PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

STATE OF NEW JERSEY
OFFICE OF THE ATTORNEY GENERAL
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF ALCOHOLIC BEVERAGE CONTROL
P.O. BOX 087
TRENTON, NJ 08625-0087
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GURBIR S. GREWAL
Attorney General

JAMES B. GRAZIANO
Acting Director

June 13, 2019

NOTICE OF PRODUCT RECALL

The Division of Alcoholic Beverage Control has been advised that the federal Alcohol and Tobacco Tax and Trade Bureau ("TTB") has requested the voluntary recall of the following product due to elevated lead levels:

Castello di Neive Grignolino 2017 (NJ Brand Registration #312481)

All sales of this product should cease immediately. The wholesaler, Winebow Group, Inc., has advised that it is making arrangements to pick-up inventory in the possession of New Jersey retailers. Consumers are urged to return the product to the retailer from which they acquired the product as soon as possible. Please see the attachments for further information.

James B. Graziano, Director

WINEBOW
FINE WINE + SPIRITS

RECEIVED
2019 JUN 10 P 1:44
ALCOHOLIC BEVERAGE CONTROL

June 6, 2019

State of New Jersey

Division of Alcoholic Beverage Control

Attn. James Graziano, Acting Director

PO Box 087

Trenton, NJ 08625-0087

Re: Voluntary TTB Class I Recall – Castello di Neive Grignolino 2017 (NJ Brand Registration # 312481)

Dear Acting Director Graziano:

Winebow, Inc. (NJ Plenary Wholesale License # 3401-23-155-011) was notified by the Alcohol and Tobacco Tax and Trade Bureau that one of the wines imported and distributed by the Company, Castello di Neive Grignolino 2017 (Grignolino 2017), was found to exceed the lead tolerance level in wine. A copy of the notification dated May 23, 2019 is attached for reference. TTB requested that Winebow, Inc. voluntarily recall the product to the retail level.

Winebow has been actively identifying retailers that purchased Grignolino 2017, and requested sales be ceased immediately. Currently, arrangements are being made to pick-up any remaining inventory from the retailers. Since the product has been in the market since spring of 2018 many of the retailers no longer have stock available. Any retailer having stock will be issued credit as the Grignolino 2017 is under voluntary TTB recall.

FDA Reportable Food Report was filed by Winebow, Inc. as required. No reported adverse health effects have been reported.

Winebow, Inc and the supplier, Castello di Neive Azienda Agricola di Italo Stupino take these matters very seriously and will continue to work to ensure a successful and complete recall of the Grignolino 2017.

If you have any questions or need additional information, please do not hesitate to contact me via e-mail at Pat.Patterson@winebow.com or via telephone at 201-930-2392

Sincerely,

Patricia Patterson

Director of Compliance

Cc: Kevin Schatz, Bureau Chief, Enforcement

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

ASSISTANT
ADMINISTRATOR

TTB5030800:jhm
5120 / P-2019-000143

May 23, 2019

Winebow, Inc.
Attn: Patricia Patterson
20 Hook Mountain Road, Suite 103A
Pine Brook, New Jersey 07058

NY-I-2017

Dear Industry Member:

As part of the Alcohol and Tobacco Tax and Trade Bureau (TTB) 2019 Alcohol Beverage Sampling Program (ABSP), the product Castello di Neive Piemonte 2017 Grignolino, lot L 8040, 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 118 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 implementing a voluntary recall. 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 an 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 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.

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[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.

As mentioned earlier, we analyzed the product Castello di Neive Piemonte 2017 Grignolino, obtained in the 2019 ABSP, and determined that it had an elevated level of lead of 118 ppb. TTB then contacted FDA and requested an HHE in order to determine if the lead detected in the product 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. Young children (aged 0-6 years) are particularly sensitive to the adverse effects of lead. If a developing fetus or young child 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. Thus, the populations of greatest concern for lead toxicity are young children and women of childbearing age.

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 30 and 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 alcoholic product containing 118 ppb lead by women of child-bearing age who are old enough to legally consume alcohol (F 21-49 years) is 40.9 µg/day. This exposure is higher than the level of 12.5 µg/day for women of childbearing age. Therefore, the estimated lead exposure from the product is likely to be a health concern for this population.

Additionally, alcohol is a teratogen and maternal alcohol consumption during any state of pregnancy can cause toxicity to the brain of the developing child. Therefore, alcohol consumption during pregnancy in combination with lead exposure can 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 place. 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 affected product from the marketplace. 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 Winebow, Inc. work with the producer to conduct a thorough analysis in order to determine the root cause of this issue. This should include review of 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.

Wines that are adulterated under the FD&C Act are mislabeled under the FAA Act. Mislabeled wines 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 an industry member 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 wine 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 jennifer.meadows@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 Winebow, Inc. 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 Specialist Jennifer Meadows at (202) 453-2160 or jennifer.meadows@ttb.gov.

Sincerely yours,

Nicholas V. Colucci
Assistant Administrator
Field Operations