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

(a) Articles Treated as Drugs for Purposes of Importation.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by adding at the end the following:

“(t) Articles Treated as Drugs for Purposes of This Section.—

“(1) Labeled articles.—An article shall not be treated as a drug pursuant to this subsection if—

“(A) an electronic import entry for such article is submitted using an authorized electronic data interchange system; and

“(B) such article is designated in such system as a drug, device, dietary supplement, or other product that is regulated under this Act.

“(2) Articles Covered.—Subject to paragraph (1), for purposes of this section, an article de-
scribed in this paragraph may be treated by the Secretary as a drug if it—

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

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

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

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

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

“(ii) substantial clinical investigation has been instituted for such drug or biological product; and

“(iii) the existence of such clinical investigation has been made public; or

“(C) is or contains a substance that has a chemical structure that is substantially similar to the chemical structure of an active ingredient
in a drug or biological product described in sub-
paragraph (A) or (B).

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

“(I)(aa) adulterated, misbranded,
or in violation of section 505; and
“(bb) present a threat of serious
adverse health consequences or death
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):

“(C) DEFINITION.—For purposes of sub-
paragraph (B), the term ‘pattern of importing
or offering for import articles of drug’ means
importing or offering for import articles of drug
described in subclause (I) or (II) of subparagraph (B)(ii) in an amount, frequency, or dosage that is inconsistent with personal or household use by the importer.”.