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(Original Signature of Member)

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TH  
CONGRESS  
\_\_\_\_\_  
SESSION

**H. R.** \_\_\_\_\_

To make technical amendments to the Federal Food, Drug, and Cosmetic Act.

\_\_\_\_\_  
IN THE HOUSE OF REPRESENTATIVES

M\_\_\_\_\_. \_\_\_\_\_ introduced the following bill; which was referred to the Committee on the Judiciary

\_\_\_\_\_  
**A BILL**

To make technical amendments to the Federal Food, Drug, and Cosmetic Act.

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. DEFINITION.**

4 In this Act, the term “the Act” means the Federal  
5 Food, Drug, and Cosmetic Act.

6 **SEC. 2. TECHNICAL AMENDMENTS.**

7 The Federal Food, Drug, and Cosmetic Act (21  
8 U.S.C. 301 et seq.) is amended as follows:

1           (1) Section 201 of the Act (21 U.S.C. 321) is  
2 amended—

3           (A) in paragraph (g)(1), by striking  
4 “United States Pharmacopoeia” and inserting  
5 “United States Pharmacopeia”;

6           (B) in paragraph (w), by striking “as used  
7 in paragraph (w)” and inserting “as used in  
8 paragraph (v)”; and

9           (C) in paragraph (ff)(3)(B), by indenting  
10 the matter after clause (ii) (beginning with  
11 “which was not before” and ending with “law-  
12 ful under this Act.”) 4 ems from the left.

13           (2) Section 301(j) of the Act (21 U.S.C. 331(j))  
14 is amended by striking “under that section..” and  
15 inserting “under that section.”.

16           (3) Section 302(a) of the Act (21 U.S.C.  
17 332(a)) is amended by striking “for cause shown”  
18 and inserting “for cause shown,”.

19           (4) Section 303 of the Act (21 U.S.C. 333) is  
20 amended—

21           (A) in subsection (a)(2), by striking “para-  
22 graph (1) of this section” and inserting “para-  
23 graph (1)”; and

24           (B) in subsection (f)(3)(B), by striking  
25 “section 402(j)(5)(C)(ii)” and inserting “sec-

1           tion 402(j)(5)(C)(ii) of the Public Health Serv-  
2           vice Act (42 U.S.C. 282(j)(5)(C)(ii))”.

3           (5) Section 306(d)(4)(B)(ii) of the Act (21  
4           U.S.C. 335a(d)(4)(B)(ii)) is amended by striking  
5           “sections 505” and inserting “section 505”.

6           (6) Section 402(a)(1) of the Act (21 U.S.C.  
7           342(a)(1)) is amended by striking “injurious to  
8           health.” and “inserting injurious to health; or”.

9           (7) Section 403(i) of the Act (21 U.S.C. 343(i))  
10          is amended, in the matter after the semicolon, by  
11          striking “section 721(c)” and inserting “section  
12          721(c),”.

13          (8) Section 408 of the Act (21 U.S.C. 346a) is  
14          amended—

15                 (A) in subsection (j)(1), by striking “sec-  
16                 tion 406(a)” and inserting “section 406”;

17                 (B) in subsection (p)(2), by striking “sec-  
18                 tion 8 of the Environmental Research, Develop-  
19                 ment, and Demonstration Act of 1978 (42  
20                 U.S.C. 4365)” and inserting “section 8 of the  
21                 Environmental Research, Development, and  
22                 Demonstration Authorization Act of 1978 (42  
23                 U.S.C. 4365)”;

24                 (C) in subsection (q)(1), in the matter  
25                 after subparagraph (C), by striking “sub-

1 sections (b)(2) or (c)(2)” and inserting “sub-  
2 section (b)(2) or (c)(2)”.

3 (9) Section 411(a)(2) of the Act (21 U.S.C.  
4 350(a)(2)) is amended by striking “this subpara-  
5 graph” and inserting “this paragraph”.

6 (10) Section 417 of the Act (21 U.S.C. 350f)  
7 is amended—

8 (A) in subsection (e)(1), by striking “sec-  
9 tion 415(a)(3)” and inserting “section  
10 415(a)(4)”;

11 (B) in subsection (h)(1), by striking “part  
12 of chain” and inserting “part of a chain”;

13 (C) in subsection (j), by striking “as pro-  
14 vided for section 414” and inserting “as pro-  
15 vided for in section 414”; and

16 (D) in subsection (k), by striking “section  
17 415(a)(4)” and inserting “section 415(a)(5)”.

18 (11) Section 418(j)(2) of the Act (21 U.S.C.  
19 350g(j)(2)) is amended by striking “part 113 of  
20 chapter 21” and inserting “part 113 of title 21”.

21 (12) Section 419(c)(1)(E) of the Act (21  
22 U.S.C. 350h(c)(1)(E)) is amended by striking “cer-  
23 tify, compliance” and inserting “or certify compli-  
24 ance”.

1           (13) Section 422(a)(3) of the Act (21 U.S.C.  
2           350k(a)(3)) is amended by striking “subparagraph  
3           (b)” and inserting “subsection (b)”.

4           (14) Section 423 of the Act (21 U.S.C. 350l)  
5           is amended—

6                   (A) in subsection (b)(1)(B)(ii), by striking  
7                   “, to immediately cease distribution of such ar-  
8                   ticle.” and inserting “;”;

9                   (B) in subsection (b)(1)(B), by inserting  
10                   “to immediately cease distribution of such arti-  
11                   cle.” as flush matter after clause (ii); and

12                   (C) in subsection (g)(3), by striking “de-  
13                   scribed in (1)” and inserting “described in  
14                   paragraph (1)”.

15           (15) Section 503 of the Act (21 U.S.C. 353) is  
16           amended—

17                   (A) in subsection (g)—

18                           (i) by striking “(2)(A)(i) To estab-  
19                           lish” and inserting “(2)(A) To establish”;  
20                           and

21                           (ii) by redesignating clauses (ii), (iii),  
22                           and (iv) of paragraph (2)(A), as amended  
23                           by clause (i), as subparagraphs (B), (C),  
24                           and (D), respectively, of paragraph (2);

1 (B) in subsection (g)((2)(B), as amended  
2 by subparagraph (A), by redesignating sub-  
3 clauses (I), (II), and (III) as clauses (i), (ii),  
4 and (iii), respectively;

5 (C) in subsection (g)(2)(D), as amended by  
6 subparagraph (A), by redesignating subclauses  
7 (I) and (II) as clauses (i) and (ii), respectively;

8 (D) in subsection (g)(8)(C)(vi)(II), in the  
9 matter after the semicolon, by inserting the  
10 word “and”; and

11 (E) in subsection (g)(8)(C)(vi)(III), by  
12 striking “such paragraph (2);” and inserting  
13 “such paragraph (2).”.

14 (16) Section 503B of the Act (21 U.S.C. 353b)  
15 is amended—

16 (A) in subsection (c)(3)(A), in the matter  
17 before clause (i), by striking “described such  
18 subsection” and inserting “described in such  
19 subsection”; and

20 (B) by redesignating subsection (d) (with  
21 the heading “OBLIGATION TO PAY FEES”) as  
22 subsection (e).

23 (17) Section 505 of the Act (21 U.S.C. 355) is  
24 amended—

1 (A) in subsection (c)(3)(E)(iv), by striking  
2 “bioavailabilty studies” and inserting “bio-  
3 availability studies”;

4 (B) in subsection (k)(4)(D)(i)(II)(bb), by  
5 striking “for a newly-approved drugs” and in-  
6 serting “for a newly-approved drug”;

7 (C) in subsection (k)(5)(A), by striking  
8 “by Adverse” and inserting “by the Adverse”;

9 (D) in subsection (k)(5)(A), in the matter  
10 after the semicolon, by striking the word “and”;

11 (E) in subsection (o)(4)(A), by striking  
12 “under section 505(b)” and inserting “under  
13 subsection (b)”;

14 (F) in subsection (o)(4)(A), by striking  
15 “under 505(j)” and inserting “under subsection  
16 (j)”;

17 (G) in subsection (v)(3)(A), by striking  
18 “subparagraphs (1)(B)(i) or (2)(B)(i)” and in-  
19 serting “paragraph (1)(B)(i) or (2)(B)(i)”;

20 (H) in subsection (v)(3)(B), by striking  
21 “subparagraph (1)(B)(i) or (2)(B)(i)” and in-  
22 serting “paragraph (1)(B)(i) or (2)(B)(i)”.

23 (18) Section 505–1(e)(3)(B) of the Act (21  
24 U.S.C. 355–1(e)(3)(B)) is amended by striking  
25 “tests)” and inserting “tests);”.

1           (19) Section 505B(k)(2) of the Act (21 U.S.C.  
2           355c(k)(2)) is amended by striking “under 526” and  
3           inserting “under section 526”.

4           (20) Section 506(f)(1) of the Act (21 U.S.C.  
5           356(f)(1)) is amended by striking “and and fast  
6           track products” and inserting “and fast track prod-  
7           ucts”.

8           (21) Section 506C(a) of the Act (21 U.S.C.  
9           356c(a)) is amended, in the matter after paragraph  
10          (2), by striking “United States,,” and inserting  
11          “United States,”.

12          (22) Section 506H(e)(2) of the Act (21 U.S.C.  
13          356h(e)(2)) is amended, in the matter before sub-  
14          paragraph (A), by striking “one approved drugs”  
15          and inserting “one approved drug”.

16          (23) Section 506I of the Act (21 U.S.C. 356i)  
17          is amended—

18                 (A) in subsection (b), in the matter before  
19                 paragraph (1), by inserting “of section 505”  
20                 after “subsection (e) or (j)”;

21                 (B) in subsection (c), in the matter before  
22                 paragraph (1), by striking “subsection  
23                 505(j)(7)(A)” and inserting “section  
24                 505(j)(7)(A)”;



1 (C) in subsection (c)(1), by striking “sub-  
2 section 505(j)(7)(A)” and inserting “section  
3 505(j)(7)(A)”;

4 (D) in subsection (c)(2), by striking “sub-  
5 section 505(j)(7)(A)” and inserting “section  
6 505(j)(7)(A)”;

7 (E) in subsection (d), by striking “pub-  
8 lished under subsection 505(j)(7)(A)” and in-  
9 serting “published under section 505(j)(7)(A)”;

10 (F) in subsection (d), by striking “in ac-  
11 cordance with subsection 505(j)(7)(C)” and in-  
12 serting “in accordance with section  
13 505(j)(7)(C)”;

14 (G) in subsection (d), by striking “safety  
15 of effectiveness” and inserting “safety or effec-  
16 tiveness”;

17 (H) in subsection (e), by striking “pub-  
18 lished under subsection 505(j)(7)(A)” and in-  
19 serting “published under section 505(j)(7)(A)”;  
20 and

21 (I) in subsection (e), by striking “in ac-  
22 cordance with subsection 505(j)(7)(C)” and in-  
23 serting “in accordance with section  
24 505(j)(7)(C)”.

1           (24) Section 506J(f) of the Act (21 U.S.C.  
2           356j(f)) is amended, in the matter before paragraph  
3           (1), by striking “an device” and inserting “a de-  
4           vice”.

5           (25) Section 510 of the Act (21 U.S.C. 360) is  
6           amended—

7                   (A) in subsection (c)(2), by striking “sub-  
8                   section (b)(2)..” and inserting “subsection  
9                   (b)(2).”; and

10                   (B) in subsection (q)(2), by striking “para-  
11                   graph (2)” and inserting “paragraph (1)”.

12           (26) Section 512 of the Act (21 U.S.C. 360b)  
13           is amended—

14                   (A) in subsection (a)(6), but striking  
15                   “Alimenterius” and inserting “Alimentarius”;  
16                   and

17                   (B) in subsection (e)(2)(D)(iv)(II), by  
18                   striking “subclause (III)” and inserting “clause  
19                   (iii)(III)”.

20           (27) Section 514(c)(1)(C)(i) of the Act (21  
21           U.S.C. 360d(c)(1)(C)(i)) is amended by striking  
22           “standard organization” and inserting “standard de-  
23           velopment organization”.

24           (28) Section 519 of the Act (21 U.S.C. 360i)  
25           is amended—

1 (A) in subsection (a)(1)(B)(iii), by insert-  
2 ing a semicolon at the end;

3 (B) in subsection (a)(8)(B), in the matter  
4 after clause (ii), by striking “misbranded. and”  
5 and inserting “misbranded.”; and

6 (C) in subsection (i)(5), in the matter be-  
7 fore subparagraph (A), by striking “this section  
8 519 or section 522” and inserting “this section  
9 or section 522”.

10 (29) Section 520 of the Act (21 U.S.C. 360j)  
11 is amended—

12 (A) in subsection (o)(1), in the matter be-  
13 fore subparagraph (A), by striking “The term  
14 device,” and inserting “The term ‘device’;” and

15 (B) in subsection (p)(4)(B)(i), by striking  
16 “section 315.2 and 601.31” and inserting “sec-  
17 tions 315.2 and 601.31”.

18 (30) Section 522(a)(2) of the Act (21 U.S.C.  
19 360l(a)(2)) is amended by striking “under the Act”  
20 and inserting “under this Act”.

21 (31) Section 524(a)(4)(A)(iv) of the Act (21  
22 U.S.C. 360n(a)(4)(A)(iv)) is amended by striking  
23 “September 27, 2007.” and inserting “September  
24 27, 2007;”.

1           (32) Section 529 of the Act (21 U.S.C. 360ff)  
2 is amended—

3           (A) in subsection (a)(4)(D), by striking  
4 “that relies” and inserting “relies”;

5           (B) in subsection (a)(4)(E), by striking  
6 “that does not” and inserting “does not”; and

7           (C) in subsection (g), by striking “made..”  
8 and inserting “made.”.

9           (33) Section 564(h)(1) of the Act (21 U.S.C.  
10 360bbb–3(h)(1)) is amended by striking “section  
11 505(i)” and inserting “section 505(i),”.

12           (34) Section 565A(c) of the Act (21 U.S.C.  
13 360bbb–4a(c)) is amended by redesignating para-  
14 graph (6) as subparagraph (B) of paragraph (5).

15           (35) Section 571 of the Act (21 U.S.C. 360ccc)  
16 is amended—

17           (A) in subsection (a)(3)(A)(i), by striking  
18 “transgenic animal.” and inserting “transgenic  
19 animal;”;

20           (B) in subsection (k)(2)(B), by striking  
21 “pursuant to (a)(1)(A)(ii)” and inserting “pur-  
22 suant to subsection (a)(1)(A)(ii)”;

23           (C) in subsection (k)(3), by striking  
24 “under 512” and inserting “under section  
25 512”; and

1 (D) in subsection (k)(3), by striking “pur-  
2 suant to (a)(1)(A)(ii)” and inserting “pursuant  
3 to subsection (a)(1)(A)(ii)”.

4 (36) Section 582 of the Act (21 U.S.C. 360eee-  
5 1) is amended—

6 (A) in subsection (a)(8), by striking “of  
7 chapter 21,” and inserting “of title 21,”; and

8 (B) in subsection (b)(1)(A)(i), by striking  
9 “in an paper or electronic format” and insert-  
10 ing “in paper or electronic format”.

11 (37) Section 586C(b)(7)(B) of the Act (21  
12 U.S.C. 360fff-3(b)(7)(B)) is amended by striking  
13 “subject to 552(b)(4)” and inserting “subject to sec-  
14 tion 552(b)(4)”.

15 (38) Section 715(b)(2) of the Act (21 U.S.C.  
16 379d-4(b)(2)) is amended by striking “part 2” and  
17 inserting “part 2 of subchapter C”.

18 (39) Section 736A(a)(2)(A) of the Act (21  
19 U.S.C. 379h-1(a)(2)(A)) is amended by striking  
20 “subject to fee” and inserting “subject to the fee”.

21 (40) Section 738A of the Act (21 U.S.C. 379j-  
22 1) is amended—

23 (A) in subsection (a)(1)(A)(ii)(III), by  
24 striking “section 515C” and inserting “section  
25 515B”;

1 (B) in subsection (a)(1)(A), by redesignat-  
2 ing clause (iv) (with the heading “ANALYSIS”)  
3 as clause (v); and

4 (C) in subsection (a)(2)(B)(iv), by striking  
5 “the such fiscal year” and inserting “the fiscal  
6 year”.

7 (41) Section 740A(d)(5) of the Act (21 U.S.C.  
8 379j–13(d)(5)) is amended by striking “paragraph  
9 (4)” and inserting “paragraph (4),”.

10 (42) Section 741(g) of the Act (21 U.S.C.  
11 379j–21(g)) is amended by redesignating paragraph  
12 (4) (with the heading “OFFSET”) as paragraph (5).

13 (43) Section 743 of the Act (21 U.S.C. 379j–  
14 31) is amended—

15 (A) in subsection (b)(2)(B)(i), by striking  
16 “In establishing the fee amounts under sub-  
17 paragraph (A)(iii) for a fiscal year” through  
18 “in the program under section 806 in such fis-  
19 cal year.” and inserting—

20 “(I) IN GENERAL.—In establish-  
21 ing the fee amounts under subpara-  
22 graph (A)(iii) for a fiscal year, the  
23 Secretary shall provide for the number  
24 of importers who have submitted to  
25 the Secretary a notice under section

1                   806(c) informing the Secretary of the  
2                   intent of such importer to participate  
3                   in the program under section 806 in  
4                   such fiscal year.”; and

5                   (B) in subsection (b)(3), by striking  
6                   “clause (i), (ii), (iii), and (iv)” each place it ap-  
7                   pears and inserting “clauses (i), (ii), (iii), and  
8                   (iv)”.

9                   (44) Section 744C(c)(2)(B) of the Act (21  
10                  U.S.C. 379j-43(c)(2)(B)) is amended by striking  
11                  “the such fiscal year” and inserting “the fiscal  
12                  year”.

13                  (45) Section 744I(a)(2)(C) of the Act (21  
14                  U.S.C. 379j-53(a)(2)(C)) is amended by striking  
15                  “approvals letters” and inserting “approvals”.

16                  (46) Section 770(a) of the Act (21 U.S.C.  
17                  379dd(a)) is amended by striking “subsection (e)”  
18                  and inserting “subsection (g)”.

19                  (47) Section 801 of the Act (21 U.S.C. 381) is  
20                  amended—

21                         (A) in subsection (a), by striking “or (5)”  
22                         and inserting “, or (5)”;

23                         (B) in subsection (a), by striking “under  
24                         subsection (b)..” and inserting “under sub-  
25                         section (b).”;

1 (C) in subsection (b), by striking “sections  
2 760 or 761,” and inserting “section 760 or  
3 761,”;

4 (D) in subsection (l), by striking “(1)”;  
5 and

6 (E) in subsection (r)(4)(A), by striking  
7 “under 505(i)” and inserting “under section  
8 505(i)”.

9 (48) Section 802(g) of the Act (21 U.S.C.  
10 382(g)) is amended by striking “subsection  
11 (b)(1)A)” and inserting “subsection (b)(1)(A)”.

12 (49) Section 805 of the Act (21 U.S.C. 384a)  
13 is amended—

14 (A) in subsection (c)(2)(A)(ii), by striking  
15 “section 402 and section 403(w)” and inserting  
16 “sections 402 and 403(w)”;

17 (B) in subsection (e), in the matter after  
18 paragraph (3), by striking “chapter 21” and in-  
19 serting “title 21”.

20 (50) Section 808 of the Act (21 U.S.C. 384d)  
21 is amended—

22 (A) in subsection (c)(2)(C)(ii), by striking  
23 “described in 801(q)(3)” and inserting “de-  
24 scribed in section 801(q)(3)”;



1 (B) in subsection (c)(2)(C)(ii), by striking  
2 “under 301(g)” and inserting “under section  
3 801(q)”; and

4 (C) in subsection (d)(1), by striking “vol-  
5 untary” and inserting “the voluntary”.

6 (51) Section 906(b)(1) of the Act (21 U.S.C.  
7 387f(b)(1)) is amended by striking “findings is  
8 based” and inserting “findings are based”.

9 (52) Section 920(a)(1) of the Act (21 U.S.C.  
10 387t(a)(1)) is amended by striking “section 201 of  
11 Family” and inserting “section 201 of the Family”.

12 (53) Section 1013(a)(1) of the Act (21 U.S.C.  
13 399d(a)(1)) is amended by striking “a violation of  
14 any provision of this Act or any order, rule, regula-  
15 tion, standard, or ban under this Act, or any order,  
16 rule, regulation, standard, or ban under this Act”  
17 and inserting “a violation of, any provision of this  
18 Act or any order, rule, regulation, standard, or ban  
19 under this Act”.