

MEMORANDUM OF UNDERSTANDING BETWEEN THE
FOOD AND DRUG ADMINISTRATION AND THE
BUREAU OF ALCOHOL, TOBACCO AND FIREARMS

I. PURPOSE

This agreement between the Food and Drug Administration (FDA) and the Bureau of Alcohol, Tobacco and Firearms (ATF) 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 of 1938, and for other related purposes. Specifically, this Memorandum of Understanding will:

- (A) Effect a more efficient system of communication and exchange between FDA and ATF;
- (B) Confirm ATF policy with respect to the labeling of ingredients and substances in alcoholic beverages that pose a public health problem; and
- (C) Clarify and coordinate the responsibilities of each agency with respect to the identification, testing, and recall of adulterated alcoholic beverages.

II. BACKGROUND

A. Pursuant to the Federal Food, Drug and Cosmetic Act of 1938, as amended (FD&C Act), 21 U.S.C. §§ 301, et seq., FDA has authority, inter alia, to take action with

respect to adulterated food products, including alcoholic beverages, both domestic and imported. Among other things, a food is adulterated under section 402 of the FD&C Act if it was produced, packed, or held under insanitary conditions; if it contains any poisonous or deleterious substance which may render the food injurious to health; or if it contains an unapproved food additive. FDA has authority to initiate seizure of adulterated foods, including alcoholic beverages, and to seek to enjoin the introduction of such products into interstate commerce. The FD&C Act also authorizes FDA to refuse entry of imported products that appear to be adulterated and 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., ATF has authority over distilled spirits, wines, and malt beverage products, both domestic and imported. In particular, section 5 of the FAA Act (27 U.S.C. § 205) vests ATF with the authority to promulgate regulations regarding the labeling and advertising of alcoholic beverages to insure ~~that they provide the consumer with adequate information~~ concerning the identity and quality of such products.

Section 5(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 distilled spirits, wine, or malt beverages in bottles, unless such products are bottled, packaged, and labeled in conformity with regulations prescribed by the Secretary of the Treasury. ATF is charged with the administration and enforcement of the FAA Act and does this through, inter alia, the issuance of permits and through procedures that require the prior approval of all labels. In addition, ATF is charged with the administration and enforcement of Chapter 51 of the IRC, relating to Distilled Spirits, Wines 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 statements of process and of formulas showing each ingredient to be used in the product. The IRC also vests authority in ATF ~~to detain any container that will be removed in violation~~ of law (26 U.S.C. § 5311) and vests ATF with seizure and forfeiture authority (26 U.S.C. § 7302).

III AGREEMENT

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

(A) ATF will be responsible for the promulgation and enforcement of regulations with respect to the labeling of distilled spirits, wine, and malt beverages pursuant to the FAA Act. When FDA has determined that the presence of an ingredient in food products, including alcoholic beverages, poses a recognized public health problem, and that the ingredient or substance must be identified on a food product label, ATF will initiate rulemaking proceedings to promulgate labeling regulations for alcoholic beverages consistent with ATF's health policy with respect to alcoholic beverages. ATF and FDA will consult on a regular basis concerning the propriety of promulgating regulations concerning the labeling of other ingredients and substances for alcoholic beverages.

(B) FDA will, upon ATF's request, provide ATF with a health hazard evaluation with respect to any substance found in alcoholic beverages. ATF agrees to provide FDA with any data or analyses it may have with respect to the substance in question.

(C) ATF 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 ATF.

(D) ATF will prepare, in consultation with FDA, comprehensive formal procedures and guidelines for implementing voluntary recalls of adulterated alcoholic beverages. These procedures and guidelines will be developed in light of the FDA procedures and guidelines for such recalls and shall be implemented by ATF after review and comment by FDA.

(E) ATF, as the agency with a system of specific statutory and regulatory controls over alcoholic beverages, will have primary responsibility for issuing recall notices and monitoring voluntary recalls of alcoholic beverages that are adulterated under FDA law or mislabeled under the FAA Act by reason of being adulterated. 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 ATF.

(G) When ATF learns or is advised that an alcoholic beverage is or may be adulterated, ATF 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 ATF with a written health hazard evaluation of each product involved in a recall situation or potential recall situation. ATF will provide FDA with any data or analyses it may have with respect to the product in question to assist FDA in undertaking a health hazard evaluation. Upon receipt of a FDA health hazard evaluation indicating a definitive hazard, ATF will advise the responsible firm as to an appropriate course of action which might include a voluntary recall.

(H) In situations involving a recall notice of an adulterated alcoholic beverage, ATF will advise FDA of how ATF intends to proceed and will keep FDA apprised of developments with respect to such recall.

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

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

(K) FDA and ATF will continue to exchange a wide variety of information, including relevant consumer complaints concerning the adulteration of alcoholic beverages.

IV PARTIES TO AGREEMENT

The parties to this agreement are:

The Bureau of Alcohol, Tobacco and Firearms
Department of the Treasury
1200 Pennsylvania Avenue, N.W.
Washington, DC 20226

and

The Food and Drug Administration
Department of Health and Human Services
200 C Street, S.W.
Washington, DC 20204

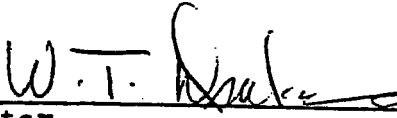
V. DURATION OF AGREEMENT

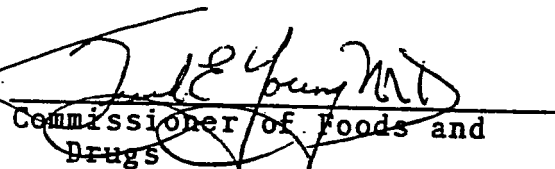
This agreement becomes effective upon acceptance by both parties and shall remain in effect indefinitely. This agreement may be modified by mutual consent or terminated by either party upon a thirty (30) day advance written notice to the other.

VI. LIASON OFFICERS

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Acting Director
Bureau of Alcohol, Tobacco
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Commissioner of Foods and
Drugs
Food and Drug Administration

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