### Memorandum of Understanding

### Between The Bureau of Alcohol, Tobacco and Firearms

and

# The Food and Drug Administration regarding the Promulgation and Enforcement of the Labeling Regulations Promulgated under the Federal Alcohol Administration Act

Whereas, The Federal Alcohol Administration Act (27 U.S.C., Chapter 8, section 201-212) was enacted in 1935 to further protect the revenue derived from distilled spirits, wine and malt beverages, to regulate inter-state and foreign commerce and enforce the twenty-first amendment; and

Whereas, The Federal Alcohol Administration Act pursuant to section 205(e) makes it unlawful for any person engaged in the business as a distiller, brewer, rectifier, blender, or other producer, or as an importer or wholesaler, of distilled spirits, wine and malt beverages, or as a bottler, or warehouseman and bottler, of distilled spirits directly or indirectly or thorough an affiliate, to sell or ship or deliver for sale or shipment, or otherwise introduce in 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; and

Whereas, The Bureau of Alcohol, Tobacco and Firearms is charged with the administration and enforcement of the Federal Alcohol Administration Act through the employment of a large field force including the:

(1) Issuance of permits to persons engaged in the business of (a) distilling distilled spirits, producing wine, rectifying or blending distilled spirits or wine, or bottling, or warehousing and bottling distilled spirits; (b) importing into the United States distilled spirits, wine or malt beverages; and (c) purchasing for resale at wholesale distilled spirits, wine or malt beverages; and

(2) procedures which require the prior approval of all labels to insure compliance with standards of identity and the requirement of showing proof, quantity and the name and address of the importer, producer or bottler; and

Whereas, The Bureau of Alcohol, Tobacco and Firearms is also charged with the administration and enforcement of Title 26 of the United States Code, Chapter 51, relating to Distilled Spirits, Wines and Beer, which establishes comprehensive system of controls over these products; including on-site inspections and procedures which require the advance approval of statements of process and of formulas showing each ingredient to be used in the product; and

Whereas, Under the Federal Food, Drug, and Cosmetic Act of 1938, as amended, administered by the Food and Drug Administration, alcoholic beverages are included within the specified articles, and, therefore, such agency has authority to prescribe regulations for ingredient labeling of distilled spirits, wine and malt beverages; and

Whereas, The Bureau of Alcohol, Tobacco and Firearms in consultation with the Food and Drug Administration is developing comprehensive ingredient labeling regulations with respect to distilled spirits, wine and malt beverages pursuant to the Federal Alcohol Administration Act which regulations will be in consonance with the Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder; and

Whereas, In the interest of economy and efficiency, it is deemed desirable to avoid unnecessary duplication of effort;

Now therefore, It is understood and agreed between the Bureau of Alcohol, Tobacco and Firearms and the Food and Drug Administration as follows:

1. The Bureau of Alcohol, Tobacco and Firearms will be the primary agency responsible for the promulgation and enforcement of labeling regulations of distilled spirits, wine and malt beverages pursuant to the Federal Alcohol Administration Act.

2. Regulations promulgated by the Bureau of Alcohol, Tobacco and Firearms under the Federal Alcohol Administration Act, will be consistent with the food labeling requirements of the Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder.

3. The Food and Drug Administration will defer to the Bureau of Alcohol, Tobacco and Firearms for primary regulation of the labeling of alcoholic beverages under the conditions of this agreement.

4. The Bureau of Alcohol, Tobacco and Firearms will continue to consult with FDA and regulations promulgated by ATF will be consistent with the Food and Drug Administration's directives and interpretations regarding any ingredient in distilled spirits, wine and malt beverages, which the Food and Drug Administration may find in violation of section 402(a)(1) or (a)(2) of the Federal Food, Drug, and Cosmetic Act.

5. This agreement, when accepted by both parties, covers an indefinite period of time and may be modified by mutual consent of both parties or may be terminated by either party upon a thirty (30) day advance written notice to the other.

6. The Liaison Officers for this Memorandum of Understanding are as follows:

Mr. James O. Pasco, Jr. Regulatory Enforcement Liaison Officer Office of the Assistant Director for Regulatory Enforcement Bureau of Alcohol, Tobacco and Firearms Washington, D.C. 20226 Telephone Number: 202-961-7557

Mr. Taylor Quinn, Director, Division of Regulatory Guidance (HFF-310) Bureau of Foods Food and Drug Administration Washington, D.C. 20240 Telephone Number: 202-245-1597

Effective date. This memorandum of understanding becomes effective on October 8, 1974.

Dated: October 2, 1974

Sam D. Fine, Associate Commissioner for Compliance

#### Approved and Accepted for the Bureau of Alcohol, Tobacco and Firearms

Signed by: Rex D. Davis, Director, Bureau of Alcohol, Tobacco and Firearms

Date: September 16, 1974

## Approved and Accepted for the Food and Drug Administration

Signed by: Alexander M. Schmidt, Commissioner of Food and Drugs

Date: September 12, 1974