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SENATE

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S.2926	AUG 10 '84 (107-II)	S10631

ACTION:

AMENDMENT NUMBER 3707 by MR. HATCH
AMENDMENT NUMBER 3708 by MR. THURMOND

FEDERAL FOOD, DRUG, AND COSMETIC ACT AMENDMENTS

HATCH AMENDMENT NO. 3707

Mr. HATCH proposed an amendment to the bill (S. 2926) to amend the Federal Food, Drug, and Cosmetic Act to revise the procedures for new drug applications, to amend title 35, United States Code, to authorize the extension of the patents for certain regulated products, and for other purposes, as follows:

Clause (iii) of section 505(j)(4)(D) of the Federal Food, Drug, and Cosmetic Act, as added by section 101(a) of the bill, is amended by striking out "(or supplement to an application)" and "(or supplement thereto)", and by inserting after "approved under subsection (b)" the following "and which contains reports of new clinical investigations (other than bioavailability studies) sponsored by the applicant".

Clause (iv) of section 505(j)(4)(D) of the Federal Food, Drug, and Cosmetic Act, as added by section 101(a) of the bill, is redesignated as clause (v), and the following new clause (iv) is inserted immediately after clause (iii):

"(iv) If a supplement to an application approved under subsection (b) includes reports of new clinical investigations (other than bioavailability studies) sponsored by the applicant and is approved after the date of enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which such supplement was submitted effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

Clause (iii) of section 505(c)(3)(D) of the Federal Food, Drug, and Cosmetic Act, as added by section 101(b) of the bill, is amended by striking out "(or supplement to an application)" and "(or supplement thereto)", and by inserting after "approved under subsection (b)" the following "and which contains reports of new clinical investigations (other than bioavailability studies) sponsored by the applicant".

Clause (iv) of section 505(c)(3)(D) of the Federal Food, Drug, and Cosmetic Act, as added by section 101(b) of the bill, is redesignated as clause (v), and the following new clause (iv) is inserted immediately after clause (iii):

"(iv) If a supplement to an application approved under subsection (b) includes reports of new clinical investigations (other than bioavailability studies) sponsored by the applicant and is approved after the date of enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which such supplement was submitted effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

Subsection (l) of section 505 of the Federal Food, Drug, and Cosmetic Act, as added by section 104 of the bill, is amended by striking out, beginning with ", including", all matter through "financial information".

THURMOND AMENDMENT NO. 3708

Mr. HATCH (for Mr. THURMOND) proposed an amendment to the bill (S. 2926), supra, as follows:

At the end of the bill insert the following new title:

TITLE—

SEC. . (a) Title 35 of the United States Code is amended by adding immediately following section 155 the following new section:

"§ 155A. Patent extension.

"(a) Notwithstanding section 154 of this title, the term of any patent which encompasses within its scope a composition of matter which is a new drug product, if such new drug product is subject to the labeling requirements for oral hypoglycemic drugs of the sulfonylurea class as promulgated by the Food and Drug Administration in its final rule of March 22, 1984 (FR Doc. 84-9640) and was approved by the Food and Drug Administration for marketing after promulgation of such final rule and prior to the date of enactment of this law, shall be extended until April 21, 1992.

"(b) The patentee or licensee or authorized representative of any patent described in such subsection (a) shall, within ninety days after the date of enactment of such subsection, notify the Commissioner of Patents and Trademarks of the number of any patent so extended. On receipt of such notice, the Commissioner shall confirm such extension by placing a notice thereof in the official file of such patent and publishing an appropriate notice of such extension in the Official Gazette of the Patent and Trademark Office.".

(b) The table of sections for chapter 14 of title 35, United States Code is amended by adding after the item relating to section 155 the following new item:

"155A. Patent extension.".

Section 25(a) of the bill, as redesignated, is amended by striking out "9 and 10" and inserting in lieu thereof "9, 10, and 24".