

115TH CONGRESS  
1ST SESSION

# S. 1062

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

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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.

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

1 of Regulatory Affairs, and the Office of the  
2 Commissioner require reporting on the amount  
3 of an employee's time that is dedicated to the  
4 review of biosimilar biological product applica-  
5 tions, including information regarding both em-  
6 ployees dedicated to such activities on a full-  
7 time basis, and employees dedicated to such ac-  
8 tivities on a part-time basis; and

9 “(D) for each of the Center for Drug Eval-  
10 uation and Research, the Center for Biologics  
11 Evaluation and Research, the Office of Regu-  
12 latory Affairs, and the Office of the Commis-  
13 sioner, the actual number of employees de-  
14 scribed in subparagraph (C) (both full-time  
15 equivalents and employees dedicated to such ac-  
16 tivities on a part-time basis) for whom time re-  
17 porting is required as described in subpara-  
18 graph (C), and the number of such employees  
19 required to estimate time dedicated to the re-  
20 view of biosimilar biological product applica-  
21 tions.”.

22 **SEC. 3. FDA ANALYSIS OF USE OF FUNDS.**

23 (a) PDUFA REPORTS.—

24 (1) ANALYSIS IN PDUFA PERFORMANCE RE-  
25 PORTS.—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-

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

9 “(C) PUBLICLY AVAILABLE UPDATES.—

10 The Secretary shall provide an update on  
11 progress made for the corrective action report  
12 during the following fiscal year on the publicly  
13 available Internet website of the Food and  
14 Drug Administration every 30 business days.”.

15 (c) GDUFA REPORTS.—

16 (1) ANALYSIS IN GDUFA PERFORMANCE RE-  
17 PORTS.—Section 744C(a) of the Federal Food,  
18 Drug, and Cosmetic Act (21 U.S.C. 379j–43(a)), as  
19 amended by section 2(c) is further amended by add-  
20 ing at the end the following:

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

24 “(A) The difference between the number of  
25 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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