

AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 639
OFFERED BY M . _____

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.—

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

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

“(1) IN GENERAL.—In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the in-

1 interim final rule controlling the drug is issued in ac-
2 cordance with section 201(j) of the Controlled Sub-
3 stances Act.

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

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

10 “(B) the date of issuance of the interim
11 final rule controlling the drug.”.

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

16 “(n) DATE OF APPROVAL IN THE CASE OF REC-
17 OMMENDED CONTROLS UNDER THE CSA.—

18 “(1) IN GENERAL.—In the case of an applica-
19 tion under subsection (a) with respect to a biological
20 product for which the Secretary provides notice to
21 the sponsor that the Secretary intends to rec-
22 ommend controls under the Controlled Substances
23 Act, approval of such application shall not take ef-
24 fect until the interim final rule controlling the bio-

1 logical product is issued in accordance with section
2 201(j) of the Controlled Substances Act.

3 “(2) DATE OF APPROVAL.—For purposes of
4 this section, with respect to an application described
5 in paragraph (1), references to the date of approval
6 of such application, or licensure of the product sub-
7 ject to such application, shall mean the later of—

8 “(A) the date an application is approved
9 under subsection (a); or

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

12 (3) EFFECTIVE DATE OF APPROVAL OF ANIMAL
13 DRUGS.—

14 (A) IN GENERAL.—Section 512 of the Fed-
15 eral Food, Drug, and Cosmetic Act (21 U.S.C.
16 360b) is amended by adding at the end the fol-
17 lowing:

18 “(q) DATE OF APPROVAL IN THE CASE OF REC-
19 OMMENDED CONTROLS UNDER THE CSA.—

20 “(1) IN GENERAL.—In the case of an applica-
21 tion under subsection (b) with respect to a drug for
22 which the Secretary provides notice to the sponsor
23 that the Secretary intends to recommend controls
24 under the Controlled Substances Act, approval of
25 such application shall not take effect until the in-

1 interim final rule controlling the drug is issued in ac-
2 cordance with section 201(j) of the Controlled Sub-
3 stances Act.

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

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

10 “(B) the date of issuance of the interim
11 final rule controlling the drug.”.

12 (B) CONDITIONAL APPROVAL.—Section
13 571(d) of the Federal Food, Drug, and Cos-
14 metic Act (21 U.S.C. 360ccc(d)) is amended by
15 adding at the end the following:

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

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

4 “(i) the date an application under sub-
5 section (a) is conditionally approved under sub-
6 section (b); or

7 “(ii) the date of issuance of the interim
8 final rule controlling the drug.”.

9 (C) INDEXING OF LEGALLY MARKETING
10 UNAPPROVED NEW ANIMAL DRUGS.—Section
11 572 of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 360ccc–1) is amended by add-
13 ing at the end the following:

14 “(k) In the case of a request under subsection (d)
15 to add a drug to the index under subsection (a) with re-
16 spect to a drug for which the Secretary provides notice
17 to the person filing the request that the Secretary intends
18 to recommend controls under the Controlled Substances
19 Act, a determination to grant the request to add such drug
20 to the index shall not take effect, and the Secretary shall
21 not list the drug on such index, until the interim final rule
22 controlling the drug is issued in accordance with section
23 201(j) of the Controlled Substances Act.”.

24 (4) DATE OF APPROVAL FOR DESIGNATED NEW
25 ANIMAL DRUGS.—Section 573(c) of the Federal

1 Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc–
2 2(c)) is amended by adding at the end the following:

3 “(3) For purposes of determining the 7-year pe-
4 riod of exclusivity under paragraph (1) for a drug
5 for which the Secretary intends to recommend con-
6 trols under the Controlled Substances Act, the drug
7 shall not be considered approved or conditionally ap-
8 proved until the date that the interim final rule con-
9 trolling the drug is issued in accordance with section
10 201(j) of the Controlled Substances Act.”.

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

15 “(j)(1) With respect to a drug referred to in sub-
16 section (f), if the Secretary of Health and Human Services
17 recommends that the Attorney General add the drug or
18 other substance to schedule II, III, IV, or V pursuant to
19 subsections (a) and (b), the Attorney General shall, not
20 later than 90 days after the date described in paragraph
21 (2), issue an interim final rule controlling the drug or
22 other substance in accordance with such subsections and
23 section 202(b) using the procedures described in para-
24 graph (3).

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

3 “(A) the date on which the Attorney General
4 receives the scientific and medical evaluation and
5 recommendations from the Secretary of Health and
6 Human Services in accordance with subsection (b);
7 or

8 “(B) the date on which the Attorney General
9 receives notification from the Secretary of Health
10 and Human Services that the Secretary has ap-
11 proved an application under section 505(c), 512,
12 571, or 572 of the Federal Food, Drug, and Cos-
13 metic Act or section 351(a) of the Public Health
14 Service Act with respect to the drug described in
15 paragraph (1).

16 “(3) A rule issued by the Attorney General under
17 paragraph (1) shall be in accordance with the procedures
18 provided in subsection (a), except that the rule shall be-
19 come immediately effective as an interim final rule without
20 requiring the Attorney General to demonstrate good cause
21 therefor. After publication of the interim final rule, the
22 Attorney General shall issue a final rule in accordance
23 with the procedures provided in subsection (a).”.

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

1 (1) in subsection (d)(1), in the matter pre-
2 ceding subparagraph (A), by inserting “, or in the
3 case of a drug described in subsection (i) within the
4 sixty-day period beginning on the covered date (as
5 defined in subsection (i))” after “marketing or use”;
6 and

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

8 “(i)(1) For purposes of this section, if the Secretary
9 of Health and Human Services provides notice to the
10 sponsor of an application for approval of a drug for which
11 the Secretary intends to recommend controls under the
12 Controlled Substances Act (21 U.S.C. 801 et seq.) with
13 respect to the drug covered by the application, beginning
14 on the covered date, the drug shall be considered to—

15 “(A) have been approved; and

16 “(B) have permission for commercial marketing
17 or use.

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

20 “(A) the date an application submitted for ap-
21 proval—

22 “(i) under section 351 of the Public Health
23 Service Act (42 U.S.C. 262) is approved under
24 subsection (a)(2)(C) of such section 351; or

1 “(ii) under section 505(b) of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C.
3 355(b)) is approved under subsection (c) of
4 such section 505; or

5 “(B) the date of issuance of the interim final
6 rule controlling the drug under section 201(j) of the
7 Controlled Substances Act.”.

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

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

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

19 “(2) For purposes of registration to manufacture a
20 controlled substance under subsection (a) for use only in
21 a clinical trial, the Attorney General shall, in accordance
22 with the regulations issued by the Attorney General, issue
23 a notice of application not later than 90 days after the
24 application is accepted for filing. Not later than 90 days
25 after the date on which the period for comment pursuant

1 to such notice ends, the Attorney General shall register
2 the applicant, or serve an order to show cause upon the
3 applicant in accordance with section 304(c), unless the At-
4 torney General has granted a hearing on the application
5 under section 1008(i) of the Controlled Substances Import
6 and Export Act.”.

Amend the long title to read as follows: “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.”.

