



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.”.

