-
13 mittee on Health, Education, Labor, and Pensions and the
14 Committee on Appropriations of the Senate upon submis-
15 sion of the performance report in section 744C(a) for the
16 corresponding fiscal year. The report shall include the fol-
17 lowing information, as applicable:

18 “(1) GOALS MET.—For each fiscal year, if the
19 Secretary determines, based on the analysis under
20 subsection (a)(4), that each of the goals for the cor-
21 responding fiscal year have been met, the corrective
22 action report shall include a summary of goals met,
23 and recommendations on ways in which the Sec-
24 retary can improve and streamline the abbreviated
25 new drug application review process.

1 “(2) GOALS MISSED.—For each of the goals for
 2 the corresponding fiscal year that the Secretary de-
 3 termines to not have been met, the corrective action
 4 report shall include a detailed justification for such
 5 determination and—

6 “(A) a detailed description of the cir-
 7 cumstances under which each abbreviated new
 8 drug application missed the review goal time
 9 but was approved during the first cycle review,
 10 as applicable;

11 “(B) aggregate data on the circumstances
 12 for all unapproved abbreviated new drug appli-
 13 cations for which the review goal time was
 14 missed; and

15 “(C) the performance enhancement goals
 16 that were not achieved during the previous fis-
 17 cal year and a detailed description of efforts the
 18 agency has put in place for the current fiscal
 19 year to improve the ability of the agency to
 20 meet each such goal for the current fiscal year.

21 “(d) ENHANCED COMMUNICATION.—

22 “(1) COMMUNICATIONS WITH CONGRESS.—
 23 Each fiscal year, as applicable, representatives from
 24 the Office of Generic Drugs shall meet with rep-
 25 resentatives from the Committee on Health, Edu-

1 cation, Labor, and Pensions of the Senate and the
2 Committee on Energy and Commerce of the House
3 of Representatives regarding the contents of the cor-
4 rective action reports described in subsection (c)(2)
5 and the annual performance reports under sub-
6 section (a).

7 “(2) PARTICIPATION IN CONGRESSIONAL HEAR-
8 ING.—Each fiscal year, as applicable, representatives
9 from the Center for Drug Evaluation and Research
10 shall participate in a public hearing before the Com-
11 mittee on Health, Education, Labor, and Pensions
12 of the Senate and the Committee on Energy and
13 Commerce of the House of Representatives, to re-
14 port on the contents described in the reports under
15 this section. Such hearing shall occur not later than
16 120 days after the end of each fiscal year for which
17 fees are collected under this part.

18 “(3) PUBLICLY AVAILABLE UPDATES.—The
19 Secretary shall provide an update on progress made
20 for the corrective action report during the following
21 fiscal year on the publicly available Internet website
22 of the Food and Drug Administration every 30 busi-
23 ness days.”.

24 (d) BSUFA REPORTS.—

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

6 “(5) ANALYSIS.—For each fiscal year, the Sec-
 7 retary shall include in the report an analysis of the
 8 following:

9 “(A) The difference between the number of
 10 biosimilar biological product applications and
 11 supplements filed and the number of approvals
 12 or complete response letters issued by the agen-
 13 cy, accounting for—

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

18 “(ii) such applications pending with
 19 the Center for Drug Evaluation and Re-
 20 search or the Center for Biologics Evalua-
 21 tion and Research that did not meet the
 22 goals for the corresponding fiscal year and
 23 the future plans of the Food and Drug Ad-
 24 ministration to meet these goals; and

1 “(iii) the most common causes within
2 the agency for missing such goals.

3 “(B) Relevant data to determine whether
4 the Center for Drug Evaluation and Research
5 and the Center for Biologics Evaluation and
6 Research have met the performance enhance-
7 ment goals for the corresponding fiscal year.

8 “(C) External or other circumstances im-
9 pacting the Center for Drug Evaluation and
10 Research, the Center for Biologics Evaluation
11 and Research, and the Food and Drug Admin-
12 istration that impacted the ability of the agency
13 to meet review time and performance enhance-
14 ment goals.”.

15 (2) ISSUANCE OF CORRECTIVE ACTION RE-
16 PORTS.—Section 744I of the Federal Food, Drug,
17 and Cosmetic Act (21 U.S.C. 379j–53) is amend-
18 ed—

19 (A) by redesignating subsections (c), (d),
20 and (e) as subsections (d), (e), and (f), respec-
21 tively; and

22 (B) inserting after subsection (a) the fol-
23 lowing:

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

1 are collected under this part, the Secretary shall prepare
2 and submit a corrective action report to the Committee
3 on Energy and Commerce and Committee on Appropria-
4 tions of the House of Representatives and the Committee
5 on Health, Education, Labor, and Pensions and Com-
6 mittee on Appropriations of the Senate upon submission
7 of the performance report in section 744I(a) for the cor-
8 responding fiscal year. The report shall include the fol-
9 lowing information, as applicable:

10 “(1) GOALS MET.—For each fiscal year, if the
11 Secretary determines, based on the analysis under
12 subsection (a)(5), that each of the goals for the cor-
13 responding fiscal year have been met, the corrective
14 action report shall include a summary of goals met,
15 and recommendations on ways in which the Sec-
16 retary can improve and streamline the biosimilar bi-
17 ological product application review process.

18 “(2) GOALS MISSED.—For each of the goals for
19 the corresponding fiscal year that the Secretary de-
20 termines to not have been met, the corrective action
21 report shall include a detailed justification for such
22 determination and—

23 “(A) a detailed description of the cir-
24 cumstances under which each biosimilar biologi-
25 cal product application missed the review goal

1 time but was approved during the first cycle re-
 2 view, as applicable;

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

6 “(C) the performance enhancement goals
 7 that were not achieved during the previous fis-
 8 cal year and a detailed description of efforts the
 9 agency has put in place for the current fiscal
 10 year to improve the ability of the agency to
 11 meet each such goal for the current fiscal year.

12 “(c) ENHANCED COMMUNICATION.—

13 “(1) COMMUNICATIONS WITH CONGRESS.—
 14 Each fiscal year, as applicable, representatives from
 15 the Center for Drug Evaluation and Research and
 16 the Center for Biologics Evaluation and Research
 17 shall meet with representatives from the Committee
 18 on Health, Education, Labor, and Pensions of the
 19 Senate and the Committee on Energy and Com-
 20 merce of the House of Representatives regarding the
 21 contents of the corrective action reports described in
 22 subsection (b) and the annual performance reports
 23 under subsection (a).

24 “(2) PARTICIPATION IN CONGRESSIONAL HEAR-
 25 ING.—Each fiscal year, as applicable, representatives

1 from the Center for Drug Evaluation and Research
 2 and the Center for Biologics Evaluation and Re-
 3 search shall participate in a public hearing before
 4 the Committee on Health, Education, Labor, and
 5 Pensions of the Senate and the Committee on En-
 6 ergy and Commerce of the House of Representa-
 7 tives, to report on the contents described in the re-
 8 ports under this section. Such hearing shall occur
 9 not later than 120 days after the end of each fiscal
 10 year for which fees are collected under this part.

11 “(3) PUBLICLY AVAILABLE UPDATES.—The
 12 Secretary shall provide an update on progress made
 13 for the corrective action report during the following
 14 fiscal year on the publicly available Internet website
 15 of the Food and Drug Administration every 30 busi-
 16 ness days.”.

17 **SEC. 4. PROHIBITING USE OF FUNDS FOR FACILITY MAIN-**
 18 **TENANCE.**

19 (a) PDUFA.—Section 735(7)(C) of the Federal
 20 Food, Drug, and Cosmetic Act (21 U.S.C. 379g(7)(C)) is
 21 amended by striking “renovation, and repair of facilities
 22 and acquisition, maintenance, and repair of fixtures, fur-
 23 niture, scientific equipment, and other necessary materials
 24 and supplies” and inserting “and necessary scientific
 25 equipment”.

1 (b) MDUFA.—Section 737(9)(C) of the Federal
 2 Food, Drug, and Cosmetic Act (21 U.S.C. 379i(9)) is
 3 amended by striking “renovation, and repair of facilities
 4 and acquisition, maintenance, and repair of fixtures, fur-
 5 niture, scientific equipment, and other necessary materials
 6 and supplies” and inserting “and necessary scientific
 7 equipment”.

8 (c) GDUFA.—Section 744A(11)(C) of the Federal
 9 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
 10 41(11)(C)) is amended by striking “renovation, and repair
 11 of facilities and acquisition, maintenance, and repair of
 12 fixtures, furniture, scientific equipment, and other nec-
 13 essary materials and supplies” and inserting “and nec-
 14 essary scientific equipment”.

15 (d) BSUFA.—Section 744G(9)(C) of the Federal
 16 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51(9)(C))
 17 is amended by striking “renovation, and repair of facilities
 18 and acquisition, maintenance, and repair of fixtures, fur-
 19 niture, scientific equipment, and other necessary materials
 20 and supplies” and inserting “and necessary scientific
 21 equipment”.

22 **SEC. 5. INFORMATION ON IT CONTRACTING.**

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

1 (1) by striking “report on the” and inserting
2 “report on—
3 “(1) the”;
4 (2) by striking the period at the end and insert-
5 ing “; and”; and
6 (3) by adding at the end the following:
7 “(2) the amount of the fees collected that are
8 invested in the information technology infrastructure
9 of the Food and Drug Administration, the entities
10 receiving contracts to develop such infrastructure,
11 the length of such contracts (including renewals),
12 and the progress such entities have made toward
13 meeting the goals described in such contracts.”.

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