105TH CONGRESS
1ST SESSION

H. CON. RES. 196

CONCURRENT RESOLUTION

To correct the enrollment of the bill S. 830.

105TH CONGRESS
1ST SESSION

H. CON. RES. 196

CONCURRENT RESOLUTION

Resolved by the House of Representatives (the Senate concurring), That, in the enrollment of the bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for

★

other purposes, the Secretary of the Senate shall make the following corrections:

(1) In section 119(b) of the bill:

(A) Strike paragraph (2) (relating to conforming amendments).

(B) Strike ''(b) SECTION 505(j).—'' and all that follows through ''`(3)(A) The Secretary shall'.'' and insert the following:

''(b) SECTION 505(j).—Section 505(j) (21 U.S.C. 355(j)) is amended by adding at the end the following paragraph:

''`(9)(A) The Secretary shall'.''.

(2) In section 123 of the bill, strike subsection (g) and insert the following:

''(g) APPLICATION OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

''(1) IN GENERAL.—Section 351 of the Public Health Service Act (42 U.S.C. 262), as amended by subsection (d), is further amended by adding at the end the following:

''`(j) The Federal Food, Drug, and Cosmetic Act applies to a biological product subject to regulation under this section, except that—

''`(1) a product for which a license has been approved under subsection (a) shall not be required to

have an approved application under section 505 of such Act; and

‘‘‘(2) the amendments made to section 505 of such Act by title I of Public Law 98–417 shall not apply to a biological product for which a license has been approved under subsection (a).’.

‘‘(2) RULE OF CONSTRUCTION.—Nothing in this Act or the amendments made by this Act shall affect the question of the applicability of any provision of section 505 of the Federal Food, Drug, and Cosmetic Act to a biological product for which an application has been approved under section 505 of such Act.’’.

(3) In section 125(d)(2) of the bill, in the matter preceding subparagraph (A), insert after ‘‘antibiotic drug’’ the second place such term appears the following: ‘‘(including any salt or ester of the antibiotic drug)’’.

(4) In section 127(a) of the bill: In section 503A of the Federal Food, Drug, and Cosmetic Act (as proposed to be inserted by such section 127(a)), in the second sentence of subsection (d)(2), strike ‘‘or other criteria’’ and insert ‘‘and other criteria’’.

(5) In section 412(c) of the bill:

(A) In subparagraph (1) of section 502(e) of the Federal Food, Drug, and Cosmetic Act (as proposed to be amended by such section 412(c)), in subclause (iii) of clause (A), insert before the period the following: ''or to prescription drugs''.

(B) Strike ''(c) MISBRANDING.—Subparagraph (1) of section 502(e)'' and insert the following:

''(c) MISBRANDING.—

''(1) IN GENERAL.—Subparagraph (1) of section 502(e)''.

(C) Add at the end the following:

''(2) RULE OF CONSTRUCTION.—Nothing in this Act or the amendments made by this Act shall affect the question of the authority of the Secretary of Health and Human Services regarding inactive ingredient labeling for prescription drugs under sections of the Federal Food, Drug, and Cosmetic Act other than section 502(e)(1)(A)(iii).''.

(6) Strike section 501 of the bill and insert the following:

''SEC. 501. EFFECTIVE DATE.

''(a) IN GENERAL.—Except as otherwise provided in this Act, this Act and the amendments made by this Act

shall take effect 90 days after the date of enactment of this Act.

''(b) IMMEDIATE EFFECT.—Notwithstanding subsection (a), the provisions of and the amendments made by sections 111, 121, 125, and 307 of this Act, and the provisions of section 510(m) of the Federal Food, Drug, and Cosmetic Act (as added by section 206(a)(2)), shall take effect on the date of enactment of this Act.''.

Passed the House of Representatives November 13, 1997.

Attest:

Clerk.