

105TH CONGRESS
1ST SESSION

H. CON. RES. 196

IN THE SENATE OF THE UNITED STATES

NOVEMBER 13, 1997

Received and referred to the Committee on Labor and Human Resources

CONCURRENT RESOLUTION

To correct the enrollment of the bill S. 830.

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

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

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

4 (A) Strike paragraph (2) (relating to con-
5 forming amendments).

6 (B) Strike “(b) SECTION 505(j).—” and
7 all that follows through ““(3)(A) The Secretary
8 shall’” and insert the following:

9 “(b) SECTION 505(j).—Section 505(j) (21 U.S.C.
10 355(j)) is amended by adding at the end the following
11 paragraph:

12 ““(9)(A) The Secretary shall’”.

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

15 “(g) APPLICATION OF FEDERAL FOOD, DRUG, AND
16 COSMETIC ACT.—

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

21 ““(j) The Federal Food, Drug, and Cosmetic Act ap-
22 plies to a biological product subject to regulation under
23 this section, except that—

24 ““(1) a product for which a license has been ap-
25 proved under subsection (a) shall not be required to

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

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

7 “(2) RULE OF CONSTRUCTION.—Nothing in
8 this Act or the amendments made by this Act shall
9 affect the question of the applicability of any provi-
10 sion of section 505 of the Federal Food, Drug, and
11 Cosmetic Act to a biological product for which an
12 application has been approved under section 505 of
13 such Act.”.

14 (3) In section 125(d)(2) of the bill, in the mat-
15 ter preceding subparagraph (A), insert after “anti-
16 biotic drug” the second place such term appears the
17 following: “(including any salt or ester of the anti-
18 biotic drug)”.

19 (4) In section 127(a) of the bill: In section
20 503A of the Federal Food, Drug, and Cosmetic Act
21 (as proposed to be inserted by such section 127(a)),
22 in the second sentence of subsection (d)(2), strike
23 “or other criteria” and insert “and other criteria”.

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

1 (A) In subparagraph (1) of section 502(e)
2 of the Federal Food, Drug, and Cosmetic Act
3 (as proposed to be amended by such section
4 412(c)), in subclause (iii) of clause (A), insert
5 before the period the following: “or to prescrip-
6 tion drugs”.

7 (B) Strike “(c) MISBRANDING.—Subpara-
8 graph (1) of section 502(e)” and insert the fol-
9 lowing:

10 “(c) MISBRANDING.—

11 “(1) IN GENERAL.—Subparagraph (1) of sec-
12 tion 502(e)”.

13 (C) Add at the end the following:

14 “(2) RULE OF CONSTRUCTION.—Nothing in
15 this Act or the amendments made by this Act shall
16 affect the question of the authority of the Secretary
17 of Health and Human Services regarding inactive
18 ingredient labeling for prescription drugs under sec-
19 tions of the Federal Food, Drug, and Cosmetic Act
20 other than section 502(e)(1)(A)(iii).”.

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

23 **“SEC. 501. EFFECTIVE DATE.**

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

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

3 “(b) IMMEDIATE EFFECT.—Notwithstanding sub-
4 section (a), the provisions of and the amendments made
5 by sections 111, 121, 125, and 307 of this Act, and the
6 provisions of section 510(m) of the Federal Food, Drug,
7 and Cosmetic Act (as added by section 206(a)(2)), shall
8 take effect on the date of enactment of this Act.”.

Passed the House of Representatives November 13,
1997.

Attest:

ROBIN H. CARLE,

Clerk.