DEPARTMENT OF THE TREASURY
ALCOHOL AND TOBACCO TAX AND TRADE BUREAU
WASHINGTON, D.C. 20005

ASSISTANT
ADMINISTRATOR

TTB5030800:JRN
5110: CC18-033

October 9th, 2018

MHW, Ltd.
1129 Northern Blvd.
Ste 312
Manhasset, NY 11030
NY-I-1727

Dear Industry Member:

As a result of a complaint, the product Clairin Casimir Rum, produced in Haiti by Distillerie Faubert Casimir Barraderes was analyzed by the TTB Scientific Services Division (SSD) for the presence of prohibited materials. The results of the tests indicated the presence of elevated levels of lead in the amount of 138 parts per billion (ppb).

TTB operates under a 1987 Memorandum of Understanding[1] (MOU) with the U.S. Food and Drug Administration (FDA) that clarifies and delineates the enforcement responsibility of each agency with respect to alcohol beverages that may be adulterated under the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 301, et seq., and establishes procedures for coordination between the agencies. Under the terms of this MOU, TTB has the primary responsibility for seeking and monitoring voluntary recalls of alcohol beverages that are adulterated under the FD&C Act and mislabeled under the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 201, et seq., by reason of being adulterated.

This MOU with FDA provides that when TTB learns or is advised that an alcohol beverage is or may be adulterated, TTB consults with FDA before taking any recall action. Furthermore, FDA has agreed to provide TTB with a written health hazard evaluation (HHE) of each product involved in a recall situation or potential recall situation. Upon receipt of FDA's HHE indicating a definitive hazard, TTB will advise the responsible firm as to the appropriate course of action, which might include a voluntary recall. FDA's determination that a distilled

[1] Memorandum of Understanding Between the Food and Drug Administration and the Bureau of Alcohol, Tobacco and Firearms, 52 FR 45502 (1987). The MOU was entered into by TTB's predecessor agency, ATF, and remains in effect between FDA and TTB.

spirit, wine or malt beverage is adulterated under the FD&C Act would have consequences under section 105(e) of the FAA Act, 27 U.S.C. 205(e), which TTB enforces.

As mentioned earlier, we analyzed the product Clairin Casimir Rum, obtained from Vanderbilt Wine Merchants at 573 Vanderbilt Ave, Brooklyn NY 11238 on August 8th, 2018, and determined that it had an elevated level of lead of 138 ppb. TTB then contacted FDA and requested an HHE in order to determine if the presence of this ingredient posed a health risk.

In its response, FDA stated that the effects of lead depend upon the amount and duration of lead exposure and age of the exposed population. If a developing fetus is exposed to lead, damage to the central nervous system can occur. This can result in learning disorders, developmental defects or other long term health problems. The blood lead level (BLL) in pregnant women should be no higher than 5 µg/dL to limit lead exposure to the developing fetus. This limit applies to all women of childbearing age to protect against possible fetal exposure in women who are not yet aware that they are pregnant. This level also applies to a mother while nursing.

The dietary lead exposure level required for women of childbearing age (including pregnant or lactating women) to achieve a BLL of 5 µg/dL is approximately 125 µg/day. FDA applied an uncertainty factor of 10 to the 125 µg/day dietary lead exposure level to achieve a level of 12.5 µg/day dietary lead for women of childbearing age.

The estimated lead exposure from consumption of this rum product containing 138 ppb lead by women of child-bearing age that are old enough to legally consume alcohol (F 21-49 years) is 17 µg/day at the 90th percentile intake level. This exposure is higher than the level of 12.5 µg/day for women of childbearing age. Therefore, this product may cause a health concern for this group.

Additionally, alcohol is a teratogen and maternal alcohol consumption during any state of pregnancy can cause toxicity to the brain of the developing child. The effects that are observed in children exposed to alcohol in utero are similar to those that could occur with lead exposure in utero; therefore, the two substances in combination could potentially be more hazardous than in isolation with respect to child neurodevelopment.

With that in mind, due to the lead levels found, as well as the associated adverse health effects possible for consumers of the product, TTB requests that you devise and inform us of an appropriate recall strategy for removal of the product from the market and the return of the products from consumers. To develop a recall strategy, you should consider the sample results identified, the usage patterns of the product, the ease in identifying the product, the degree to which the product's non-compliance with the law is obvious to the consumer, and

the degree to which the product remains in the marketplace. In addition, your recall strategy should address the following elements regarding the conduct of the recall: the need for publicity, the scope of the recall, and a measurement of effectiveness. The targeted outcome is removal of any adulterated product from the marketplace, and the return of those products from consumers. For additional information on voluntary recalls, please review TTB Industry Circular 2017-4 Voluntary Alcohol Beverage Recalls at: https://www.ttb.gov/industry_circulars/archives/17-4.shtml.

In addition, TTB requests that MHW, Ltd. conduct a thorough analysis in order to determine the root cause of this issue. This should include working with the foreign producers to review raw materials, ingredients, flavoring, and coloring to determine the potential source of the lead. Once this analysis is complete, please provide a detailed description of the cause to TTB in writing, as well as what steps you will take in order to prevent this from reoccurring in the future.

It is TTB's position that adulterated distilled spirits are mislabeled within the meaning of the FAA Act. Mislabeled distilled spirits 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 the bottler or importer of the product in question has obtained a certificate of label approval (COLA) or an approved formula. It is therefore unlawful, under 27 U.S.C. 205(e), for you to sell or ship, deliver for sale or shipment, or otherwise introduce or receive in interstate or foreign commerce, or remove from customs custody for consumption, a distilled spirit which is adulterated.

As provided in 27 U.S.C. 204(d), the FAA Act basic permit is conditioned upon compliance with 27 U.S.C. 205(e), as well as other federal laws relating to distilled spirits, wine and malt beverages. TTB may, among other things, pursue action to suspend or to revoke the FAA Act basic permit of industry members who willfully violate the conditions of their permit with respect to mislabeled, adulterated products. *See* 27 U.S.C. 204(e).

Please advise this office within five business days of receipt of this letter as to the specific steps you will be taking to address this matter. Please submit your response by email to James.Neely@ttb.gov or by mail to:

Alcohol and Tobacco Tax and Trade Bureau
Market Compliance Office, 2nd Floor West
1310 G Street, NW, Box 12
Washington, DC 20005

We trust that MHW, Ltd. understands the serious nature of this beverage safety issue and will act upon it swiftly. If you have any additional questions in this matter, please contact Program Manager James Neely at (202) 453-2035 or James.Neely@ttb.gov.

Sincerely yours,

Ronald Hancock
Acting Assistant Administrator
Field Operations