

114TH CONGRESS
1ST SESSION

H. R. 639

IN THE SENATE OF THE UNITED STATES

MARCH 17, 2015

Received; read twice and referred to the Committee on Health, Education,
Labor, and Pensions

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

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.—

8 Section 505 of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 355) is amended by adding at
10 the end the following:

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

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

22 “(2) DATE OF APPROVAL.—For purposes of
23 this section, with respect to an application described
24 in paragraph (1), the term ‘date of approval’ shall
25 mean the later of—

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

3 “(B) the date of issuance of the interim
4 final rule controlling the drug.”.

5 (2) EFFECTIVE DATE OF APPROVAL OF BIO-
6 LOGICAL PRODUCTS.—Section 351 of the Public
7 Health Service Act (42 U.S.C. 262) is amended by
8 adding at the end the following:

9 “(n) DATE OF APPROVAL IN THE CASE OF REC-
10 COMMENDED CONTROLS UNDER THE CSA.—

11 “(1) IN GENERAL.—In the case of an applica-
12 tion under subsection (a) with respect to a biological
13 product for which the Secretary provides notice to
14 the sponsor that the Secretary intends to rec-
15 ommend controls under the Controlled Substances
16 Act, approval of such application shall not take ef-
17 fect until the interim final rule controlling the bio-
18 logical product is issued in accordance with section
19 201(j) of the Controlled Substances Act.

20 “(2) DATE OF APPROVAL.—For purposes of
21 this section, with respect to an application described
22 in paragraph (1), references to the date of approval
23 of such application, or licensure of the product sub-
24 ject to such application, shall mean the later of—

1 “(A) the date an application is approved
2 under subsection (a); or

3 “(B) the date of issuance of the interim
4 final rule controlling the biological product.”.

5 (3) EFFECTIVE DATE OF APPROVAL OF ANIMAL
6 DRUGS.—

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

11 “(q) DATE OF APPROVAL IN THE CASE OF REC-
12 COMMENDED CONTROLS UNDER THE CSA.—

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

22 “(2) DATE OF APPROVAL.—For purposes of
23 this section, with respect to an application described
24 in paragraph (1), the term ‘date of approval’ shall
25 mean the later of—

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

3 “(B) the date of issuance of the interim
4 final rule controlling the drug.”.

5 (B) **CONDITIONAL APPROVAL.**—Section
6 571(d) of the Federal Food, Drug, and Cos-
7 metic Act (21 U.S.C. 360ccc(d)) is amended by
8 adding at the end the following:

9 “(4)(A) In the case of an application under
10 subsection (a) with respect to a drug for which the
11 Secretary provides notice to the sponsor that the
12 Secretary intends to recommend controls under the
13 Controlled Substances Act, conditional approval of
14 such application shall not take effect until the in-
15 terim final rule controlling the drug is issued in ac-
16 cordance with section 201(j) of the Controlled Sub-
17 stances Act.

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

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

24 “(ii) the date of issuance of the interim
25 final rule controlling the drug.”.

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

6 “(k) In the case of a request under subsection (d)
7 to add a drug to the index under subsection (a) with re-
8 spect to a drug for which the Secretary provides notice
9 to the person filing the request that the Secretary intends
10 to recommend controls under the Controlled Substances
11 Act, a determination to grant the request to add such drug
12 to the index shall not take effect, and the Secretary shall
13 not list the drug on such index, until the interim final rule
14 controlling the drug is issued in accordance with section
15 201(j) of the Controlled Substances Act.”.

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

20 “(3) For purposes of determining the 7-year pe-
21 riod of exclusivity under paragraph (1) for a drug
22 for which the Secretary intends to recommend con-
23 trols under the Controlled Substances Act, the drug
24 shall not be considered approved or conditionally ap-
25 proved until the date that the interim final rule con-

1 trolling the drug is issued in accordance with section
2 201(j) of the Controlled Substances Act.”.

3 (b) SCHEDULING OF NEWLY APPROVED DRUGS.—

4 Section 201 of the Controlled Substances Act (21 U.S.C.
5 811) is amended by inserting after subsection (i) the fol-
6 lowing:

7 “(j)(1) With respect to a drug referred to in sub-
8 section (f), if the Secretary of Health and Human Services
9 recommends that the Attorney General add the drug to
10 schedule II, III, IV, or V pursuant to subsections (a) and
11 (b), the Attorney General shall, not later than 90 days
12 after the date described in paragraph (2), issue an interim
13 final rule controlling the drug in accordance with such
14 subsections and section 202(b) using the procedures de-
15 scribed in paragraph (3).

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

18 “(A) the date on which the Attorney General
19 receives the scientific and medical evaluation and
20 recommendations from the Secretary of Health and
21 Human Services in accordance with subsection (b);
22 or

23 “(B) the date on which the Attorney General
24 receives notification from the Secretary of Health
25 and Human Services that the Secretary has ap-

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

6 “(3) A rule issued by the Attorney General under
7 paragraph (1) shall be in accordance with the procedures
8 provided in subsection (a), except that the rule shall be-
9 come immediately effective as an interim final rule without
10 requiring the Attorney General to demonstrate good cause
11 therefor. After publication of the interim final rule, the
12 Attorney General shall issue a final rule in accordance
13 with the procedures provided in subsection (a).”.

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

16 (1) in subsection (d)(1), in the matter pre-
17 ceding subparagraph (A), by inserting “, or in the
18 case of a drug product described in subsection (i)
19 within the 60-day period beginning on the covered
20 date (as defined in subsection (i))” after “marketing
21 or use”; and

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

23 “(i)(1) For purposes of this section, if the Secretary
24 of Health and Human Services provides notice to the
25 sponsor of an application or request for approval, condi-

1 tional approval, or indexing of a drug product for which
2 the Secretary intends to recommend controls under the
3 Controlled Substances Act, beginning on the covered date,
4 the drug product shall be considered to—

5 “(A) have been approved under the relevant
6 provision of the Public Health Service Act or Fed-
7 eral Food, Drug, and Cosmetic Act; and

8 “(B) have permission for commercial marketing
9 or use.

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

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

13 “(i) under section 351(a)(2)(C) of the
14 Public Health Service Act; or

15 “(ii) under section 505(b) or 512(e) of the
16 Federal Food, Drug, and Cosmetic Act;

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

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

23 “(D) the date of issuance of the interim final
24 rule controlling the drug under section 201(j) of the
25 Controlled Substances Act.”.

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

2 Section 303 of the Controlled Substances Act (21
3 U.S.C. 823) is amended by adding at the end the fol-
4 lowing:

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

12 “(2) For purposes of registration to manufacture a
13 controlled substance under subsection (a) for use only in
14 a clinical trial, the Attorney General shall, in accordance
15 with the regulations issued by the Attorney General, issue
16 a notice of application not later than 90 days after the
17 application is accepted for filing. Not later than 90 days
18 after the date on which the period for comment pursuant
19 to such notice ends, the Attorney General shall register
20 the applicant, or serve an order to show cause upon the
21 applicant in accordance with section 304(c), unless the At-
22 torney General has granted a hearing on the application

1 under section 1008(i) of the Controlled Substances Import
2 and Export Act.”.

Passed the House of Representatives March 16,
2015.

Attest:

KAREN L. HAAS,

Clerk.