II

107TH CONGRESS
1ST SESSION

S. 1341

To amend the Internal Revenue Code of 1986 to expand human clinical trials qualifying for the orphan drug credit, and for other purposes.

IN THE SENATE OF THE UNITED STATES

AUGUST 2, 2001

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

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A BILL

To amend the Internal Revenue Code of 1986 to expand human clinical trials qualifying for the orphan drug credit, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. EXPANDED HUMAN CLINICAL TRIALS QUALIFYING FOR ORPHAN DRUG CREDIT.

(a) IN GENERAL.—Subclause (I) of section 45C(b)(2)(A)(ii) of the Internal Revenue Code of 1986 is amended to read as follows:

"(I) after the date that the application is filed for designation under such section 526, and".

(b) CONFORMING AMENDMENT.—Clause (i) of section 45C(b)(2)(A) of the Internal Revenue Code of 1986 is amended by inserting ''which is'' before ''being'' and by inserting before the comma at the end ''and which is designated under section 526 of such Act''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to amounts paid or incurred after December 31, 2001.

SEC. 2. PUBLICATION OF FILING AND APPROVAL OF REQUESTS FOR DESIGNATION OF DRUGS FOR RARE DISEASES OR CONDITIONS.

Subsection (c) of section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) is amended to read as follows:

''(c) Not less than monthly, the Secretary shall publish in the Federal Register, and otherwise make available to the public, notice of requests for designation of a drug under subsection (a) and approvals of such requests. Such notice shall include—

''(1) the name and address of the manufacturer and the sponsor;

''(2) the date of the request for designation or of the approval of such request;

''(3) the nonproprietary name of the drug and the name of the drug under which an application is

filed under section 505(b) or section 351 of the Public Health Service Act;

''(4) the rare disease or condition for which the designation is requested or approved; and

''(5) the proposed indication for use of the product.''.

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