Re-Exporting Seized Drugs: A User's Guide to 21 U.S.C. § 334(d)(1)

by Frederick R. Ball

Your company operates a manufacturing plant located overseas. The plant is registered with the Food and Drug Administration (FDA). You import to the United States a shipment of drugs manufactured at your overseas manufacturing plant. FDA seizes the drugs pursuant to 21 U.S.C. § 334(a), claiming that the drugs are adulterated and misbranded. It would be cost-prohibitive for you to attempt to recondition the drugs to comply with the Federal Food, Drug, and Cosmetic Act (FDCA). FDA is, therefore, seeking to destroy the drugs. What can you do? Provided you can meet certain requirements of 21 U.S.C. § 334(d)(1), you may be able to re-export the drugs.

Both Congress and the courts have recognized that importers should be permitted to re-export drugs that do not meet FDCA requirements for introduction into interstate commerce in the United States.[1] The congressional intent of section 334 is to prevent the waste of drugs when it can be done safely.[2] Importers seeking to re-export drugs under 21 U.S.C. §§ 334(d)(1) and 381(d)(1),[3] must meet certain statutory requirements. Specifically,

- the adulteration, misbranding, or violation must have occurred before the article was imported;
- the proponent must have had no cause to believe the article was adulterated, misbranded, or in violation before it was seized; and
- it can meet the requirements of 21 U.S.C. § 381(d)(1) unless the articles are returned to the original supplier.[4]

In addition, the product, or a portion of the product, cannot have been offered for sale in domestic commerce.[5] The importer seeking to re-export the drugs has the burden of pleading and proving these statutory requirements.[6] Failure to comply with all of the requirements of section 334(d)(1) will prevent the claimant from garnering the benefits of the import-export provisions of section 334(d)(1).[7]

So what does all this mean? If you re-export the drugs to the original manufacturer, you must demonstrate four things. First, you must demonstrate that the adulteration took place prior to the importation of the offending drug. Failure to do so will lead to the condemnation of the drug.[8]

Second, you must demonstrate that you had no cause to believe that the article was adulterated, misbranded, or in violation of the FDCA before it was seized by Customs or FDA. In short, you must demonstrate that you did not know you were violating the FDCA. Having said that, courts, in the interest of equity, have allowed re-exportation "regardless of the claimant's *mala fides*."[9] Courts have based this on the premise that nothing in the FDCA or in FDA's regulations suggests that destruction should be used a punitive measure when a company unintentionally imports a product that violates the FDCA.[10]

Third, you must demonstrate that you intend to re-export the drugs to the original supplier.[11] Finally, you must demonstrate that no part of the seized shipment was offered for sale or domestic commerce.[12]

As a practical matter, you should, via motion, demonstrate these factors and present a plan for how the re-exportation will occur. That plan should include:

- proposing to enter into reasonable evidentiary stipulations;
- proposing to allow the government to retain samples of the seized drugs;
- agreeing to post a bond to ensure compliance;
- labeling the shipping packages "For Export Only";

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- providing notification to regional FDA and Customs offices when you are prepared to export;
- agreeing to use of a bonded carrier under Customs seal;
- providing FDA and Customs with the name of the carrier, its address, and the port of embarkation;
- allowing FDA inspection prior to exportation, provided the inspection does not impede embarkation;
- providing a reasonable time for exportation (90 days);
- providing proof of delivery to the importer;
- agreeing not to attempt to re-import the drugs for sale in the United States; and
- providing a method for demonstrating compliance and releasing the bond.

If you can—and are willing to—do these things, 21 U.S.C. § 334(d)(1) potentially can save millions of dollars of product when FDA or Customs seizes an imported drug product for a technical violation of the FDCA.

[1] 21 U.S.C. § 334(d)(1) (FDCA § 304(d)(1)).

[2] United States v. Articles of Drug, 634 F. Supp. 435, 464 n.33 (N.D. Ill. 1986), *vacated as moot* 818 F.2d 569 (7th Cir. 1987).

[3] FDCA §§ 304(d)(1) and 801(d)(1), respectively.

[4] *United States v. Articles of Drugs*, 634 F. Supp. at 440. FDCA section 801(d)(1) covers the export of domestically-manufactured drugs covered by the FDCA. In other words, if you plan to re-export the drugs to an entity other than the original supplier, you must meet the requirements for exporting domestically-manufactured drugs.

[5] United States v. 76,552 Pounds of Frog Legs, 423 F. Supp. 329, 337 (S.D. Tex. 1976).

[6] *Id.*

[7] *Frog Legs*, 423 F. Supp. at 338.

[8] *See* United States v. An Article of Food consisting of 12 barrels, More or Less, labeled in part: (Barrel) one Lumpfish Roe 100 kilogram net color black; 477 F. Supp 1185, 1189-90 (S.D.N.Y. 1979).

[9] *See United States v. Articles of Drugs*, 634 F. Supp. at 464 n.33; *Frog Legs*, 423 F. Supp. at 338.

[10] *United States v. Articles of Drugs*, 634 F. Supp. at 463-64.

[11] This may be easier than demonstrating that you can meet the requirements of FDCA section 801(d).

[12] *Frog Legs*, 423 F. Supp. at 337.