

AMENDMENT TO H.R. 5752

OFFERED BY M. _____

[Page and line numbers refer to the posted draft dated May 8, 2018]

Page 2, line 3, through page 3, line 19, amend subsection (a) to read as follows:

1 (a) ARTICLES TREATED AS DRUGS FOR PURPOSES
2 OF IMPORTATION.—Section 801 of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 381) is amended by
4 adding at the end the following:

5 “(t) ARTICLES TREATED AS DRUGS FOR PURPOSES
6 OF THIS SECTION.—

7 “(1) LABELED ARTICLES.—An article shall not
8 be treated as a drug pursuant to this subsection if—

9 “(A) an electronic import entry for such
10 article is submitted using an authorized elec-
11 tronic data interchange system; and

12 “(B) such article is designated in such sys-
13 tem as a drug, device, dietary supplement, or
14 other product that is regulated under this Act.

15 “(2) ARTICLES COVERED.—Subject to para-
16 graph (1), for purposes of this section, an article de-

1 scribed in this paragraph may be treated by the Sec-
2 retary as a drug if it—

3 “(A) is or contains an ingredient that is an
4 active ingredient that is contained within—

5 “(i) a drug that has been approved
6 under section 505 of this Act; or

7 “(ii) a biological product that has
8 been approved under section 351 of the
9 Public Health Service Act;

10 “(B) is or contains an ingredient that is an
11 active ingredient in a drug or biological product
12 if—

13 “(i) an investigational use exemption
14 is in effect for such drug or biological
15 product under section 505(i) of this Act or
16 section 351(a) of the Public Health Service
17 Act;

18 “(ii) substantial clinical investigation
19 has been instituted for such drug or bio-
20 logical product; and

21 “(iii) the existence of such clinical in-
22 vestigation has been made public; or

23 “(C) is or contains a substance that has a
24 chemical structure that is substantially similar
25 to the chemical structure of an active ingredient

1 in a drug or biological product described in sub-
2 paragraph (A) or (B).

3 “(3) EFFECT.—Except to the extent that an ar-
4 ticle may be treated as a drug pursuant to para-
5 graph (2), this subsection shall not be construed as
6 bearing on or being relevant to the question of
7 whether any article is a drug as defined in section
8 201(g).”.

Page 3, line 2, strike “is in effect” and insert “has
been authorized”.

Page 8, lines 24 and 25, amend subclause (I) to
read as follows:

9 “(I)(aa) adulterated, misbranded,
10 or in violation of section 505; and
11 “(bb) present a threat of serious
12 adverse health consequences or death
13 to humans or animals; or

Page 9, after line 4, insert the following new sub-
paragraph (and make such conforming changes as may
be necessary):

14 “(C) DEFINITION.—For purposes of sub-
15 paragraph (B), the term ‘pattern of importing
16 or offering for import articles of drug’ means
17 importing or offering for import articles of drug

1 described in subclause (I) or (II) of subpara-
2 graph (B)(ii) in an amount, frequency, or dos-
3 age that is inconsistent with personal or house-
4 hold use by the importer.”.

