



MEMORANDUM ON PROPOSED TARIFF LEGISLATION of the 112th Congress

Date approved

I. Background

Bill number:

Sponsor name:

Sponsor state:

Interested entity:

Name

City

State

Other bills on product (112th Congress only):

Nature of bill:

Expiration date:

Current or previous chapter 99 heading:

Retroactive date:

CAS number (if applicable):

Industry analyst:

Telephone:

Tariff Affairs contact:

Telephone:

Note:

1. Access to an electronic copy of this memorandum is available at http://www.usitc.gov/tariff_affairs/congress_reports/.
2. In regard to the country(ies) of origin listed in section III, this report focuses on dutiable imports and does not take into account any tariff preference programs or special rates of duty.

II. Suggested article description(s) for enactment (including appropriate HTS subheading(s)):

Placebos, composed of D-mannitol, sodium starch glycolate, and magnesium stearate, to be used in clinical trials for the drug ASP0777 (provided for in HTS subheading 2106.90.99).

(If enacted, the tariff relief provided for in this bill would be available to any entity that imports the product that is covered by the bill.)

Description above compared with bill as introduced:

- Same
 Different (see Technical Comments section)

III. Other product information, including uses/applications and source(s) of imports

The subject product is placebos composed of of D-mannitol, sodium starch glycolate, and magnesium stearate. Placebos are used as a control in clinical drug trials to determine the effectiveness of a medicinal drug. The subject placebos are used in a drug trial for a drug assigned the code ASP0777.

The subject product is provided for in HTS subheading 2106.90.99, which is a basket category for food preparations not elsewhere specified or included. U.S. imports under HTS subheading 2106.90.99 totaled \$1.6 billion in 2011, about one-third of these imports were from Canada and about 9 percent were from Mexico and Thailand each.

IV. Estimated effect on customs revenue

Table with 6 columns: Item, 2013, 2014, 2015, 2016, 2017. Rows include Subject product HTS subheading(s) (2106.90.99), Col.1-general rate of duty or percentage point reduction (%), Estimated value of dutiable imports (\$), and Customs revenue loss (\$).

Note: Customs revenue loss is provided for 5 years, although the effective period of the proposed legislation may differ. Regarding the HTS subheading listed in the article description of the bill, the Commission may express an opinion on the HTS classification of a product to facilitate consideration of the bill. However, by law, only U.S. Customs and Border Protection is authorized to issue a binding ruling on this matter. The Commission believes that Customs should be consulted prior to enactment of the bill.

Dutiable imports were based on (more than one may apply):

- Official statistics of the U.S. Department of Commerce
 Provided by industry sources
 Industry information
 Commission estimates

Duty reduction notes:

- This bill is not a duty reduction
 This bill is a temporary duty reduction. Rates are shown below.

Col.1-general duty rate (%) [] Temporary rate (%) [] Percentage point reduction (%) []

V. Technical comments

None

VI. Continuation

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VII. Contacts with domestic firms/organizations

	#	Firm/organization and contact name	Telephone number	Claims same or competing product made in the United States	Submission attached	Opposition noted
	1	Astellas Pharma US, Inc. (interested party) Tim Catalano	224-205-8235	No	No	No
	2	Pfizer, Doug Goudie	202-783-7070	No	No	No

112TH CONGRESS
2D SESSION

H. R. 5358

To suspend temporarily the duty on placebos to be used in clinical trials
for the drug ASP0777.

IN THE HOUSE OF REPRESENTATIVES

MAY 7, 2012

Mr. DOLD introduced the following bill; which was referred to the Committee
on Ways and Means

A BILL

To suspend temporarily the duty on placebos to be used
in clinical trials for the drug ASP0777.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. PLACEBOS TO BE USED IN CLINICAL TRIALS**

4 **FOR THE DRUG ASP0777.**

5 (a) IN GENERAL.—Subchapter II of chapter 99 of
6 the Harmonized Tariff Schedule of the United States is
7 amended by inserting in numerical sequence the following
8 new heading:

“	9902.01.00	Placebos, composed of D-mannitol, sodium starch glycolate, and magnesium stearate, to be used in clinical trials for the drug ASP0777 (provided for in subheading 2106.90.99)	Free	No change	No change	On or before 12/31/2015	”.
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1 (b) **EFFECTIVE DATE.**—The amendment made by
2 subsection (a) applies to goods entered, or withdrawn from
3 warehouse for consumption, on or after the 15th day after
4 the date of the enactment of this Act.

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