

**AMENDMENT TO COMMITTEE PRINT**

**OFFERED BY M\_\_\_.** \_\_\_\_\_

**[Page and line numbers refer to May 4th committee print]**

Page 18, strike line 16 through page 19, line 19 and  
insert the following:

1                   “(B) the progress of the Center for Drug  
2                   Evaluation and Research and the Center for  
3                   Biologics Evaluation and Research in achieving  
4                   the goals, and future plans for meeting the  
5                   goals, including, for each review division—

6                   “(i) the number of original standard  
7                   new drug applications and biologics license  
8                   applications filed per fiscal year for each  
9                   review division;

10                  “(ii) the number of original priority  
11                  new drug applications and biologics license  
12                  applications filed per fiscal year for each  
13                  review division;

14                  “(iii) the number of standard efficacy  
15                  supplements filed per fiscal year for each  
16                  review division;

1 “(iv) the number of priority efficacy  
2 supplements filed per fiscal year for each  
3 review division;

4 “(v) the number of applications filed  
5 for review under accelerated approval per  
6 fiscal year for each review division;

7 “(vi) the number of applications filed  
8 for review as fast track products per fiscal  
9 year for each review division; and

10 “(vii) the number of applications filed  
11 for orphan-designated products per fiscal  
12 year for each review division.

Page 33, lines 4 and 5, strike “quarterly and”.

Strike page 33, line 13, through page 34, line 21,  
and insert the following:

13 “(B) PUBLICATION.—With regard to infor-  
14 mation to be reported by the Food and Drug  
15 Administration to industry on a quarterly and  
16 annual basis pursuant to the letters described  
17 in section 201(b) of the Medical Device User  
18 Fee Amendments Act of 2012, the Secretary  
19 shall make such information publicly available  
20 on the Internet Website of the Food and Drug  
21 Administration not later than 60 days after the

1 end of each quarter or 120 days after the end  
2 of each fiscal year, respectively, to which such  
3 information applies. This information shall in-  
4 clude the status of the independent assessment  
5 identified in the letters described in such sec-  
6 tion 201(b).

7 “(C) UPDATES.—The Secretary shall in-  
8 clude in each report under subparagraph (A)  
9 information on all previous cohorts for which  
10 the Secretary has not given a complete response  
11 on all device premarket applications and re-  
12 ports, supplements, and premarket notifications  
13 in the cohort.”; and

Page 35, lines 7 to 8, strike “premarket applica-  
tions, premarket reports, premarket notification submis-  
sions, and supplements” and insert “the submissions list-  
ed in section 738(a)(2)(A) of such Act”.

Page 35, lines 19 to 21, strike “premarket applica-  
tions, premarket reports, supplements, 30-day notices,  
and premarket notification submissions” and insert “sub-  
missions listed in section 738(a)(2)(A) of such Act”.

Page 110, line 23, strike “section 736(c)(5)” and in-  
sert “section 736(c)(4)”.

Page 111, line 6, strike “section 736(c)(5)” and insert “section 736(c)(4)”.

Page 138, line 1, strike “300” and insert “330”.

Page 142, line 7, insert “of” after “number”.

Page 159, line 4, strike “draft guidance” and insert “draft or final guidance”.

Page 159, line 10, insert “Health,” before “Education”.

Page 170, lines 7 to 12, amend clause (iv) to read as follows:

1       “(iv) Notwithstanding clause (iii), the Secretary may  
2 decline to undertake a classification of a device pursuant  
3 to a request under clause (ii) if the Secretary—  
4           “(I) identifies a legally marketed device that  
5 would permit a substantial equivalence determina-  
6 tion under paragraph (1) for the device; or  
7           “(II) determines that the device submitted is  
8 not of low-moderate risk or special controls to miti-  
9 gate the risks cannot be developed.

Page 170, lines 13 through 15, strike “A person submitting a request under clause (i) or (ii) may, in the request, recommend to the Secretary a classification for the device.” and insert “The person submitting the re-

quest for classification under this subparagraph may recommend to the Secretary a classification for the device and shall, if recommending classification in class II, include in the request an initial draft proposal for applicable special controls, as described in subsection (a)(1)(B), that are necessary, in conjunction with general controls, to provide reasonable assurance of safety and effectiveness and a description of how the special controls provide such assurance.”.

Page 179, line 23, insert “, mitigation, and analysis” after “risk identification”.

Page 181, line 25, insert “of individuals” after “unique needs”.

Page 185, line 7, strike “CONFORMING AMENDMENT” and insert “ESTABLISHMENTS NOT DULY REGISTERED; MISBRANDING”.

Page 186, line 8, strike “on a frequency based”.

Page 189, line 10, strike “delays” and insert “delays, denies,”.

Page 189, lines 11 and 12, strike “, under section 510(h) or section 704”.

Page 189, line 16, strike “delaying” and insert “delaying, denying,”.

Page 190, lines 15 and 16, strike “an informal hearing” and insert “a hearing”.

Page 190, line 23, strike “an informal hearing” and insert “a hearing”.

Page 191, lines 8 and 9, strike “an informal hearing” and insert “a hearing”.

Page 191, line 17, strike “an informal hearing” and insert “a hearing”.

Page 192, line 25, strike “paragraph (1) or”.

Page 194, lines 15 through 17, strike “in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection,”.

Page 195, lines 9 through 15, strike subsection (d) and insert the following:

1       (d) IMPORTATION.—Section 801(a) (21 U.S.C.  
2 381(a)) is amended by inserting “or (5) for an article that  
3 is a drug, the appropriate unique facility identifiers under  
4 subsection (s) (relating to commercial importers) and sec-  
5 tion 510(i) (relating to foreign establishments), as speci-  
6 fied by the Secretary, are not provided,” before “then such  
7 article shall be refused admission”.

Page 197, lines 9 through 12, strike paragraph (4) and insert the following:

1           “(4) EFFECTIVE DATE.—The final rule under  
2           paragraph (3)(A) shall take effect not less than 180  
3           days after the Secretary promulgates such final rule.

Page 201, line 6, strike “in commerce”.

Page 201, line 16, insert “or may reasonably be expected to be offered for import into the United States” after “United States”.

Page 201, line 19, strike “require” and insert “specify”.

Page 201, after line 20, insert the following (and make such conforming changes as may be necessary):

4           “(c) SAVINGS CLAUSE.—Nothing in this section shall  
5           be construed as limiting any other authority of the Sec-  
6           retary to require notifications related to a drug under any  
7           other provision of this Act or the Public Health Service  
8           Act.

Page 205, line 26, strike “is entitled to request” and insert “may inspect”.

Page 213, lines 20 and 21, strike “in combination with another designated medical gas or gases, as medi-

cally appropriate” and insert “in combination, as medically appropriate, with another designated medical gas or gases for which a certification or certifications have been granted”.

Page 217, line 12, strike the period and insert “, the gas is approved for use without a prescription pursuant to an application under section 505 or 512, or the use in question is authorized pursuant to another provision of this Act relating to use of medical products in emergencies.”.

Page 222, after line 19, insert the following (and make such conforming changes as may be necessary):

1           “(3) a product that does not meet the definition  
2           of a qualified infectious disease product under sub-  
3           section (f) based upon its approved uses.

Page 225, line 14, strike “guidelines” and insert “guidance”.

Page 225, line 16, strike “antibiotic drugs” and insert “antibacterial and antifungal drugs”.

Page 225, line 21, strike “antibiotic drug” and insert “antibacterial and antifungal drug”.

Page 226, line 9, strike “guidelines” and insert “guidance”.

Page 226, line 13, strike “treat, detect, prevent, or identify” and insert “treat or prevent”.

Page 228, line 14, strike “antimicrobial” and insert “antibacterial”.

Page 228, line 25, strike “antibiotic” and insert “antibacterial drug”.

Page 229, line 3, strike “antibiotics” and insert “antibacterial drugs”.

Page 229, line 6, strike “antibiotics” and insert “antibacterial drugs”.

Page 234, line 25 through page 235, line 2, strike “(taking into account” through “alternative treatments)”.

Page 235, line 10, strike the period and insert a comma.

Page 235, line 11, strike “The” and insert “taking into account the severity or rarity of the disease or condition and the availability of alternative treatments. The”.

Page 280, after line 19, insert the following (and redesignate the matter on lines 20 through 25 as subsection (b) and make such conforming changes as may be necessary):

1 (a) QUALIFIED TESTING DEFINITION.—Section  
2 5(b)(1)(A)(ii) of the Orphan Drug Act (21 U.S.C.  
3 360ee(b)(1)(A)(ii)) is amended by striking “after the date  
4 such drug is designated under section 526 of such Act  
5 and”.

Page 285, lines 12 through 13, strike “the supply of  
the manufacturer’s drug” and insert “the manufacturer’s  
supply of the drug,”.

Page 298, line 15, strike “Federal”.

