

In the Senate of the United States,

October 26, 2015.

Resolved, That the bill from the House of Representatives (H.R. 639) entitled “An Act 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.”, do pass with the following

AMENDMENT:

Strike all after the enacting clause and insert the following:

1 ***SECTION 1. SHORT TITLE.***

2 *This Act may be cited as the “Improving Regulatory*
3 *Transparency for New Medical Therapies Act”.*

4 ***SEC. 2. SCHEDULING OF SUBSTANCES INCLUDED IN NEW***
5 ***FDA-APPROVED DRUGS.***

6 *(a) EFFECTIVE DATE OF APPROVAL.—*

7 *(1) EFFECTIVE DATE OF DRUG APPROVAL.—Sec-*
8 *tion 505 of the Federal Food, Drug, and Cosmetic Act*

1 (21 U.S.C. 355) is amended by adding at the end the
 2 following:

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

5 “(1) *IN GENERAL.*—In the case of an application
 6 under subsection (b) with respect to a drug for which
 7 the Secretary provides notice to the sponsor that the
 8 Secretary intends to issue a scientific and medical
 9 evaluation and recommend controls under the Con-
 10 trolled Substances Act, approval of such application
 11 shall not take effect until the interim final rule con-
 12 trolling the drug is issued in accordance with section
 13 201(j) of the Controlled Substances Act.

14 “(2) *DATE OF APPROVAL.*—For purposes of this
 15 section, with respect to an application described in
 16 paragraph (1), the term ‘date of approval’ shall mean
 17 the later of—

18 “(A) the date an application under sub-
 19 section (b) is approved under subsection (c); or

20 “(B) the date of issuance of the interim
 21 final rule controlling the drug.”.

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

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

3 “(1) *IN GENERAL.*—*In the case of an application*
4 *under subsection (a) with respect to a biological prod-*
5 *uct for which the Secretary provides notice to the*
6 *sponsor that the Secretary intends to issue a scientific*
7 *and medical evaluation and recommend controls*
8 *under the Controlled Substances Act, approval of such*
9 *application shall not take effect until the interim*
10 *final rule controlling the biological product is issued*
11 *in accordance with section 201(j) of the Controlled*
12 *Substances Act.*

13 “(2) *DATE OF APPROVAL.*—*For purposes of this*
14 *section, with respect to an application described in*
15 *paragraph (1), references to the date of approval of*
16 *such application, or licensure of the product subject to*
17 *such application, shall mean the later of—*

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

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

22 “(3) *EFFECTIVE DATE OF APPROVAL OF ANIMAL*
23 *DRUGS.*—

24 “(A) *IN GENERAL.*—*Section 512 of the Fed-*
25 *eral Food, Drug, and Cosmetic Act (21 U.S.C.*

1 360b) is amended by adding at the end the fol-
 2 lowing:

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

5 “(1) *IN GENERAL.*—*In the case of an application*
 6 *under subsection (b) with respect to a drug for which*
 7 *the Secretary provides notice to the sponsor that the*
 8 *Secretary intends to issue a scientific and medical*
 9 *evaluation and recommend controls under the Con-*
 10 *trolled Substances Act, approval of such application*
 11 *shall not take effect until the interim final rule con-*
 12 *trolling the drug is issued in accordance with section*
 13 *201(j) of the Controlled Substances Act.*

14 “(2) *DATE OF APPROVAL.*—*For purposes of this*
 15 *section, with respect to an application described in*
 16 *paragraph (1), the term ‘date of approval’ shall mean*
 17 *the later of—*

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

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

22 “(B) *CONDITIONAL APPROVAL.*—*Section*
 23 *571(d) of the Federal Food, Drug, and Cosmetic*
 24 *Act (21 U.S.C. 360ccc(d)) is amended by adding*
 25 *at the end the following:*

1 “(4)(A) *In the case of an application under sub-*
 2 *section (a) with respect to a drug for which the Sec-*
 3 *retary provides notice to the sponsor that the Sec-*
 4 *retary intends to issue a scientific and medical eval-*
 5 *uation and recommend controls under the Controlled*
 6 *Substances Act, conditional approval of such applica-*
 7 *tion shall not take effect until the interim final rule*
 8 *controlling the drug is issued in accordance with sec-*
 9 *tion 201(j) of the Controlled Substances Act.*

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

13 “(i) *the date an application under sub-*
 14 *section (a) is conditionally approved under sub-*
 15 *section (b); or*

16 “(ii) *the date of issuance of the interim*
 17 *final rule controlling the drug.”.*

18 (C) INDEXING OF LEGALLY MARKETED UN-
 19 APPROVED NEW ANIMAL DRUGS.—*Section 572 of*
 20 *the Federal Food, Drug, and Cosmetic Act (21*
 21 *U.S.C. 360ccc–1) is amended by adding at the*
 22 *end the following:*

23 “(k) *In the case of a request under subsection (d) to*
 24 *add a drug to the index under subsection (a) with respect*
 25 *to a drug for which the Secretary provides notice to the*

1 *person filing the request that the Secretary intends to issue*
 2 *a scientific and medical evaluation and recommend controls*
 3 *under the Controlled Substances Act, a determination to*
 4 *grant the request to add such drug to the index shall not*
 5 *take effect until the interim final rule controlling the drug*
 6 *is issued in accordance with section 201(j) of the Controlled*
 7 *Substances Act.”.*

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

12 “(3) *For purposes of determining the 7-year pe-*
 13 *riod of exclusivity under paragraph (1) for a drug for*
 14 *which the Secretary intends to issue a scientific and*
 15 *medical evaluation and recommend controls under the*
 16 *Controlled Substances Act, the drug shall not be con-*
 17 *sidered approved or conditionally approved until the*
 18 *date that the interim final rule controlling the drug*
 19 *is issued in accordance with section 201(j) of the Con-*
 20 *trolled Substances Act.”.*

21 (b) *SCHEDULING OF NEWLY APPROVED DRUGS.—Sec-*
 22 *tion 201 of the Controlled Substances Act (21 U.S.C. 811)*
 23 *is amended by inserting after subsection (i) the following:*

24 “(j)(1) *With respect to a drug referred to in subsection*
 25 *(f), if the Secretary of Health and Human Services rec-*

1 *ommends that the Attorney General control the drug in*
2 *schedule II, III, IV, or V pursuant to subsections (a) and*
3 *(b), the Attorney General shall, not later than 90 days after*
4 *the date described in paragraph (2), issue an interim final*
5 *rule controlling the drug in accordance with such sub-*
6 *sections and section 202(b) using the procedures described*
7 *in paragraph (3).*

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

10 “(A) *the date on which the Attorney General re-*
11 *ceives the scientific and medical evaluation and the*
12 *scheduling recommendation from the Secretary of*
13 *Health and Human Services in accordance with sub-*
14 *section (b); or*

15 “(B) *the date on which the Attorney General re-*
16 *ceives notification from the Secretary of Health and*
17 *Human Services that the Secretary has approved an*
18 *application under section 505(c), 512, or 571 of the*
19 *Federal Food, Drug, and Cosmetic Act or section*
20 *351(a) of the Public Health Service Act, or indexed*
21 *a drug under section 572 of the Federal Food, Drug,*
22 *and Cosmetic Act, with respect to the drug described*
23 *in paragraph (1).*

24 “(3) *A rule issued by the Attorney General under para-*
25 *graph (1) shall become immediately effective as an interim*

1 *final rule without requiring the Attorney General to dem-*
 2 *onstrate good cause therefor. The interim final rule shall*
 3 *give interested persons the opportunity to comment and to*
 4 *request a hearing. After the conclusion of such proceedings,*
 5 *the Attorney General shall issue a final rule in accordance*
 6 *with the scheduling criteria of subsections (b), (c), and (d)*
 7 *of this section and section 202(b).”.*

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

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

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

17 “(i)(1) *For purposes of this section, if the Secretary*
 18 *of Health and Human Services provides notice to the spon-*
 19 *sor of an application or request for approval, conditional*
 20 *approval, or indexing of a drug product for which the Sec-*
 21 *retary intends to recommend controls under the Controlled*
 22 *Substances Act, beginning on the covered date, the drug*
 23 *product shall be considered to—*

1 “(A) have been approved or indexed under the
 2 relevant provision of the Public Health Service Act or
 3 Federal Food, Drug, and Cosmetic Act; and

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

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

8 “(A) the date an application is approved—

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

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

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

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

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

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

23 Section 303 of the Controlled Substances Act (21
 24 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.”.*

21 **SEC. 4. RE-EXPORTATION AMONG MEMBERS OF THE EURO-**
 22 **PEAN ECONOMIC AREA.**

23 *Section 1003 of the Controlled Substances Import and*
 24 *Export Act (21 U.S.C. 953) is amended—*

25 *(1) in subsection(f)—*

1 (A) in paragraph (5)—

2 (i) by striking “(5)” and inserting
3 “(5)(A)”;

4 (ii) by inserting “, except that the con-
5 trolled substance may be exported from a
6 second country that is a member of the Eu-
7 ropean Economic Area to another country
8 that is a member of the European Economic
9 Area, provided that the first country is also
10 a member of the European Economic Area”
11 before the period at the end; and

12 (iii) by adding at the end the fol-
13 lowing:

14 “(B) Subsequent to any re-exportation described
15 in subparagraph (A), a controlled substance may con-
16 tinue to be exported from any country that is a mem-
17 ber of the European Economic Area to any other such
18 country, if—

19 “(i) the conditions applicable with respect
20 to the first country under paragraphs (1), (2),
21 (3), (4), (6), and (7) are met by each subsequent
22 country from which the controlled substance is
23 exported pursuant to this paragraph; and

24 “(ii) the conditions applicable with respect
25 to the second country under paragraphs (1), (2),

1 (3), (4), (6), and (7) are met by each subsequent
2 country to which the controlled substance is ex-
3 ported pursuant to this paragraph.”; and

4 (B) in paragraph (6)—

5 (i) by striking “(6)” and inserting
6 “(6)(A)”; and

7 (ii) by adding at the end the following:

8 “(B) In the case of re-exportation among mem-
9 bers of the European Economic Area, within 30 days
10 after each re-exportation, the person who exported the
11 controlled substance from the United States delivers to
12 the Attorney General—

13 “(i) documentation certifying that such re-
14 exportation has occurred; and

15 “(ii) information concerning the consignee,
16 country, and product.”; and

17 (2) by adding at the end the following:

18 “(g) *LIMITATION.*—Subject to paragraphs (5) and (6)
19 of subsection (f) in the case of any controlled substance in
20 schedule I or II or any narcotic drug in schedule III or
21 IV, the Attorney General shall not promulgate nor enforce
22 any regulation, subregulatory guidance, or enforcement pol-
23 icy which impedes re-exportation of any controlled sub-
24 stance among European Economic Area countries, includ-
25 ing by promulgating or enforcing any requirement that—

1 “(1) re-exportation from the first country to the
2 second country or re-exportation from the second
3 country to another country occur within a specified
4 period of time; or

5 “(2) information concerning the consignee, coun-
6 try, and product be provided prior to exportation of
7 the controlled substance from the United States or
8 prior to each re-exportation among members of the
9 European Economic Area.”.

Attest:

Secretary.

114TH CONGRESS
1ST SESSION

H.R. 639

AMENDMENT