MEMORANDUM OF UNDERSTANDING
BETWEEN
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
U.S. FOOD AND DRUG ADMINISTRATION
AND
U.S. DEPARTMENT OF THE TREASURY
ALCOHOL AND TOBACCO TAX AND TRADE BUREAU

PURPOSE

This agreement between the Food and Drug Administration (FDA) and the Alcohol and Tobacco Tax and Trade Bureau (TTB) is to clarify and to delineate the enforcement responsibilities of each agency with respect to alcoholic beverages considered adulterated under the Federal Food, Drug, and Cosmetic Act, and for other related purposes. Specifically, this Memorandum of Understanding (MOU) will:

(A) Effect a more efficient system of communication and exchange of information between FDA and TTB;

(B) Confirm TTB policy with respect to the labeling of certain substances in alcoholic beverages that FDA has determined may pose a public health problem or are otherwise in violation of the law; and

(C) Clarify and coordinate the responsibilities of each agency with respect to the identification, testing, and recall of adulterated alcoholic beverages.

This agreement replaces MOU 225-88-2000, published as Notice No. 648, 52 FR 45502 (November 30, 1987).

BACKGROUND

A. Pursuant to the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 301 et seq., FDA has authority over food, including alcoholic beverages, both domestic and imported. As such, alcoholic beverages are subject to the FD&C Act's adulteration and misbranding provisions, and implementing regulations, related to food, and FDA can take action against alcoholic beverages that are adulterated or misbranded under the FD&C Act. This includes FDA's mandatory recall authority for food under certain circumstances, subject to section 423 of the FD&C Act (21 U.S.C. § 350l). Among other things, a food is adulterated under section 402 of the FD&C Act if it was produced, packed, or held under unsanitary conditions; if it contains any poisonous or deleterious substance which may render the food injurious to health; or if it contains an unapproved food or color additive. FDA has authority to initiate seizure of adulterated

or misbranded foods, to seek to enjoin the introduction of such products into interstate commerce, and to refuse entry of imported foods that appear to be adulterated or misbranded.

B. Pursuant to the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. §§ 201 et seq., and the Internal Revenue Code of 1986 (IRC), Title 26, U.S.C., TTB also has authority over alcoholic beverages, both domestic and imported. In particular, section 105 of the FAA Act (27 U.S.C. § 205) vests TTB with the authority to promulgate regulations regarding the labeling and advertising of wine, distilled spirits, and malt beverages to prevent deception of the consumer, provide the consumer with adequate information concerning the identity and quality of the product, and prohibit false or misleading statements. In general, 27 U.S.C. § 205(e) also makes it unlawful to sell or ship or deliver for sale or shipment, or otherwise introduce into interstate or foreign commerce, or to receive therein, or to remove from customs custody for consumption, any wine, distilled spirits, and malt beverages in bottles, unless such products are bottled, packaged, and labeled in conformity with regulations prescribed by the Secretary of the Treasury. TTB is charged with the administration and enforcement of the FAA Act and does this through, among other things, the issuance of permits and through procedures that generally require the prior approval of labels. In addition, TTB is charged with the administration and enforcement of Chapter 51 of the IRC, relating to wines, distilled spirits, and beer. This chapter, in conjunction with the FAA Act, establishes a comprehensive system of controls of alcoholic beverages, including on-site inspections and procedures that require the advance approval of formulas showing each substance to be used in certain products. The IRC also vests authority in TTB to detain any container that will be removed in violation of law (26 U.S.C. § 5311) and vests TTB with seizure and forfeiture authority (26 U.S.C. § 7302).

RESPONSIBILITIES

It is understood and agreed between the agencies, as follows:

(A) TTB will be responsible for the promulgation and enforcement of regulations with respect to the labeling of wine, distilled spirits, and malt beverages pursuant to the FAA Act. When FDA has determined that the presence of a substance in food products, including alcoholic beverages, poses a recognized health concern for certain individuals and that the substance must be identified on a food product label, TTB will initiate rulemaking proceedings to promulgate labeling regulations for such products, consistent with TTB's labeling authority under the FAA Act. TTB and FDA will consult on a regular basis concerning the promulgation of regulations concerning the labeling of substances for alcoholic beverages regulated by TTB under the FAA Act.

(B) FDA will, upon TTB's request, provide TTB with a health hazard evaluation (HHE) with respect to any substance found in alcoholic beverages (with the exception of substances

that FDA informs TTB are unapproved food or color additives). TTB agrees to provide FDA with any data or analyses it may have with respect to the substance in question.

(C) TTB will be responsible for testing alcoholic beverages to determine the extent of an adulteration problem. To the extent practicable, FDA will provide laboratory assistance at the request of TTB.

(D) TTB will consult with FDA on any major changes to comprehensive formal procedures and guidelines for implementing voluntary recalls of wines, distilled spirits, and malt beverages, as defined by the FAA Act, that FDA informs TTB are adulterated under the FD&C Act. These procedures and guidelines will be developed in light of the FDA procedures and guidelines for such recalls and shall be implemented by TTB after review and comment by FDA. TTB will continue to notify FDA of market withdrawals for product quality issues.

(E) TTB will have primary responsibility for issuing recall notices and monitoring voluntary recalls when wines, distilled spirits, and malt beverages are adulterated under the FD&C Act or mislabeled under the FAA Act by reason of being adulterated. With respect to certain alcoholic beverages that are regulated under the IRC but not the FAA Act (generally, wines that contain less than 7 percent alcohol-by-volume and beers produced without both malted barley and hops), FDA will have primary recall responsibility, as such products are generally not subject to TTB's labeling authority under the FAA Act. This agreement does not affect or otherwise attempt to restrict the seizure or other statutory and regulatory authorities of the respective agencies.

(F) When FDA learns or is advised that an alcoholic beverage is or may be adulterated, FDA will contact TTB.

(G) When TTB learns or is advised that a wine, distilled spirit, or malt beverage is or may be adulterated, TTB will consult with FDA before it takes any action with respect to a notice of recall for the product. FDA, in turn, will expeditiously provide TTB with a written HHE and suggested appropriate course of action with respect to each product that may be subject to a recall. TTB will provide FDA with any data or analyses it may have or obtain, within its authorities, with respect to the product in question to assist FDA in undertaking a HHE. Upon receipt of a FDA HHE indicating a health concern, TTB will advise the responsible person or entity as to an appropriate course of action which might include a voluntary recall.

In the case of unapproved food and color additives, FDA will not provide an HHE. A food (including an alcoholic beverage) containing an unapproved food or color additive is adulterated under sections 402(a)(2)(C)(i) and 409(a), or 402(c) and 721(a), of the FD&C Act, respectively. In such circumstances, FDA will provide TTB with an opinion regarding the regulatory status of such substance. Upon receipt of this information, TTB will take appropriate action, which may include seeking a voluntary recall.

(H) In situations involving a recall notice of an adulterated wine, distilled spirit, or malt beverage, TTB will advise FDA of how TTB intends to proceed and will keep FDA apprised of developments with respect to such recall.

(I) In situations involving a recall of an adulterated wine, distilled spirit, or malt beverage that poses a significant risk to the public health, TTB will consult with FDA before issuing any press release. Press releases will be issued in accordance with established TTB procedures and guidelines.

(J) In situations involving a person or entity that is unwilling to voluntarily cease the distribution and/or initiate a voluntary recall of an adulterated alcoholic beverage that meets the definition of wine, distilled spirit, or malt beverage under the FAA Act, TTB will notify FDA, as provided in section 423(e) of the FD&C Act (21 U.S.C. § 350I(e)).

(K) FDA and TTB laboratories will continue to exchange information concerning methodologies and techniques for testing alcoholic beverages.

(L) FDA and TTB will exchange a wide variety of information, including relevant consumer complaints concerning the adulteration of alcoholic beverages. Any non-public information sharing will be done in accordance with 21 C.F.R. § 20.85, Disclosure to other Federal Government departments and agencies, and as noted in the Proprietary Information section below.

(M) TTB will consult with FDA, as needed, on substances for products regulated by or being reviewed by TTB prior to label and/or formula approval; however, any TTB approval shall not indicate FDA concurrence or approval. In cases where TTB has approved product labels and/or formulas for products that are considered adulterated under the FD&C Act, TTB will evaluate appropriate actions, including seeking voluntary product recalls, revocation of formula and label approvals, or issuing policy guidance or other public information.

(N) TTB will consult with FDA, as needed, on the use of health-related statements and/or health claims in the labeling and advertising of wines, distilled spirits, and malt beverages.

GENERAL PROVISIONS

The provisions of this MOU are not intended to add to, nor detract from, any of the statutory authorities of each agency or the regulations promulgated by each agency under such authorities. Each agency reserves the authority to review, independently of the other, matters of concern to their respective authorities.

MOU POINT OF CONTACTS

For FDA:

Jesse Lunzer, Ph.D.
Biologist, Office of Post Market Assessment
Office of Food Chemical Safety, Dietary Supplements, and Innovation
Human Foods Program
5001 Campus Drive
College Park, MD 20741
Telephone Number: (240) 402-2879

For TTB:

James R. Neely
Assistant Director, Trade Investigations Division
Alcohol and Tobacco Tax and Trade Bureau
Washington, DC 20005
Telephone Number: (202) 453-2251

PROPRIETARY INFORMATION

Confidential or nonpublic information includes but is not limited to: (1) confidential commercial information, such as the information that would be protected from public disclosure pursuant to Exemption 4 of the Freedom of Information Act (FOIA); (2) personal privacy information, such as the information that would be protected from public disclosure pursuant to Exemption 6 or 7(c) of the FOIA; or (3) information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g. Trade Secrets Act (18 U.S.C. § 1905)), the Privacy Act (5 U.S.C. § 552a), other FOIA exemptions not mentioned above (5 U.S.C. § 552(v)), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.), and the Health Insurance Portability and Accountability Act (HIPAA), Pub. L. 104-191).

Proper safeguards shall include the adoption of policies and procedures to ensure that the information shared under this MOU shall be used consistent with the Trade Secrets Act (18 U.S.C. § 1905), the FD&C Act (21 U.S.C. §§ 301 et seq.), the Privacy Act of 1974, as amended (5 U.S.C. § 552a), the FOIA (5 U.S.C. § 552), and any other applicable Federal laws and their implementing regulations. Pursuant to the FD&C Act section 301(j) (21 U.S.C. § 331(j)), FDA will not reveal to TTB any method or process which is entitled to protection as a trade secret.

Access to the confidential and non-public information shared under this MOU shall be restricted to authorized FDA and TTB employees, agents, and officials (i.e., Authorized Contact Person(s)) who require access to perform their official duties in accordance with the uses of the information as authorized in this MOU and any such non-public information is shared by FDA pursuant to 21 C.F.R. § 20.85. Such personnel shall be advised of (1) the confidential nature of the information; (2) the required safeguards against the unauthorized disclosure of confidential information, and (3) the administrative and civil penalties contained in applicable Federal laws for the unauthorized disclosure of confidential information.

When an Authorized Contact Person requests information, documents, or data, the request should be made in writing, which may include email, and contain all substantive requirements of 21 C.F.R. § 20.85 to include the following language:
Information is being requested pursuant to Memorandum of Understanding [MOU NUMBER]. We agree not to disclose any shared information in any manner without your written permission or, if such disclosure is required by law, without advance notice to the originating agency.

By including this statement, requestors do not have to use a particular format or include other pre-specified text. Additionally, information can be requested using the 20.85 Model Request Letter (Attachment A). TTB and FDA each agree to clearly identify, in writing, any such non-public information disclosed. TTB and FDA agree not to disclose, copy, reproduce or otherwise make available in any form whatsoever to any other person, firm, corporation, partnership, association or other entity information designated as proprietary or confidential information without consent of the other agency except as such information is subject to disclosure under the FOIA (5 U.S.C. § 552), FDA regulations at 21 C.F.R. part 20, or as otherwise authorized or required by law.

If an agency receives a FOIA request for any shared information, the receiving agency will: (a) if the request implicates documents from the sharing agency in their original form, refer the request to the sharing agency for the sharing agency to respond directly to the requester, and notify the FOIA requester of the referral and that a response will issue directly from the sharing agency regarding the releasability of the information; and (b) if the request implicates documents from the receiving agency that incorporate information from the sharing agency, consult with the sharing agency before releasing records in response to the FOIA request. The receiving agency will not indicate to the FOIA requester whether the sharing agency has responsive or releasable records. All actions taken under this paragraph must be in compliance with 45 C.F.R. § 5.25.

ENTIRETY

This MOU represents the entire agreement of the agencies with respect to the subject matter hereof and supersedes all prior and/or contemporaneous agreements or understandings, written or oral, with respect to the subject matter of this MOU.

EFFECTIVE DATE

This MOU will become effective on the date of the last signatory to the agreement.

REVISIONS/AMENDMENTS

It is understood and agreed that the agencies may revise or modify this MOU by written amendment hereto, provided such revisions or modifications are mutually agreed upon.

TERMINATION

This MOU is entered into voluntarily by all agencies and may be modified by mutual consent of authorized officials from the TTB and FDA. This MOU may be terminated by either agency with thirty (30) days advance written notice.

APPROVED AND ACCEPTED BY:
U.S. FOOD AND DRUG ADMINISTRATION

KYLE A. DIAMANTAS -S
Digitally signed by KYLE A. DIAMANTAS -S
Date: 2025.06.13 09:38:17 -04'00'

6/13/25

Kyle Diamantas, J.D. — Date
Deputy Commissioner for Human Foods

APPROVED AND ACCEPTED BY:
ALCOHOL AND TOBACCO TAX AND TRADE BUREAU

Elisabeth C. Kann
Digitally signed by Elisabeth C. Kann
Date: 2025.06.30 17:20:03 -04'00'

06/30/2025

Elisabeth Kann — Date
Deputy Administrator

Attachment A: 20.85 Model Request Letter

[PARTNER'S LETTERHEAD] *Please copy and paste onto your agency's letterhead

Attn: Information Sharing Specialist
Division of Information Disclosure
Office of Disclosure, Information Governance, and Accessibility
Office of Management and Enterprise Services
Office of the Commissioner

Food and Drug Administration
ORAInfoShare@fda.hhs.gov

Dear Information Sharing Specialist,

The [PARTNER (s) AND OFFICE] requests access to the following non-public information, pursuant to MOU [MOU NUMBER], [REQUEST: LIST THE TYPE OF RECORDS/INFORMATION REQUESTED, INCLUDING THE PERSON OR ENTITY AND/OR PRODUCT NAME AND THE RELEVANT TIME FRAME] pursuant to 21 C.F.R. § 20.85.
*(Requests for *all* documents, or *all* communications relating to a product/person or entity, is usually overly broad and can result in processing delays).

The purpose for which the information is requested is to assist in the [STATE THE NATURE OF YOUR INTEREST] The records will only be used for the following authorized activity: [STATE THE ACTIVITY].
*If the request for information is the result of an ongoing investigation give the details.

I certify that the ACTIVITY is authorized by law, that the records or information will be used only for the stated purpose and will not be disclosed outside [PARTNER (s) AND OFFICE] without the prior written permission of the Food and Drug Administration. I also certify that disclosure within [PARTNER] will be limited to the specific purpose stated above, and that I will provide a copy of this letter to any person(s) with whom I share the non-public information.

I understand that 21 U.S.C. § 331 of the Federal Food, Drug, and Cosmetic Act prohibits disclosure of trade secret information outside the Department of Health and Human Services. If you have any questions, please contact [PROVIDE YOUR NAME AND EMAIL (ADDITIONAL CONTACT INFORMATION)].

Sincerely,
[INSERT SIGNATURE LINE]

cc: [INSERT NAME OF BOTH FDA AND TTB LIASIONS]