

FDA Law Update

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[Elimination of Customs Duties Possible for Over 700 Additional Pharmaceutical Products and Chemical Intermediates](#)

By [Peter S. Reichertz](#)

By letter dated May 27, 2010, the U.S. Trade Representative (“USTR”) sent a letter to the U.S. International Trade Commission (“ITC”) requesting that the ITC provide information about over 700 pharmaceutical products and chemical intermediates for which the elimination of custom duties may be proposed. As part of the “zero-for-zero” initiative of the Uruguay Round Agreements Act, the President can proclaim changes to duties for certain classes of goods as part of the “zero-for-zero” initiative. Pharmaceutical and chemical intermediates are in such categories. To date over 2,000 pharmaceutical products and intermediates have been added to the Pharmaceutical Appendix in the HTUS. The current review is the fourth periodic proposal to add additional pharmaceuticals and intermediates to the list. The United States and 21 other major trading countries agreed during the Uruguay Round to eliminate duties on pharmaceuticals and to periodically conduct reviews to identify additional products to be covered by the initiative. If added to the Appendix, the products included in the new USITC investigation would receive duty-free treatment.

The USTR, an office in the Executive Office of the President, has requested that ITC provide: (1) a summary description of the products currently covered under the initiative as set out in the Pharmaceutical Appendix to the U.S. Harmonized Tariff Schedule (Appendix) and those proposed to be added to that Appendix; (2) an explanation of the relationship between the various elements in the Appendix and the Harmonized Tariff Schedule of the United States; and (3) an estimate of current U.S. imports and, where possible, current U.S. exports of the products included in the current Appendix and the proposed additions to the Appendix, based on product groupings as necessary. The USTR requested that this review be completed by September 1, 2010. A copy of the USTR request, with the lists of pharmaceutical products and chemical intermediates proposed to be added, is attached below.

By notice dated June 9, 2010, the ITC instituted an investigation in response to USTR’s request and said it would submit its report by September 1, 2010. See notice [attached](#). The investigation – entitled *Pharmaceutical Products and Chemical Intermediates, Fourth Review: Advice Concerning the Addition of Certain Products to the Pharmaceutical Appendix to the HTS* – has been designated Investigation No. 332-520. The ITC will not hold a public hearing in connection with its investigation, but is seeking written input from interested parties. Written comments are

to be submitted by no later than July 14, 2010.

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