

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC 20436

**MEMORANDUM ON PROPOSED TARIFF LEGISLATION
of the 109th Congress¹**

[Date approved: September 12, 2005]²

Bill No. and sponsor: H.R. 2077 (Mr. Kevin Brady of Texas)

Proponent name, location: Schering-Plough
Kenilworth, N.J. 07033-0530

Other bills on product (109th Congress only): None.

Nature of bill: Temporary duty suspension through December 31, 2008.

Retroactive effect: None.

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

1-Cyclopropyl-8-(difluoromethoxy)-7-[(1R)-1-methyl-2,3-dihydro-1H-5-isoindolyl]-4-oxo-1,4-dihydroquinoline-3-carboxylic acid monoethanesulfonate monohydrate (Garenoxacin mesylate) (CAS No. 223652-90-2) (provided for in subheading 2933.49.26)

Check one: Same as that in bill as introduced
 Different from that in bill as introduced (see Technical comments section)

Product information, including uses/applications and source(s) of imports:

1-Cyclopropyl-8-(difluoromethoxy)-7-[(1R)-1-methyl-2,3-dihydro-1H-5-isoindolyl]-4-oxo-1,4-dihydroquinoline-3-carboxylic acid monoethanesulfonate monohydrate (trade name Garenoxacin mesylate) is a synthetic organic chemical not produced in the United States (produced in Japan) used in the manufacture in the United States of pharmaceutical products. Garenoxacin mesylate is a novel quinoline antibacterial agent that has shown potent activity against a wide range of Gram-positive and Gram-negative bacterial pathogens, including anaerobic organisms, and resistant strains such as penicillin-resistant streptococcus pneumoniae. Garenoxacin mesylate has completed Phase III trials development and is expected to be the subject of a U.S. New Drug Application by late 2005. The proponent has an exclusive license to develop and market Garenoxacin mesylate worldwide, excluding Japan, Korea, and China (licensed to Toyama). Toyama owns the U.S. patent on Garenoxacin mesylate, which expires in 2018. Japan is the source for the anticipated imports.

¹ Industry analyst preparing report: Eric Land (202-205-3349); Tariff Affairs contact: Dave Michels (202-205-3352).

² Access to an electronic copy of this memorandum is available at http://usitc.gov/tata/hts/other/rel_doc/bill_reports/index.htm.

Estimated effect on customs revenue:

HTS subheading: <u>2933.49.26</u>					
	2005	2006	2007	2008	2009
Col. 1-General rate of duty	6.5%	6.5%	6.5%	6.5%	6.5%
Estimated value <i>dutiable</i> imports	\$7,700,000	\$15,000,000	\$15,000,000	\$15,000,000	\$15,000,000
Customs revenue loss	\$500,500	\$975,000	\$975,000	\$975,000	\$975,000

Source of estimated dutiable import data: Industry estimates.

Contacts with domestic firms/organizations (including the proponent):

Name of firm/organization	Date contacted	US production of same or competitive product claimed?	Submission attached?	Opposition noted?
		(Yes/No)		
Schering-Plough (proponent) Scott McCandless e-mail: scott.mccandless@us.pwc.com	7/21/2005	No	No	No
Abbott Laboratories David Landsidle fax:202-466-8386	7/21/2005	No	No	No
Bayer Julie Von Egmond fax:202-737-8908	7/21/2005	No	No	No
Bristol-Meyers Squibb David Warr fax:202-783-2308	7/21/2005	No	No	No
Endo Labs Camille Ali Jackson fax:610-558-5853	7/21/2005	No	No	No
Gilead Sciences Cheryl Myriad fax:650-522-5853	7/21/2005	No	No	No
Glaxo Welcome Sara Froelich fax:202-715-1001	7/21/2005	No	No	No
Interferon Sciences, Inc. Samuel Ronel fax:732-249-6895	7/21/2005	No	No	No

Merck & Company Thomas Bombelles fax:202-638-3670	7/21/2005	No	No	No
Niche Pharmaceuticals Steve Brandon fax:817-491-3533	7/21/2005	No	No	No
Novartis Tracy Haller fax:202-628-4763	7/21/2005	No	No	No
Noviant Tom Dirmyer fax:214-415-6001	7/21/2005	No	No	No
Pfizer Philip Ellsworth fax:212-309-5317	7/21/2005	No	No	No
Pfizer Katherine Bennett fax:202-347-2024	7/21/2005	No	No	No
Pharmacia & Upjohn Kevin Kirby fax:202-393-6050	7/21/2005	No	No	No
Procter & Gamble Jim McCarthy fax:202-393-4606	7/21/2005	No	No	No
Schering-Plough Rob Lively fax:202-463-8809	7/21/2005	No	No	No
Smith Klein-Beechem Ann Davis fax:202-452-8489	7/21/2005	No	No	No
Warner-Lambert Lou Lamarca fax:202-296-0623	7/21/2005	No	No	No
Watson Sarah Swee fax:909-270-1429	7/21/2005	No	No	No

Technical comments:³

The Commission suggests that the article description on page 1 of this report be used in the proposed new heading in order to correct italicization and provide the INN name in parentheses.

³ The Commission may express an opinion on the HTS classification of a product to facilitate consideration of the bill. However, by law, only the U.S. Customs Service is authorized to issue a binding ruling on this matter. The Commission believes that the U.S. Customs Service should be consulted prior to enactment of the bill.

109TH CONGRESS
1ST SESSION

H. R. 2077

To suspend temporarily the duty on Garenoxacin mesylate.

IN THE HOUSE OF REPRESENTATIVES

MAY 4, 2005

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

A BILL

To suspend temporarily the duty on Garenoxacin mesylate.

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. GARENOXACIN MESYLATE.**

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

“	9902.04.81	1-cyclopropyl-8-(difluoromethoxy)-7-[(1R)-1-methyl-2,3-dihydro-1H-5-isoindolyl]-4-oxo-1,4-dihydroquinoline-3-carboxylic acid monomethanesulfonate monohydrate (CAS No. 223652-90-2) (provided for in subheading 2933.49.26) ..	Free	No change	No change	On or before 12/31/2008	”.
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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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