KER09A11 S.L.C.

AMENDMENT NO._____ Calendar No._____

Purpose: To ensure that rules for the approval of generic pharmaceutical products do not require violations of medical ethics in the testing of products in humans.

IN THE SENATE OF THE UNITED STATES—111th Cong., 1st Sess.

H. R. 3590

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AMENDMENT Nº 2858

By Sanders

To: Amdt. 2786

Referred

3
Page(s)

GPO: 2008 45-603 (mac)

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. SANDERS to the amendment (No. 2786) proposed by Mr. REID

Viz:

On page 1925, between lines 14 and 15, insert the following:

Subtitle C—Ethical Pathway for Pharmaceutical Products

SEC. 7201. ETHICAL PATHWAY FOR THE APPROVAL AND LICENSURE OF GENERIC PHARMACEUTICAL PRODUCTS.

(a) DEFINITIONS.—In this section—

(1) the term "abbreviated new drug application" means an abbreviated application for a new drug submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j);

(2) the term "Commissioner" means the Commissioner of Food and Drugs; and

(3) the term "Secretary" means the Secretary of Health and Human Services.

(b) ETHICAL PATHWAY.—As soon as practicable after the date of enactment of this Act, the Secretary, acting through the Commissioner, shall establish a mechanism by which the filer of an abbreviated new drug application for approval of a drug or an application for licensure of a biological product under section 351(k) of the Public Health Service Act may request a cost-sharing arrangement described in subsection (c). Such a filer may request such an arrangement if, but for the arrangement, such filer would be required to conduct clinical investigations involving human subjects that violate Article 20 of the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects in order to obtain such approval or licensure from the Secretary.

(c) COST-SHARING ARRANGEMENT.—The cost-sharing arrangement described in this subsection is an arrangement in which—

(1) the filer of the abbreviated new drug application or the application under section 351(k) of the Public Health Service Act pays a fee to the Commissioner;

(2) notwithstanding any other provision of law, the Commissioner provides such reports to such filer;

(3) such filer may, notwithstanding any provision of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) or of the Public Health Service Act (42 U.S.C. 301 et seq.), rely in such application on reports of investigations, conducted by a holder of an approved application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or a holder of a license under section 351(a) of the Public Health Service Act, which have been made to show whether or not such drug or biological product is safe for use and whether such drug or biological product is effective in use; and

(4) the Commissioner remits the amount of such fee to the holder of the approved application under such section 505(b) or of the license under such section 351(a), as appropriate.