

**AMENDMENT TO THE AMENDMENT IN THE
NATURE OF A SUBSTITUTE TO H.R. 639
OFFERED BY M . _____**

Page 6, line 17 and 18, strike “or other substance”.

Page 6, lines 21 and 22, strike “or other substance”.

Strike page 7, line 24, through page 9, line 7, and insert the following:

1 (c) EXTENSION OF PATENT TERM.—Section 156 of
2 title 35, United States Code, is amended—

3 (1) in subsection (d)(1), in the matter pre-
4 ceding subparagraph (A), by inserting “, or in the
5 case of a drug product described in subsection (i)
6 within the sixty-day period beginning on the covered
7 date (as defined in subsection (i))” after “marketing
8 or use”; and

9 (2) by adding at the end the following:

10 “(i)(1) For purposes of this section, if the Secretary
11 of Health and Human Services provides notice to the
12 sponsor of an application or request for approval, condi-
13 tional approval, or indexing of a drug product for which
14 the Secretary intends to recommend controls under the

1 Controlled Substances Act, beginning on the covered date,
2 the drug product shall be considered to—

3 “(A) have been approved; and

4 “(B) have permission for commercial marketing
5 or use.

6 “(2) In this subsection, the term ‘covered date’ means
7 the later of—

8 “(A) the date an application is approved—

9 “(i) under section 351(a)(2)(C) of the
10 Public Health Service Act; or

11 “(ii) under section 505(b) or 512(c) of the
12 Federal Food, Drug, and Cosmetic Act;

13 “(B) the date an application is conditionally ap-
14 proved under section 571(b) of the Federal Food,
15 Drug, and Cosmetic Act;

16 “(C) the date a request for indexing is granted
17 under section 572(d) of the Federal Food, Drug,
18 and Cosmetic Act; or

19 “(D) the date of issuance of the interim final
20 rule controlling the drug under section 201(j) of the
21 Controlled Substances Act.”.

