

105TH CONGRESS
1ST SESSION

H. CON. RES. 196

To correct the enrollment of the bill S. 830.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 13, 1997

Mr. BLILEY submitted the following concurrent resolution; which was
considered under suspension of the rules and agreed to

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

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

9 (A) Strike paragraph (2) (relating to con-
10 forming amendments).

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

4 “(b) SECTION 505(j).—Section 505(j) (21 U.S.C.
 5 355(j)) is amended by adding at the end the following
 6 paragraph:

7 ““(9)(A) The Secretary shall”.

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

10 “(g) APPLICATION OF FEDERAL FOOD, DRUG, AND
 11 COSMETIC ACT.—

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

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

19 ““(1) a product for which a license has been ap-
 20 proved under subsection (a) shall not be required to
 21 have an approved application under section 505 of
 22 such Act; and

23 ““(2) the amendments made to section 505 of
 24 such Act by title I of Public Law 98–417 shall not

1 apply to a biological product for which a license has
2 been approved under subsection (a).’”.

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

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

15 (4) In section 127(a) of the bill: In section
16 503A of the Federal Food, Drug, and Cosmetic Act
17 (as proposed to be inserted by such section 127(a)),
18 in the second sentence of subsection (d)(2), strike
19 “or other criteria” and insert “and other criteria”.

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

21 (A) In subparagraph (1) of section 502(e)
22 of the Federal Food, Drug, and Cosmetic Act
23 (as proposed to be amended by such section
24 412(c)), in subclause (iii) of clause (A), insert

1 before the period the following: “or to prescrip-
 2 tion drugs”.

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

6 “(c) MISBRANDING.—

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

9 (C) Add at the end the following:

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

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

19 **“SEC. 501. EFFECTIVE DATE.**

20 “(a) IN GENERAL.—Except as otherwise provided in
 21 this Act, this Act and the amendments made by this Act
 22 shall take effect 90 days after the date of enactment of
 23 this Act.

24 “(b) IMMEDIATE EFFECT.—Notwithstanding sub-
 25 section (a), the provisions of and the amendments made

1 by sections 111, 121, 125, and 307 of this Act, and the
2 provisions of section 510(m) of the Federal Food, Drug,
3 and Cosmetic Act (as added by section 206(a)(2)), shall
4 take effect on the date of enactment of this Act.”.

