

114TH CONGRESS
1ST SESSION

H. R. 639

[Report No. 114-]

To amend the Controlled Substances Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 2, 2015

Mr. PITTS (for himself, Mr. PALLONE, and Mr. GENE GREEN of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

FEBRUARY --, 2015

Reported from the Committee on Energy and Commerce with amendments

[Strike out all after the enacting clause and insert the part printed in *italic*]

[For text of introduced bill, see copy of bill as introduced on February 2, 2015]

A BILL

To amend the Controlled Substances Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing.

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 “Improving Regulatory*
5 *Transparency for New Medical Therapies Act”.*

6 **SEC. 2. SCHEDULING OF SUBSTANCES INCLUDED IN NEW**

7 **FDA-APPROVED DRUGS.**

8 *(a) EFFECTIVE DATE OF APPROVAL.—*

9 *(1) EFFECTIVE DATE OF DRUG APPROVAL.—Sec-*
10 *tion 505 of the Federal Food, Drug, and Cosmetic Act*
11 *(21 U.S.C. 355) is amended by adding at the end the*
12 *following:*

13 *“(x) DATE OF APPROVAL IN THE CASE OF REC-*
14 *OMMENDED CONTROLS UNDER THE CSA.—*

15 *“(1) IN GENERAL.—In the case of an application*
16 *under subsection (b) with respect to a drug for which*
17 *the Secretary provides notice to the sponsor that the*
18 *Secretary intends to recommend controls under the*
19 *Controlled Substances Act, approval of such applica-*
20 *tion shall not take effect until the interim final rule*
21 *controlling the drug is issued in accordance with sec-*
22 *tion 201(j) of the Controlled Substances Act.*

23 *“(2) DATE OF APPROVAL.—For purposes of this*
24 *section, with respect to an application described in*

1 *paragraph (1), the term ‘date of approval’ shall mean*
2 *the later of—*

3 “(A) *the date an application under sub-*
4 *section (b) is approved under subsection (c); or*
5 “(B) *the date of issuance of the interim*
6 *final rule controlling the drug.”.*

7 (2) *EFFECTIVE DATE OF APPROVAL OF BIOLOGI-*
8 *CAL PRODUCTS.—Section 351 of the Public Health*
9 *Service Act (42 U.S.C. 262) is amended by adding at*
10 *the end the following:*

11 “(n) *DATE OF APPROVAL IN THE CASE OF REC-*
12 *OMMENDED CONTROLS UNDER THE CSA.—*

13 “(1) *IN GENERAL.—In the case of an application*
14 *under subsection (a) with respect to a biological prod-*
15 *uct for which the Secretary provides notice to the*
16 *sponsor that the Secretary intends to recommend con-*
17 *trols under the Controlled Substances Act, approval of*
18 *such application shall not take effect until the interim*
19 *final rule controlling the biological product is issued*
20 *in accordance with section 201(j) of the Controlled*
21 *Substances Act.*

22 “(2) *DATE OF APPROVAL.—For purposes of this*
23 *section, with respect to an application described in*
24 *paragraph (1), references to the date of approval of*

1 *such application, or licensure of the product subject to*
2 *such application, shall mean the later of—*

3 *“(A) the date an application is approved*
4 *under subsection (a); or*

5 *“(B) the date of issuance of the interim*
6 *final rule controlling the biological product.”.*

7 *(3) EFFECTIVE DATE OF APPROVAL OF ANIMAL*
8 *DRUGS.—*

9 *(A) IN GENERAL.—Section 512 of the Fed-*
10 *eral Food, Drug, and Cosmetic Act (21 U.S.C.*
11 *360b) is amended by adding at the end the fol-*
12 *lowing:*

13 *“(q) DATE OF APPROVAL IN THE CASE OF REC-*
14 *OMMENDED CONTROLS UNDER THE CSA.—*

15 *“(1) IN GENERAL.—In the case of an application*
16 *under subsection (b) with respect to a drug for which*
17 *the Secretary provides notice to the sponsor that the*
18 *Secretary intends to recommend controls under the*
19 *Controlled Substances Act, approval of such applica-*
20 *tion shall not take effect until the interim final rule*
21 *controlling the drug is issued in accordance with sec-*
22 *tion 201(j) of the Controlled Substances Act.*

23 *“(2) DATE OF APPROVAL.—For purposes of this*
24 *section, with respect to an application described in*

1 *paragraph (1), the term ‘date of approval’ shall mean*
2 *the later of—*

3 “(A) *the date an application under sub-*
4 *section (b) is approved under subsection (c); or*

5 “(B) *the date of issuance of the interim*
6 *final rule controlling the drug.”.*

7 (B) *CONDITIONAL APPROVAL.—Section*
8 *571(d) of the Federal Food, Drug, and Cosmetic*
9 *Act (21 U.S.C. 360ccc(d)) is amended by adding*
10 *at the end the following:*

11 “(4)(A) *In the case of an application under sub-*
12 *section (a) with respect to a drug for which the Sec-*
13 *retary provides notice to the sponsor that the Sec-*
14 *retary intends to recommend controls under the Con-*
15 *trolled Substances Act, conditional approval of such*
16 *application shall not take effect until the interim*
17 *final rule controlling the drug is issued in accordance*
18 *with section 201(j) of the Controlled Substances Act.*

19 “(B) *For purposes of this section, with respect to*
20 *an application described in subparagraph (A), the*
21 *term ‘date of approval’ shall mean the later of—*

22 “(i) *the date an application under sub-*
23 *section (a) is conditionally approved under sub-*
24 *section (b); or*

1 “(ii) the date of issuance of the interim
2 final rule controlling the drug.”.

3 (C) INDEXING OF LEGALLY MARKETED UN-
4 APPROVED NEW ANIMAL DRUGS.—Section 572 of
5 the Federal Food, Drug, and Cosmetic Act (21
6 U.S.C. 360ccc-1) is amended by adding at the
7 end the following:

8 “(k) In the case of a request under subsection (d) to
9 add a drug to the index under subsection (a) with respect
10 to a drug for which the Secretary provides notice to the
11 person filing the request that the Secretary intends to rec-
12 ommend controls under the Controlled Substances Act, a de-
13 termination to grant the request to add such drug to the
14 index shall not take effect, and the Secretary shall not list
15 the drug on such index, until the interim final rule control-
16 ling the drug is issued in accordance with section 201(j)
17 of the Controlled Substances Act.”.

18 (4) DATE OF APPROVAL FOR DESIGNATED NEW
19 ANIMAL DRUGS.—Section 573(c) of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 360ccc-2(c)) is
21 amended by adding at the end the following:

22 “(3) For purposes of determining the 7-year pe-
23 riod of exclusivity under paragraph (1) for a drug for
24 which the Secretary intends to recommend controls
25 under the Controlled Substances Act, the drug shall

1 *not be considered approved or conditionally approved*
2 *until the date that the interim final rule controlling*
3 *the drug is issued in accordance with section 201(j)*
4 *of the Controlled Substances Act.”.*

5 ***(b) SCHEDULING OF NEWLY APPROVED DRUGS.—****Sec-*
6 *tion 201 of the Controlled Substances Act (21 U.S.C. 811)*
7 *is amended by inserting after subsection (i) the following:*
8 *“(j)(1) With respect to a drug referred to in subsection*
9 *(f), if the Secretary of Health and Human Services rec-*
10 *ommends that the Attorney General add the drug to sched-*
11 *ule II, III, IV, or V pursuant to subsections (a) and (b),*
12 *the Attorney General shall, not later than 90 days after the*
13 *date described in paragraph (2), issue an interim final rule*
14 *controlling the drug in accordance with such subsections*
15 *and section 202(b) using the procedures described in para-*
16 *graph (3).*

17 *“(2) The date described in this paragraph shall be the*
18 *later of—*

19 *“(A) the date on which the Attorney General re-*
20 *ceives the scientific and medical evaluation and rec-*
21 *ommendations from the Secretary of Health and*
22 *Human Services in accordance with subsection (b); or*

23 *“(B) the date on which the Attorney General re-*
24 *ceives notification from the Secretary of Health and*
25 *Human Services that the Secretary has approved an*

1 *application under section 505(c), 512, 571, or 572 of*
2 *the Federal Food, Drug, and Cosmetic Act or section*
3 *351(a) of the Public Health Service Act with respect*
4 *to the drug described in paragraph (1).*

5 *“(3) A rule issued by the Attorney General under para-*
6 *graph (1) shall be in accordance with the procedures pro-*
7 *vided in subsection (a), except that the rule shall become*
8 *immediately effective as an interim final rule without re-*
9 *quiring the Attorney General to demonstrate good cause*
10 *therefor. After publication of the interim final rule, the At-*
11 *torney General shall issue a final rule in accordance with*
12 *the procedures provided in subsection (a).”.*

13 *(c) EXTENSION OF PATENT TERM.—Section 156 of*
14 *title 35, United States Code, is amended—*

15 *(1) in subsection (d)(1), in the matter preceding*
16 *subparagraph (A), by inserting “, or in the case of a*
17 *drug product described in subsection (i) within the*
18 *sixty-day period beginning on the covered date (as de-*
19 *fined in subsection (i))” after “marketing or use”;*
20 *and*

21 *(2) by adding at the end the following:*

22 *“(i)(1) For purposes of this section, if the Secretary*
23 *of Health and Human Services provides notice to the spon-*
24 *sor of an application or request for approval, conditional*
25 *approval, or indexing of a drug product for which the Sec-*

1 *retary intends to recommend controls under the Controlled*
2 *Substances Act, beginning on the covered date, the drug*
3 *product shall be considered to—*

4 “(A) *have been approved; and*

5 “(B) *have permission for commercial marketing*
6 *or use.*

7 “(2) *In this subsection, the term ‘covered date’ means*
8 *the later of—*

9 “(A) *the date an application is approved—*

10 “(i) *under section 351(a)(2)(C) of the Pub-*
11 *lic Health Service Act; or*

12 “(ii) *under section 505(b) or 512(c) of the*
13 *Federal Food, Drug, and Cosmetic Act;*

14 “(B) *the date an application is conditionally ap-*
15 *proved under section 571(b) of the Federal Food,*
16 *Drug, and Cosmetic Act;*

17 “(C) *the date a request for indexing is granted*
18 *under section 572(d) of the Federal Food, Drug, and*
19 *Cosmetic Act; or*

20 “(D) *the date of issuance of the interim final*
21 *rule controlling the drug under section 201(j) of the*
22 *Controlled Substances Act.”.*

23 **SEC. 3. ENHANCING NEW DRUG DEVELOPMENT.**

24 *Section 303 of the Controlled Substances Act (21*
25 *U.S.C. 823) is amended by adding at the end the following:*

1 “(i)(1) For purposes of registration to manufacture a
2 controlled substance under subsection (d) for use only in
3 a clinical trial, the Attorney General shall register the ap-
4 plicant, or serve an order to show cause upon the applicant
5 in accordance with section 304(c), not later than 180 days
6 after the date on which the application is accepted for fil-
7 ing.

8 “(2) For purposes of registration to manufacture a
9 controlled substance under subsection (a) for use only in
10 a clinical trial, the Attorney General shall, in accordance
11 with the regulations issued by the Attorney General, issue
12 a notice of application not later than 90 days after the ap-
13 plication is accepted for filing. Not later than 90 days after
14 the date on which the period for comment pursuant to such
15 notice ends, the Attorney General shall register the appli-
16 cant, or serve an order to show cause upon the applicant
17 in accordance with section 304(c), unless the Attorney Gen-
18 eral has granted a hearing on the application under section
19 1008(i) of the Controlled Substances Import and Export
20 Act.”.

Amend the title so as to read: “A bill to amend the Controlled Substances Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing, and for other purposes.”.