DEPARTMENT OF THE TREASURY
Alcohol and Tobacco Tax and Trade Bureau

Industry Circular

Number: 2017 - 1 January 13, 2017

Levels of Lead in Wine

To: Proprietors of Bonded Wineries, Proprietors of Bonded Wine Cellars, Importers, and Others Concerned.

1. Purpose.

The Alcohol and Tobacco Tax and Trade Bureau (TTB) is advising wine industry members and others concerned that the Food and Drug Administration (FDA) has withdrawn a guidance for industry entitled, "Guidance for Industry and FDA: 1991 Letter to Bureau of Alcohol, Tobacco and Firearms Regarding Lead in Wine." As a result of FDA's action, TTB is canceling Industry Circular 91-11, "Table Wines Found to Contain Lead." TTB will continue to consult with the FDA on a case-by-case basis on whether a particular wine containing lead meets the standards for adulteration under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

2. Authority.

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), provides for the issuance of certificates of label approval (COLAs) for wines sold, shipped, or otherwise introduced in interstate or foreign commerce, and authorizes the Secretary of the Treasury to prescribe regulations for the labeling of such products. TTB administers the regulations promulgated under the FAA Act. The FAA Act requires that these regulations, among other things, ensure that labels provide the consumer with adequate information about the identity and quality of the product.

Under the FD&C Act, FDA has authority to take action with respect to adulterated food products, including wine, both domestic and imported. FDA and TTB have entered into a Memorandum of Understanding (MOU, 52 FR 45502, Nov. 30, 1987), in which they have delineated their enforcement responsibilities with respect to adulterated alcohol beverages and provided for collaborative efforts.

TTB takes the position that wines which FDA determines to be adulterated under the FD&C Act, are mislabeled under the FAA Act. Mislabeled wines, including adulterated products, may not be sold or shipped, delivered for sale or shipment, or otherwise introduced or received in interstate or foreign commerce, or removed from customs custody for consumption, by a producer, importer, or wholesaler, or other industry member subject to 27 U.S.C 205(e), even if such wines are covered by a COLA.

3. Cancellation.

This Industry Circular cancels Industry Circular No. 91–11.

4. Background.

On January 12, 2017, FDA sent a letter to TTB notifying it about the withdrawal of a guidance document entitled, "Guidance for Industry and FDA: 1991 Letter to Bureau of Alcohol, Tobacco and Firearms Regarding Lead in Wine." The guidance, dated March 2007, was issued to make accessible on the website of FDA's Center for Food Safety and Applied Nutrition a letter that FDA issued in 1991 to the Deputy Director of TTB's predecessor agency, the Bureau of Alcohol, Tobacco, and Firearms (ATF). The 1991 letter stated, among other things, that FDA was willing to advise ATF, on a case-by-case basis, whether a particular table wine product containing more than 300 parts per billion (ppb) of lead meets the standards for adulteration under the FD&C Act. Based on FDA's letter, ATF issued Industry Circular 91-11, "Table Wines Found to Contain Lead."

In its recent letter, FDA notes that since 1991, FDA has gained a greater understanding of the health risks associated with lead exposure, and recent data on lead in wine indicate levels well below 300 ppb are achievable through the use of good manufacturing practices. FDA stated that the withdrawal of the outdated 2007 guidance is consistent with FDA's requirements for good guidance practices, under which FDA guidance documents that are obsolete and no longer useful should be withdrawn. FDA also stated that this 2017 letter replaces FDA's 1991 letter to ATF.

Because FDA has withdrawn this 2007 guidance, TTB is cancelling its own guidance on lead in wine, Industry Circular 91-11, which is based on FDA's 1991 letter to ATF. Consistent with the existing MOU between FDA and TTB, FDA will continue to advise TTB on a case-by-case basis, whether a particular product containing lead meets the standards for adulteration under the FD&C Act.

Questions. If you have any questions concerning this circular, please contact the Market Compliance Office at 1-866-927-2533 or at TTBInternetQuestions@ttb.gov.

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