

**AMENDMENT TO THE AMENDMENT IN THE
NATURE OF A SUBSTITUTE TO H.R. 2873
OFFERED BY MR. FITZGERALD OF WISCONSIN**

Page 2, line 25, strike “and” at the end.

Page 3, line 7, strike the period at the end and insert “; and”.

Page 3, after line 7, insert the following:

1 “(C) excludes such an application or sup-
2 plement to an application submitted under sec-
3 tion 505(b) of the Federal Food, Drug, and
4 Cosmetic Act (21 U.S.C. 355(c)) that has been
5 granted New Chemical Entity exclusivity (21
6 U.S.C. 355(c)(3)(E)(ii)) by the Food and Drug
7 Administration; and

8 “(D) excludes such an application or sup-
9 plement submitted under section 351(a) of the
10 Public Health Service Act (42 U.S.C. 262(a))
11 that has been granted exclusivity pursuant to
12 section 351(k)(7) of such Act (42 U.S.C.
13 262(k)(7)).”.

