

AMENDMENT TO _____
OFFERED BY MR. BARTON OF TEXAS

At the end of section 103(2) of the bill (amending section 736(b) of the Federal Food, Drug, and Cosmetic Act; relating to fees in connection with brand name drugs and biological products), add the following (and make such conforming changes as may be necessary):

1 (C) by adding at the end the following:

2 “(4) INCENTIVE FOR FDA TO MEET GOALS.—

3 “(A) INCENTIVE.—If the Secretary, in a
4 performance report under section 736B for fis-
5 cal year 2014 or any subsequent fiscal year
6 through 2017, demonstrates that the Food and
7 Drug Administration failed, during such fiscal
8 year, to make adequate progress towards its
9 goals, the total amount of fees authorized under
10 this section shall be reduced by 20 percent for
11 the first fiscal year beginning after the date
12 such performance report is submitted under
13 section 736B(a).

14 “(B) FAILURE TO MAKE ADEQUATE
15 PROGRESS DEFINED.—For purposes of sub-
16 paragraph (A), the term ‘failed, during such fis-

1 cal year, to make adequate progress towards its
2 goals’ means failed, with respect to the fiscal
3 year, to review and act on at least 90 percent
4 of the submissions covered by the goals identi-
5 fied for such year in the letters described in
6 section 101(b) of the Prescription Drug Use
7 Fee Amendments of 2012 within the time-
8 frames specified in such goals.

9 “(C) YEARS SUBSEQUENT TO REDUC-
10 TION.—The total amount of fees authorized
11 under this section for a fiscal year shall be de-
12 termined as if a reduction under subparagraph
13 (A) for any prior year (if any) did not occur.”.

In section 738(b) of the Federal Food, Drug, and
Cosmetic Act (relating to fees in connection with devices),
as amended by section 203(b) of the bill, add at the end
the following (and make such conforming changes as may
be necessary):

14 “(4) INCENTIVE FOR FDA TO MEET GOALS.—
15 “(A) INCENTIVE.—If the Secretary, in a
16 performance report under section 738A(a)(1)
17 for fiscal year 2014 or any subsequent fiscal
18 year through 2017, demonstrates that the Food
19 and Drug Administration failed, during such
20 fiscal year, to make adequate progress towards

1 its goals, the total amount of fees authorized
2 under this section shall be reduced by 20 per-
3 cent for the first fiscal year beginning after the
4 date such performance report is submitted
5 under section 738A(a)(1).

6 “(B) FAILURE TO MAKE ADEQUATE
7 PROGRESS TOWARDS ITS GOALS.—For purposes
8 of subparagraph (A), the term ‘failed, during
9 such fiscal year, to make adequate progress to-
10 wards its goals’ means failed, with respect to
11 the fiscal year, to review and act on at least 90
12 percent of the submissions covered by the goals
13 identified for such year in the letters described
14 in section 201(b) of the Medical Device User
15 Fee Amendments of 2012 within the time-
16 frames specified in such goals.

17 “(C) YEARS SUBSEQUENT TO REDUC-
18 TION.—The total amount of fees authorized
19 under this section for a fiscal year shall be de-
20 termined as if a reduction under subparagraph
21 (A) for any prior year (if any) did not occur.

 In section 744B(b) of the Federal Food, Drug, and
 Cosmetic Act (relating to fees in connection with generic
 drugs), as added by section 302 of the bill, add at the

end the following (and make such conforming changes as may be necessary):

1 “(3) INCENTIVE FOR FDA TO MEET GOALS.—

2 “(A) INCENTIVE.—If the Secretary, in a
3 performance report under section 744C(a) for
4 fiscal year 2014 or any subsequent fiscal year
5 through 2017, demonstrates that the Food and
6 Drug Administration failed, during such fiscal
7 year, to make adequate progress towards its
8 goals, the total amount of fees authorized under
9 this section shall be reduced by 20 percent for
10 the first fiscal year beginning after the date
11 such performance report is submitted under
12 section 744C(a).

13 “(B) FAILURE TO MAKE ADEQUATE
14 PROGRESS TOWARDS ITS GOALS.—For purposes
15 of subparagraph (A), the term ‘failed, during
16 such fiscal year, to make adequate progress to-
17 wards its goals’ means failed, with respect to
18 the fiscal year, to review and act on at least 90
19 percent of the submissions covered by the goals
20 identified for such year in the letters described
21 in section 301(b) of the Generic Drug User Fee
22 Amendments of 2012 within the timeframes
23 specified in such goals.

1 “(C) YEARS SUBSEQUENT TO REDUC-
2 TION.—The total amount of fees authorized
3 under this section for a fiscal year shall be de-
4 termined as if a reduction under subparagraph
5 (A) for any prior year (if any) did not occur.

In section 744H(b) of the Federal Food, Drug, and
Cosmetic Act (relating to fees in connection with
biosimilars), as added by section 402 of the bill, add at
the end the following (and make such conforming
changes as may be necessary):

6 “(3) INCENTIVE FOR FDA TO MEET GOALS.—
7 “(A) INCENTIVE.—Subject to subpara-
8 graph (D), if the Secretary, in a performance
9 report under section 744I(a) for fiscal year
10 2014 or any subsequent fiscal year through
11 2017, demonstrates that the Food and Drug
12 Administration failed, during such fiscal year,
13 to make adequate progress towards its goals,
14 the total amount of fees authorized under this
15 section shall be reduced by 20 percent for the
16 first fiscal year beginning after the date such
17 performance report is submitted under section
18 744I(a).

19 “(B) FAILURE TO MAKE ADEQUATE
20 PROGRESS TOWARDS ITS GOALS.—For purposes

1 of subparagraph (A), the term ‘failed, during
2 such fiscal year, to make adequate progress to-
3 wards its goals’ means failed, with respect to
4 the fiscal year, to review and act on at least 90
5 percent of the submissions covered by the goals
6 identified for such year in the letters described
7 in section 401(b) of the Biosimilar User Fee
8 Act of 2012 within the timeframes specified in
9 such goals.

10 “(C) YEARS SUBSEQUENT TO REDUC-
11 TION.—The total amount of fees authorized
12 under this section for a fiscal year shall be de-
13 termined as if a reduction under subparagraph
14 (A) for any prior year (if any) did not occur.

15 “(D) SPECIAL RULES.—

16 “(i) If the amount of fees under sec-
17 tion 736 is reduced for a fiscal year pursu-
18 ant to section 736(b)(4), no reduction shall
19 be made for such fiscal year under sub-
20 paragraph (A).

21 “(ii) If the amount of fees under sec-
22 tion 736 is reduced for a fiscal year pursu-
23 ant to section 736(b)(4) and, notwith-
24 standing clause (i), no reduction in fees is
25 required under subparagraph (A), the

1 amount of fees under this section for such
2 fiscal year shall be determined as if the re-
3 duction pursuant to section 736(b)(4) did
4 not occur.

