

MEMORANDUM

TO: Food & Drug Administration

FROM: Express Delivery & Logistic Association

DATE: April 25, 2005

RE: Legal Basis for Exemption of Lab Samples from PN Requirements,
FDA Docket No. 2002N-0278

Issue

At a recent meeting between Express Delivery & Logistics Association (XLA) members and Food & Drug Administration (FDA) officials, there was a discussion regarding XLA's filed comments in response to FDA's Interim Final Rule Prior Notice (PN) requirements in which XLA members requested exemption of lab samples from PN requirements under the Final Rule, scheduled to be published in June 2005. Specifically, the issue discussed was whether there existed a *legal* basis from exempting lab samples from PN requirements pursuant to the provisions of the Bioterrorism Act of 2002 (BTA). For purposes of this requested exemption, XLA's use of the term "lab samples" refers to lab samples intended for testing and analysis only, and does not include samples or any other items that are intended for human or animal consumption. It is XLA's position that there is a legal basis from exempting lab samples from such PN requirements.

Legal Analysis and Conclusion

In order to determine whether FDA legally has the discretion to exempt lab samples from PN requirements, it is necessary to determine the articles Congress intended FDA to regulate pursuant to the BTA. Section 307(a) of the BTA specifically states that the Prior Notice provision of the BTA amends Section 801 of the Federal Food, Drug and Cosmetic Act (the "Act"). Section 201(f) of the Act (21 U.S.C. §321) provides the following definition for "food" for purposes of the Act: The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." In Prior Notice of Imported Food, Interim Final Rule, 68 *Fed. Reg.* 59070 (October 10, 2003), §1.276(b), the FDA states as follows: "The definitions of terms in section 201 of the act (21 U.S.C. 321) apply when the terms are used in this subpart, unless defined below." Then in Section 1.276(b)(5) of the PN provisions of the Interim Final Rule, it states that "*Food* has the meaning given in section 201(f) of the act...." Therefore, XLA would argue that lab samples, as defined above, are not "articles used for food or drink for man or other animals...", 21 U.S.C. §321(f),

and therefore, are outside the scope of the articles that Congress intended for the FDA to regulate under the BTA. In addition, XLA would argue that Section 1.277(a) of the Interim Final Rule actually goes beyond the scope of Congress' intent as stated in the BTA when it provides that this Prior Notice "subpart applies to all food for humans and other animals that is imported or offered for import into the United States for use, storage, or distribution in the United States, including food for gifts and trade and quality assurance/quality control samples, food for transshipment through the United states to another country, food for future export, and food for use in a U.S. Foreign Trade Zone."

In conclusion, it is XLA's position that FDA has the discretion to exempt lab samples not intended for human or animal consumption from the Prior Notice requirements since such lab samples are not "(1) articles used food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article" (21 U.S.C. §321(f)) and since Congress did not otherwise specifically define food to include lab samples in the BTA.

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