

114TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

To amend the Controlled Substances Act and the Federal Food, Drug, and Cosmetic 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.

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IN THE SENATE OF THE UNITED STATES

Mr. HATCH (for himself and Mr. WHITEHOUSE) introduced the following bill; which was read twice and referred to the Committee on

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**A BILL**

To amend the Controlled Substances Act and the Federal Food, Drug, and Cosmetic 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.

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”.

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

3 (a) EFFECTIVE DATE OF APPROVAL.—

4 (1) EFFECTIVE DATE OF DRUG APPROVAL.—

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

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

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

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

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

25 “(B) the date of issuance of the interim  
26 final rule controlling the drug.”.

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

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

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

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

21                  “(A) the date an application is approved  
22                  under subsection (a); or

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

1           (3) EFFECTIVE DATE OF APPROVAL OF ANIMAL  
2           DRUGS.—

3           (A) IN GENERAL.—Section 512 of the Fed-  
4           eral Food, Drug, and Cosmetic Act (21 U.S.C.  
5           360b) is amended by adding at the end the fol-  
6           lowing:

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

9           “(1) IN GENERAL.—In the case of an applica-  
10          tion under subsection (b) with respect to a drug for  
11          which the Secretary provides notice to the sponsor  
12          that the Secretary intends to recommend controls  
13          under the Controlled Substances Act, 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          “(2) DATE OF APPROVAL.—For purposes of  
19          this section, with respect to an application described  
20          in paragraph (1), the term ‘date of approval’ shall  
21          mean the later of—

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

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

1           (B)   CONDITIONAL   APPROVAL.—Section  
2           571(d) of the Federal Food, Drug, and Cos-  
3           metic Act (21 U.S.C. 360ccc(d)) is amended by  
4           adding at the end the following:

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

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

17                 “(i) the date an application under sub-  
18                 section (a) is conditionally approved under sub-  
19                 section (b); or

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

22          (C)   INDEXING   OF   LEGALLY   MARKETED  
23          UNAPPROVED   NEW   ANIMAL   DRUGS.—Section  
24          572 of the Federal Food, Drug, and Cosmetic

1 Act (21 U.S.C. 360ccc–1) is amended by add-  
2 ing at the end the following:

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

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

17 “(3) For purposes of determining the 7-year pe-  
18 riod of exclusivity under paragraph (1) for a drug  
19 for which the Secretary intends to recommend con-  
20 trols under the Controlled Substances Act, the drug  
21 shall not be considered approved or conditionally ap-  
22 proved until the date that the interim final rule con-  
23 trolling the drug is issued in accordance with section  
24 201(j) of the Controlled Substances Act.”.

1 (b) SCHEDULING OF NEWLY APPROVED DRUGS.—  
2 Section 201 of the Controlled Substances Act (21 U.S.C.  
3 811) is amended by inserting after subsection (i) the fol-  
4 lowing:

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

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

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

21 “(B) the date on which the Attorney General  
22 receives notification from the Secretary of Health  
23 and Human Services that the Secretary has ap-  
24 proved an application under section 505(c), 512,  
25 571, or 572 of the Federal Food, Drug, and Cos-

1        metric Act or section 351(a) of the Public Health  
2        Service Act with respect to the drug described in  
3        paragraph (1).

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

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

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

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

21                “(i)(1) For purposes of this section, if the Secretary  
22                of Health and Human Services provides notice to the  
23                sponsor of an application or request for approval, condi-  
24                tional approval, or indexing of a drug product for which  
25                the Secretary intends to recommend controls under the

1 Controlled Substances Act, beginning on the covered date,  
2 the drug product shall be considered to—

3 “(A) have been approved; 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  
10 Public 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,  
18 and 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 fol-  
25 lowing:

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

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  
13 application is accepted for filing. Not later than 90 days  
14 after the date on which the period for comment pursuant  
15 to such notice ends, the Attorney General shall register  
16 the applicant, or serve an order to show cause upon the  
17 applicant in accordance with section 304(c), unless the At-  
18 torney General has granted a hearing on the application  
19 under section 1008(i) of the Controlled Substances Import  
20 and Export Act.”.