AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 639

OFFERED BY M__. _____

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Improving Regulatory Transparency for New Medical Therapies Act''.

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

(a) EFFECTIVE DATE OF APPROVAL.—

(1) EFFECTIVE DATE OF DRUG APPROVAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

''(x) DATE OF APPROVAL IN THE CASE OF RECOMMENDED 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-

terim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

''(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), the term 'date of approval' shall mean the later of—

''(A) the date an application under subsection (b) is approved under subsection (c); or

''(B) the date of issuance of the interim final rule controlling the drug.''.

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

''(n) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

''(1) IN GENERAL.—In the case of an application under subsection (a) with respect to a biological product 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 interim final rule controlling the bio-

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

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

''(A) the date an application is approved under subsection (a); or

''(B) the date of issuance of the interim final rule controlling the biological product.''.

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

(A) IN GENERAL.—Section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) is amended by adding at the end the following:

''(q) DATE OF APPROVAL IN THE CASE OF RECOMMENDED 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-

terim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

''(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), the term 'date of approval' shall mean the later of—

''(A) the date an application under subsection (b) is approved under subsection (c); or

''(B) the date of issuance of the interim final rule controlling the drug.''.

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

''(4)(A) In the case of an application under subsection (a) 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, conditional approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

''(B) For purposes of this section, with respect to an application described in subparagraph (A), the term 'date of approval' shall mean the later of—

''(i) the date an application under subsection (a) is conditionally approved under subsection (b); or

''(ii) the date of issuance of the interim final rule controlling the drug.''.

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

''(k) In the case of a request under subsection (d) to add a drug to the index under subsection (a) with respect to a drug for which the Secretary provides notice to the person filing the request that the Secretary intends to recommend controls under the Controlled Substances Act, a determination to grant the request to add such drug to the index shall not take effect, and the Secretary shall not list the drug on such index, until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.''.

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

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

''(3) For purposes of determining the 7-year period of exclusivity under paragraph (1) for a drug for which the Secretary intends to recommend controls under the Controlled Substances Act, the drug shall not be considered approved or conditionally approved until the date that the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.''.

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

''(j)(1) With respect to a drug referred to in subsection (f), if the Secretary of Health and Human Services recommends that the Attorney General add the drug or other substance to schedule II, III, IV, or V pursuant to subsections (a) and (b), the Attorney General shall, not later than 90 days after the date described in paragraph (2), issue an interim final rule controlling the drug or other substance in accordance with such subsections and section 202(b) using the procedures described in paragraph (3).

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

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

''(B) the date on which the Attorney General receives notification from the Secretary of Health and Human Services that the Secretary has approved an application under section 505(c), 512, 571, or 572 of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act with respect to the drug described in paragraph (1).

''(3) A rule issued by the Attorney General under paragraph (1) shall be in accordance with the procedures provided in subsection (a), except that the rule shall become immediately effective as an interim final rule without requiring the Attorney General to demonstrate good cause therefor. After publication of the interim final rule, the Attorney General shall issue a final rule in accordance with the procedures provided in subsection (a).''.

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

(1) in subsection (d)(1), in the matter preceding subparagraph (A), by inserting ", or in the case of a drug described in subsection (i) within the sixty-day period beginning on the covered date (as defined in subsection (i))" after "marketing or use"; and

(2) by adding at the end the following:

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

"(A) have been approved; and

"(B) have permission for commercial marketing or use.

"(2) In this subsection, the term 'covered date' means the later of—

"(A) the date an application submitted for approval—

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

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

''(B) the date of issuance of the interim final rule controlling the drug under section 201(j) of the Controlled Substances Act.''.

SEC. 3. ENHANCING NEW DRUG DEVELOPMENT.

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

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

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

to such notice ends, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c), unless the Attorney General has granted a hearing on the application under section 1008(i) of the Controlled Substances Import 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.''.