
From: [redacted]@dhs.gov
Sent: Monday, October 02, 2006 12:13 PM
To:
Subject: CBP Interdiction of Prescription Drugs

Attachments:

Office of Congressional Affairs

As many of you are aware, Customs and Border Protection (CBP) implemented an informed compliance policy on November 17, 2005 to process non-controlled prescription drug interdictions at international mail branches and express consignment facilities. This informed compliance policy enabled CBP Officers to fulfill the drug interdiction mission without the administrative burdens associated with formally seizing and entering substance interdictions in the Seized Assets and Case Tracking System (SEACATS).

The Office of Congressional Affairs is now providing advance notification that, effective October 9, 2006, CBP Officers will no longer process non-controlled prescription drugs under the November 2005 guidelines and, instead, will refer these shipments to the Food and Drug Administration (FDA) for admissibility determinations as authorized under 21 U.S.C. 381.

In other words, all non-controlled prescription drug interdictions not subject to exclusion orders or which do not violate CBP law will be referred to FDA for their review. The informed compliance policy for schedules III, IV, and V controlled substance interdictions will remain in effect.

CBP will maintain an active role in addressing the pharmaceutical importation issue by increasing examinations of products identified during laboratory analysis to be counterfeit or to have the wrong active ingredient. In addition, we will be developing special operations to identify other drug importations that pose potential health and safety risks to U.S. residents. CBP will also be implementing a compliance measurement methodology at all International Mail Branches during FY07 to validate the results of a statistical sampling exercise conducted in May 2006. The compliance measurement methodology will be conducted on randomly generated days throughout the fiscal year and all shipments identified to contain controlled substances or non-controlled prescription drugs will be sent to a CBP laboratory for analysis. These laboratory results will be utilized to identify drug importations from specific countries which are counterfeit or have discrepant active ingredients. The results will provide important trend analysis information that will help focus future enforcement operations.

Additional information regarding the rescission of the November 2005 informed compliance guidelines for non-controlled prescription drugs will be available soon on the CBP website <http://www.cbp.gov>. CBP has also revised the basic response format for constituent inquiries to reflect these changes. CBP's Office of Congressional Affairs will be happy to address any questions or to discuss further the implications of this new guideline.

Please feel free to contact Darren Mackaly, Andrew Farrelly or Christa Brzozowski at (202) 344.1750.