AMENDMENT TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 7667 OFFERED BY MR. CURTIS OF UTAH

At the end of title VIII, add the following new section (and update the table of contents in section 2 accordingly):

SEC. 814. THERAPEUTIC EQUIVALENCE DETERMINATIONS.

Section 505(j)(7)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)(A)) is amended by adding at the end the following:

''(v)(I) The Secretary shall make a determination under clause (i)(III)—

''(aa) with respect to an application submitted under this subsection, at the time of approval of such application or not later than 30 days after the date of such approval; or

''(bb) with respect to an application submitted under subsection (b)(2), at the time of approval of such application or not later than 30 days after the date of such approval, provided that the sponsor requests such a determination in the original application, in a form prescribed by the Secretary.

''(II) When the Secretary makes a determination under clause (i)(III), the Secretary shall, in revisions made to the list pursuant to clause (ii), include such information for such drug.

''(III) When the Secretary makes a determination under clause (i)(III) with respect to a drug, the Secretary shall, at the same time, make such a determination with respect to any other drug—

''(aa) whose application under subsection (b)(2) was approved;

''(bb) which references the same listed drug as the application for the first drug for which such determination is made; and

''(cc) for which there is a citizen petition pending requesting that the Secretary make a determination under clause (i)(III).''.