



# Fomentation About Fermentation: A Study on Ingredient Labeling on Alcoholic Beverages

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Fomentation About Fermentation:

A Study on Ingredient Labeling on Alcoholic Beverages

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**Abstract:** Since the creation of the Federal Food and Drug law in 1906 up until a district court decision in 1976, the Food and Drug Administration (FDA) shared concurrent jurisdiction with the Bureau of Alcohol Tobacco and Firearms (BATF) over both the adulteration and misbranding (labeling) of alcoholic beverages. As a policy matter, the FDA deferred the regulation of alcoholic beverages labeling to the BATF in order to avoid duplication, as long as the regulations were consistent with the food labeling requirements of the Food, Drugs and Cosmetics Act. However, as a result of a District court ruling in 1976, the BATF now possesses exclusive jurisdiction over the labeling of alcoholic beverages under the Federal Alcohol Administration Act. This has led to the some peculiar results and a confusing regulatory scheme. For instance, the FDA requires affirmative ingredient and nutritional labeling of all “food and drinks” within its jurisdictional boundaries, whereas the BATF does not require ingredient labeling requirements for any alcoholic beverages within its jurisdictional boundaries and still follows the mandate of an alcohol labeling law that dates back to the enactment of the Federal Administration Act in 1935. This has resulted in a lack of consumer information regarding the ingredients and contents in alcoholic beverages, as ingredient and nutritional labeling give consumers the information they need to make responsible choices about their consumption of food and beverages. Today, the FDA still holds concurrent jurisdiction over the adulteration of all alcoholic beverages, and exclusive labeling jurisdiction over wine and cider with less than ten percent alcohol, but the BATF has not yet issued ingredient labeling requirements, nor has a congressional mandate granted the FDA the power to assume jurisdiction over the labeling of alcoholic beverages.

## **I.**

### **History and Overview of Legislative Background**

## **A.**

## The Federal Food and Drug Administration

The history of a national agency to regulate the adulteration and misbranding of food in the United States can be traced back to the creation by Congress of the United States Department of Agriculture in 1862.<sup>1</sup> The Chemical Division was immediately formed by the Commissioner of Agriculture, which subsequently became the Division of Chemistry in 1890.<sup>2</sup> Under the guidance of Dr. Harvey Wiley, the Chief Chemist for the Division of Chemistry from 1883-1912, the Division began to investigate the adulteration of food, drugs, and liquors to campaign for a federal food and drug law.<sup>3</sup>

Dr. Wiley took his investigations and reports of misbranding, adulteration, and unsanitary conditions to the public, becoming a popular speaker at women's clubs, civic and business organizations.<sup>4</sup> In 1903, Wiley captured the attention of the country by establishing a volunteer poison squad of twelve young United States Department of Agriculture employees who agreed to eat foods treated with measured amounts of chemical preservatives, with the object of demonstrating whether these ingredients were injurious to their health.<sup>5</sup> Strenuous opposition to Wiley's campaign for a federal food and drug law came from whiskey distillers and the patent medicine firms, who were then the largest advertisers in the country, as many of these men thought they would be put out of business by Federal regulation.<sup>6</sup>

Despite the above opposition, in January of 1906, the Heyburn Bill was enacted to become the Federal Food and Drug Act of 1906 (hereinafter the 1906 Act).<sup>7</sup> The Division of Chemistry became the Bureau of Chemistry in 1901, which enforced the 1906 Act law until 1927 when it was reorganized in the Food, Drug, and Insecticide Administration and law enforcement functions were separated from agricultural research in order

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<sup>1</sup>Hutt, *Symposium on the History of Fifty Years of Food Regulation Under the Federal Food, Drug, and Cosmetic Act: A Historical Introduction*, 45 FDC LJ 17, 18 (1990).

<sup>2</sup>*Id.*, at 18.

<sup>3</sup>Hutt, *A History of the Government Regulation of Adulteration and Misbranding of Food*, 39 FDC LJ 2, 51 (1984).

<sup>4</sup><http://www.cfsan.fda.gov/~lrd/history1.html>

<sup>5</sup>Hutt, *A History of the Government Regulation of Adulteration and Misbranding of Food*, *Supra*, note 3 at 51.

<sup>6</sup><http://www.cfsan.fda.gov/~lrd/history1.html>, *Supra*, note 4.

<sup>7</sup>34 Stat. 768 (1906)

to emphasize and secure better funding for the latter. Finally in 1930, the Food and Drug Administration (hereinafter the FDA) was formed to enforce the laws of the 1906 Act.<sup>8</sup> The 1906 Act prohibited the manufacture and interstate shipment of adulterated and misbranded foods, but did not require any form of affirmative labeling.<sup>9</sup> A food was deemed to be misbranded if:

The package containing it or its label shall bear any statement, design, or device regarding the ingredients or the substances contained therein, which statement, design, or device shall be false or misleading in any particular.<sup>10</sup>

However, food adulteration and misbranding continued to flourish under the 1906 Act due, in part, to its deficiencies in a legal standard for food, authority to inspect food establishments, and a lack of jurisdiction over false or misleading claims not made on food labels.<sup>11</sup> Judges also had a very difficult time finding specific authority in the law for the standards of purity and content, which FDA had set up under the 1906 Act.<sup>12</sup>

By 1933 the insufficiencies in the 1906 Act had become apparent, and Senate introduced a bill that eventually was enacted in 1938 to become the Federal Food, Drug, and Cosmetic Act of 1938,<sup>13</sup> (hereinafter the FD&C Act). The FD&C Act replaced the 1906 Act, and greatly increased the federal government's powers with respect to food safety and labeling by prohibiting the adulteration and misbranding of foods in interstate commerce, and the alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any act, to an article of food which resulted in the article being misbranded.<sup>14</sup> The FD&C Act also required the labeling of foods with, among other things, the net quantity of contents, the name of the food and the ingredients and it gave the FDA authority to promulgate standards for food.<sup>15</sup>

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<sup>8</sup>46 Stat. 392, 422 (1930).

<sup>9</sup>Hutt, *A History of the Government Regulation of Adulteration and Misbranding of Food*, *Supra* note 3 at 58.

<sup>11</sup>Hutt, *A History of the Government Regulation of Adulteration and Misbranding of Food*, *Supra*, note 3 at 62.

<sup>12</sup><http://www.cfsan.fda.gov/~lrd/history1.html>, *Supra*, note 4

<sup>13</sup>21 U.S.C. § 301, et seq.,

<sup>14</sup>*Id.*

<sup>15</sup>*Id.*, § 301 (k).

With respect to enforcement of the FD&C Act, in order to prevent recurring conflicts between producer interests and consumer interests, the FDA was transferred from the U.S. Department of Agriculture to the Federal Security Agency in 1940, which, in 1953, became the Department of Health, Education, and Welfare – now the Department of Health and Human Services.<sup>16</sup> Today the Center for Food Safety and Applied Nutrition, known as CFSAN, is one of six product-oriented centers that carry out the mission of the FDA. CFSAN is presently responsible for promoting and protecting the public’s health by ensuring that the nation’s food supply is safe, sanitary, wholesome, and honestly labeled.<sup>17</sup>

## B.

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

The regulation of alcoholic beverages by the Bureau of Alcohol, Firearms, and Tobacco (hereinafter the BATF), began with the repeal of Prohibition on December 5, 1933 in the Twenty-First Amendment to the Constitution. President Roosevelt created by executive order the Federal Alcohol Control Administration (FACA) to act as the regulatory body for the alcoholic beverage industry while Congress was in recess.<sup>18</sup> The FACA, in cooperation with the Departments of Agriculture and Treasury, endeavored to guide wineries and distilleries under a system based on brewers’ voluntary codes of fair competition.<sup>19</sup> However, the FACA was based on the National Industry Recovery Act,<sup>20</sup> which was declared unconstitutional by the Supreme Court in the Schechter Poultry Corp. V. United States decision in 1935.<sup>21</sup> Within three months of the decision, recognizing the absence of a specific regulatory body for the alcoholic beverage industry, Congress

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<sup>16</sup><http://www.cfsan.fda.gov/~lrd/history1.html>, *Supra*, note 4.

<sup>17</sup><http://www.cfsan.fda.gov/~lrd/cfsan4.html>

<sup>18</sup>Executive Order No. 6474 (Dec. 4, 1933).

<sup>19</sup><http://www.atf.treas.gov/about/history.htm>

<sup>20</sup>48 Stat. 195 (1933).

<sup>21</sup>*Schechter Poultry Corp. v. US.*, 295 US 495 (1935).

passed the Federal Alcohol Administration Act signed into law on August 29, 1935.<sup>22</sup>

The Federal Alcohol Administration Act, (hereinafter the FAA Act) gives the Treasury Department authority over the regulation of alcoholic beverages, which was first exercised through the Federal Alcohol Administration until 1939, then through the Alcohol Tax Unit of the Department of Internal Revenue.<sup>23</sup> Finally administration of the FAA Act was separated from the Internal Revenue Service by a treasury department order in 1972,<sup>24</sup> resting the responsibility in the BATF.<sup>25</sup> The FAA Act directs the Secretary of the Treasury to prescribe comprehensive regulations with, among other things, a function to protect consumers from deception in the labeling and advertising of alcoholic beverages.

Today the BATF regulates the qualification and operations of distilleries, wineries, and breweries, as well as importers and wholesalers in the alcoholic beverage industry.<sup>26</sup> To ensure alcohol beverage labels do not contain misleading information and adhere to regulatory mandates, the BATF Alcohol Labeling and Formulation Division examines all label applications for approval. The stated goals of the BATF with respect to alcoholic beverages is to:

[E]nsure the collection of alcohol beverage excise taxes; to provide for accurate deposit and accounting for these taxes; to prevent entry into the industry by criminals or persons whose business experience or associations pose a risk of tax fraud; and to suppress label fraud, commercial bribery, diversion and smuggling, and other unlawful practices in the alcohol beverage marketplace.<sup>27</sup>

Thus, unlike the FDA, the BATF's primary goal is not to protect consumer interest,<sup>28</sup> but rather to act as a tax-collecting entity and to ensure a fair marketplace for both producers and consumers.

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<sup>22</sup>27 U.S.C. § 201, et seq.

<sup>23</sup>Hancock, *Federal Jurisdictional Disputes in the Labeling and Advertising of Malt Beverages*, 34 FDC LJ 271, 273 (1979).

<sup>24</sup>37 Fed. Reg. 11696 (June 6, 1972)

<sup>25</sup><http://www.atf.treas.gov/about/history.htm>, *Supra*, Note 19.

<sup>26</sup>The alcoholic beverage industry includes brewers (malt beverages), distillers (distilled spirits or hard liquor), and vintners (wine).

<sup>28</sup>However, one of the stated purposes of the FAA Act is to protect and inform the consumer under section 205(e). See *Infra*, note 45.

## II.

### Regulation of Alcoholic Beverages From 1906 Through 1976

#### A.

#### Statutory Authority over the Labeling of Alcoholic Beverages

##### FDA Regulation of Alcoholic Beverages Under the 1906 Act

Under Section 6 of the 1906 Act “food” was defined as “articles used for food, drink. . . by man.” Although no specific regulations were issued for alcoholic beverages under the 1906 Act, the Department of Agriculture (of which the FDA was then a part of), issued a few decisions with respect to the labeling of alcoholic beverages.<sup>29</sup> Also, under the 1906 Act, there had been a broad range of case law which established that alcoholic beverages were considered within the definition of “food” and hence within the jurisdiction of the FDA.<sup>30</sup>

##### FDA Regulation of Alcoholic Beverages Under the FD&C Act

With the passing of the FD&C Act, Congress reported in the bill, through the Committee on Interstate and Foreign Commerce that with respect to the scope of definition of food:

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<sup>29</sup>Russell, *Controls over Labeling and Advertising of Alcoholic Beverages*, 7 Law & Contemp. Prob. 645, 648 (1940).

<sup>30</sup>See *Infra*, note 52 for citations for judicial decisions under the 1906 Act.



The definition of food is simply a clarification of the definition in the Food and Drugs Act of June 30, 1906.<sup>31</sup>

As introduced, the bill, later to become the Food, Drug and Cosmetic Act of 1938, contained the following definition of ‘food,’ “The term ‘food’ includes all substances and preparations used for, or entering into the composition of, food, drink, confectionary, chewing gum, or condiment for man or other animals.”<sup>32</sup> This definition of food remained unchanged when the bill was referred to the Commerce Committee. The bill also contained the following statement:

For purposes of enforcement of this [FD&C] Act, records kept by the Treasury Department in accordance with laws, and regulations thereunder, relating to alcoholic beverages and medicinal liquors, shall be open to inspection by any official of the Department of Agriculture duly authorized by the Secretary of Agriculture to make such inspections. Section 25(c).<sup>33</sup>

As the FDA was then part of the Department of Agriculture and the BATF was part of the Treasury Department, the bill suggests that Congress intended the FDA to exercise control over alcoholic beverages by providing the FDA access to alcoholic beverage records. Passed by the Senate on March 9, 1937, the bill was sent to the House of Representatives where it was referred to the Committee on Interstate and Foreign Commerce. The amendments made by the House Committee included minor changes in the definition of food and in the provision concerning access to records. The access to records provision upon enactment stated:

For purposes of enforcement of this chapter, records of any department or independent establishment in the executive branch of the Government shall be open to inspection by any official of the Department (of Agriculture) duly authorized by the Secretary to make such inspection. Section 702(c).<sup>34</sup>

The amendments’ purpose was to provide generally for access to records from “any” executive department,

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<sup>32</sup>Brown-Forman Distillers v. Mathews, 435 F.Supp 5 (W.D.Ky., 1976) [hereinafter Brown-Forman Case].

thus technical in nature, and not meant to effect substantive change in the scope of the definition of food as to exempt alcoholic beverages from it.<sup>35</sup> The House Committee of Interstate and Foreign Commerce verified this by reporting that the bill merely clarified the definition of “food” judicially interpreted to include alcoholic beverages. The definition of “food” as enacted in the FD&C Act in section 321(f), defines it as “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such particle.”<sup>36</sup>

Absent a specific provision exempting alcoholic beverages from this provision, the definition on “food” in the FD&C Act would suggest that alcoholic beverages were within the meaning of it. The only proposed amendment to the bill, which would have exempted whiskey, a kind of distilled spirit, from the food misbranding provision of the FD&C Act, but not from the FAA Act was deleted by the conference committee.<sup>37</sup> Also, unlike the Fair Packaging and Labeling Act which adopts the FD&C Act definition of “food” and then expressly exempts beverages from complying with the FAA Act as listed in 15 U.S.C. section 1459(a)(4), the FD&C Act contains no such qualification. It therefore signifies that Congress intended to include alcoholic beverages within the definition of “food” in the FD&C Act and give the FDA statutory regulation over alcoholic beverages.

Under the FD&C Act, Congress granted FDA affirmative labeling jurisdiction over “food” and provides that a “food” shall be deemed to be misbranded unless it complies with the labeling provisions of Section 403.<sup>38</sup> Also, pursuant to the FD&C Act, the FDA has authority to take action with respect to adulterated

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<sup>35</sup>Brown-Forman, *Supra*, Note 32 in Defendant’s Brief on page 8, reprinted in Russell, *Supra*, Note 29.

<sup>36</sup>21 U.S.C. § 301, et seq., *Supra*, Note 13.

<sup>37</sup>The Committee of Conference removed the following provision from the bill in the Statement of Managers on the Part of the House without explanation: “Whiskey.—Under the House amendment if any article is labeled as “whisky” (with or without qualifying words) and it or any part of it is distilled from a source other than grain, it shall be deemed not to provide the consumer with adequate information as to its identity within the meaning of certain provisions of the Federal Alcohol Administration Act. This provision is omitted by the conference agreement.” Reprinted in Dunn, *Supra*, note 33 at 994.

<sup>38</sup>21 U.S.C. § 403 imposes basic labeling requirements for food intended to provide the consumer with fundamental information about the articles of food and drink. A food shall be deemed to be misbranded, inter alia, if: (a) False or misleading label. . . (b) Offer for sale under another name. . . (c) Imitation of another food. . . (d) Misleading container. (e) Package form. If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor. . . (f) Prominence of information on label. (g) Representation as to definition and standard of identity. . . (j) Representation for special dietary use. (k) Artificial flavoring, artificial coloring, or chemical preservatives. (m) Color additives.

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 unsanitary conditions; when an added poisonous or deleterious substance is present if the added substance may render it injurious to health or bears or contains any food additive which is unsafe within the meaning of § 348 of this title.<sup>39</sup> FDA has authority to initiate seizure of adulterated foods, and to seek to enjoin the introduction of such products into interstate commerce.<sup>40</sup> The FD&C Act also authorizes FDA to refuse entry of imported products that appear to be adulterated and misbranded. Thus it appears that alcoholic beverages should be subject to the adulteration and misbranding provisions of the FD&C Act, along with all food products regulated by the FDA.

## **BATF Regulation of Alcoholic Beverages Under the FAA Act**

The FAA Act requires that the alcoholic beverage industry seek approval of their labels. BATF is charged with the administration and enforcement of the FAA Act and does this through the issuance of permits and through procedures that require the prior approval of all labels. In addition, BATF 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 system of controls of alcoholic beverages, including formulas showing each ingredient to be used in the product. The IRC also vests authority in

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(q) Nutrition labeling; information required. (A) the serving size... (B) the number of servings or other units of measure per container... (C) the total number of calories... (D) the amount of the following nutrients: Total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein contained in each serving size or other unit of measure... (E) any vitamin, mineral, or other nutrient required to be placed on the label and labeling of food under this Act before October 1, 1990, if the Secretary determines that such information will assist consumers in maintaining healthy dietary practices.

<sup>39</sup>21 U.S.C. § 342(a).

<sup>40</sup>21 U.S.C. § 331.

BATF to detain any container that will be removed in violation of law<sup>41</sup> and vests BATF with seizures and forfeiture authority.<sup>42</sup>

The BATF issues regulations governing the labeling and advertising of wine, distilled spirits, and malt beer in accordance with 27 CFR 4, 5, and 7 respectively. Pursuant to the FAA Act, section 5, BATF is vested with the authority to promulgate regulations to make sure that they provide the consumer with adequate information concerning the identity and quality of such products.<sup>43</sup>

However, these regulations can only be issued after “reasonable public notice” and opportunity for hearing under Section 5(e). These hearings are held after reasonable notice to members of the industry, state officials and others who may be interested in the subject matter.<sup>44</sup> 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 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.<sup>45</sup>

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<sup>41</sup>26 U.S.C. § 5311.

<sup>42</sup>26 U.S.C. § 7302.

<sup>43</sup>27 U.S.C. § 205(e)

<sup>44</sup>Russell, *Supra*, note 29 at 652.

<sup>45</sup>In 27 U.S.C. § 205(e), *Supra*, note 43, Congress authorizes the Secretary of the Treasury, who in turn delegated authority to BATF to prescribe such labeling regulations:

(1) As will prohibit deception of the consumer with respect to such products or the quantity thereof and as will prohibit, irrespective of falsity, such statements relating to age, manufacturing processes, analyses, guarantees, and scientific or irrelevant matters as the Secretary of the Treasury finds to be likely to mislead the consumer;

(2) As will provide the consumer with adequate information as to the identity and quality of the products, the alcoholic content thereof (except that statements of, or statements likely to be considered as statements of alcoholic content of malt beverages are prohibited unless required by State law and except that, in the case of wines, statements of alcoholic content should be required only for wines containing more than 14 per centum of alcohol by volume), the net contents of the package, and the manufacturer or bottler or importer of the product;

(3) as will require an accurate statement, in the case of distilled spirits (other than cordials, liqueurs, and specialties) produced by blending or rectification, if neutral spirits have been used in the production thereof, informing the consumer of the percentage of neutral spirits so used and of the name of the commodity from which such neutral spirits have been distilled, or in case of neutral spirits or of gin produced by a process of continuous distillation, the name of the commodity from which distilled;

(4) As will prohibit statements on the label that are disparaging of a competitor’s products or are false, misleading, obscene, or indecent; and

(5) As will prevent deception of the consumer by use of a trade or brand name that is the name of any living individual of public prominence, or existing private or public organization, or is a name that is in simulation or is an abbreviation thereof, and as will prevent the use of a graphic, pictorial, or emblematic representation of any such individual or organization, if the use of

At the time the Act was passed, the Director of the FACA, predecessor of BATF, explained the congressional intent of Section 205 (e) was to provide the consumer with information:

Now, the provisions of this bill show that the purpose was to carry that regulation into certain particular fields in which control of interstate commerce in liquors was paramount and necessary....These regulations were intended to insure that the purchaser should get what he thought he was getting, that representations both in labels and advertising should be honest and straightforward and truthful. They should not be confined, as the pure food regulations have been confined, to prohibitions of falsity, but they should also provide for the information of the consumer, that he should be told what was in the bottle, and all the important factors which were of interest to him about what was in the bottle.<sup>46</sup>

Interestingly, the 1935 Act's purpose of consumer protection still falls short of the way it was envisioned at its inception, as the "pure food regulations" have far exceeded the alcoholic beverage regulations with respect to protecting and informing the consumer.<sup>47</sup>

When the bill which was eventually going to become the 1935 Act was reported to the House by the Ways and Means Committee, it was noted that the existing laws, including the food and drug laws (presumably a reference to the 1906 Act), were insufficient.<sup>48</sup> The Committee insisted the new legislation must include affirmative labeling provisions. The labeling and advertising provision's purpose stated in the proposed legislation was to:

They... *must make* provision for informing the consumer adequately as to the identity and quality of the product, its alcoholic content, the net contents of the package, and the person responsible for the package or the advertisement (emphasis added).<sup>49</sup>

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such name or representation is likely falsely to lead the consumer to believe that the product has been indorsed, made, or used by, or produced for, or under the supervision of, or in accordance with the specifications of, such individual or organization...

<sup>47</sup>Hancock, *Supra*, note 23 at 273.

<sup>48</sup>H.R. Rep. No. 1542, 74th Cong. 1st Sess. at 3 (1935), reprinted in *Brown-Forman Case*, *Supra*, note 42 at 8.

For this reason, the FAA Act specifically included labeling authority not only to prohibit falsity and deception, then the extent of the labeling authority possessed by the FDA under the 1906 Act, but also expanded the scope of labeling authority so that the BATF should require, among other things, the identity and quality of the product and the net contents of the package.<sup>50</sup> Consequently, the language associated with the statute’s enactment suggests that alcoholic beverages would be subject to the general jurisdiction of the FDA and then to the more specific, stringent regulations to be issued by the BATF.<sup>51</sup>

## B.

### **Regulatory Activity of Alcoholic Beverages by the FDA and the BATF Up Until the mid 1970’s**

#### **Judicial Regulation**

Through the mid 1970’s both the case law and the actions taken by the BATF and the FDA recognized a concurrent jurisdiction with respect to the misbranding and adulteration of alcoholic beverages. Under Section 6 of the 1906 Act “food”, defined as “articles used for food, drink, ...by man”, was sufficiently broad to cover alcoholic beverages, and was readily recognized by the courts.<sup>52</sup> Congress, in adopting the FD&C Act stated that the definition of “food” was simply a clarification of the definition in the 1906 Act.<sup>53</sup> Therefore, case law following the adoption of the FD&C Act also established that alcoholic beverages

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<sup>50</sup>*Brown-Forman Case, Supra*, note 32 at 11.

<sup>51</sup>See also Executive Order No. 6474 (Dec. 4, 1933), *Supra*, note 28. Whereby under FACA mislabeled products were considered those “not labeled in compliance with the Federal Food and Drugs Act.”

<sup>52</sup>*See, e.g.*, *United States v. 50 Barrels of Whiskey*, 165 Fed. 966 (D.C. Md. 1908); *United States v. Sweet Valley Wine Co.*, 208 Fed. 85 (D.C. N.D. Ohio 1913); *United States v. Five Cases of Champagne*, 205 Fed. 817 (D.C. N.D.N.Y 1913).

<sup>53</sup>Committee on Interstate and Foreign Commerce, *Supra*, note 31.

were considered “food” within the meaning of the FD&C Act. In Abernathy v. Schenley Industries, Inc.,<sup>54</sup> having reviewed the definition of “food” in the FD&C Act, the district court held that “Bourbon whiskey is obviously included among ‘articles used for food or drink for man’ within the above definition. . .”<sup>55</sup> On appeal, the Appeals Court affirmed the lower court’s interpretation stating that, “the district court concluded that there was no cause of action under the Food, Drug, and Cosmetic Act, because the whiskey was neither misbranded nor adulterated within the meaning of the statute. 21 U.S.C. ss 331, 343, and 351.”<sup>56</sup> The Appeals Court further held that the Consumer Products Safety Act did not apply to food (the term “food” was defined in the Consumer Products Safety Act as “all ‘food’, as defined in section 321(f) of the FD&C Act”) and that alcoholic beverage was a food under the statute.<sup>57</sup>

In United States v. 1,800.2625 Wine Gallons of Distilled Spirits<sup>58</sup> the alcohol under seizure was considered both adulterated and misbranded foods within the meaning of the FD&C Act. The court elaborated that “the purpose of Federal Food, Drug and Cosmetic Act is to safeguard consumers by applying its requirements to articles from the moment of their introduction into interstate commerce, all the way to the moment of their delivery to the ultimate consumer, and the Act embraces *misbranding and adulteration* while held for sale after shipment in interstate commerce. Federal Food, Drug, and Cosmetic Act.” (Emphasis added). Thus this court considered the misbranding and labeling of alcoholic beverages within the jurisdictional mandate of the FD&C Act.

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<sup>54</sup>Abernathy v. Schenley Industries, Inc., 420 F.Supp. 1 W.D.N.C. (1976).

<sup>55</sup>*Id.* at 3.

<sup>56</sup>Abernathy v. Schenley Industries, Inc., 556 F.2d 242 4th Cir.(N.C.) (1977) at 243.

<sup>57</sup>*Id.*

<sup>58</sup>United States v. 1,800.2625 Wine Gallons of Distilled Spirits, 121 F.Supp. 735 (W.D. Mo. 1954).

## FDA and BATF Regulations Promulgated through 1976

Since the passage of the 1906 Act up until 1975, the FDA took the position that alcoholic beverages were “food” within the meaning of the FDC Act. Although the FDA did not issue standards for alcoholic beverages under the FD&C Act, in a FDA Trade Correspondence the FDA asserted concurrent jurisdiction with the Alcohol Tax Unit of the Internal Revenue Service (what is now the BATF) over the labeling of alcoholic beverages on April 11, 1940.<sup>59</sup> The Internal Revenue Service formally notified manufacturers that the possession of certificates of label approval pursuant to the FAA Act did not excuse them from complying with the laws and regulations administered by the FDA.<sup>60</sup> However, they did not insist their labels comply with Section 403(i)(2) of the FD&C Act, the misbranding provisions, which specifically required that all fabricated foods list their ingredients on the label.<sup>61</sup> This understanding, later to be confirmed in a memorandum of understanding signed by the two agencies in 1974, recognized that although alcoholic beverages were subject to the FD&C Act, the FDA would defer the regulation of alcoholic beverages labeling to the FAA in order to avoid duplication, as long as the regulations were consistent with the food labeling requirements of the FD&C Act.

Under Section 403 of the FD&C Act, the FDA required a statement of the ingredients, the net quality of

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<sup>59</sup>FDA Trade Correspondence No. 224 (April 11, 1940) stated that “While we have indicated that cordials, wine, and whiskey are subject to the (FD&C) Act, we will continue, as in the past, to leave to the Federal Alcohol Administration the regulations of the labeling of these alcoholic beverages under the more specific Federal Alcohol Administration Act. While beer is classified as food under the Act, and would therefore, be subject to the adulteration and misbranding provisions of the Act when shipped within its jurisdiction, we expect to continue our policy of not duplicating the work of the Federal Alcohol Administration with respect to the labeling of such products. That Administration, as you know, is charged with the enforcement of specific legislation dealing with alcoholic beverages.” Reprinted in Dunn, *Supra*, note 33 at 657.

<sup>60</sup>Alcohol and Tobacco Tax Division Industry Circular 62-33 (Oct. 26, 1962)

<sup>61</sup>21 U.S.C. § 403(i), *Supra*, note 38, reads that a food shall be deemed to be misbranded if: Label where no representation as to definition and standard of identity:

”Unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food; except that spices, flavorings, and colors not required to be certified under section 379e(c) of this title, unless sold as spices, flavorings, or such colors, may be designated as spices, flavorings, and colorings without naming each. To the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.”



contents, and the name and the address of the manufacturer on the label of all food products. By contrast, the BATF had never required general ingredient labeling on any alcoholic beverages within its jurisdiction. In 1972, the Center for Science and the Public Interest approached the BATF to require ingredient labeling requirements under section 205(f) of the FAA Act by considering alcoholic beverages not labeled with ingredient contents as misleading. Simultaneously they approached FDA to enforce ingredient labeling requirements for the alcoholic beverage industry under Section 403(i)(2) of the FD&C Act.<sup>62</sup> To which the FDA replied that it normally deferred to the BATF. But as the attractiveness of ingredient labeling grew, FDA urged BATF to reconsider its policies with respect to ingredient labeling.<sup>63</sup> As a result, on August 1, 1974 the BATF published proposed amendments to 27 CFR Parts 4,5, and 7<sup>64</sup> regarding ingredient labeling of wine, distilled spirits, and malt beverages respectively. Two months later, on October 8, 1974, the FDA announced that it would defer to the BATF for primary regulation of the labeling of alcoholic beverages under the conditions of a memorandum of understanding of 1974, “in the interest of economy and efficiency and to avoid duplication of effort...” (hereinafter the MOU of 1974).<sup>65</sup> The MOU of 1974 stated, among other things, that the FDA and the BATF:

Have drawn up a memorandum of understanding regarding the promulgation and enforcement of the labeling regulations promulgated under the FAA Act... Whereas, under the Federal Food, Drug, and Cosmetic Act of 1938... alcoholic beverages are included within the specified articles, and therefore, such agency has authority to prescribe regulations for ingredient labeling of distilled spirits, wines, and malt beverages; and Whereas, the Bureau of Alcohol, Tobacco, and Firearms in consultation with the Food and Drug Administration is developing comprehensive labeling regulations with respect to distilled spirits, wines, and malt beverages pursuant to the FAA Act which regulations will be in consonance with the FD&C Act and regulations promulgated thereunder...<sup>66</sup>

Despite the MOU of 1974, on November 11, 1975 the BATF, through the Department of the Treasury, rejected “ingredient labeling” of alcoholic beverages after holding public hearings for six days on the matter,

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<sup>62</sup>Cooper, The FDA, the BATF, and Liquor Labeling: A Case Study of Interagency Jurisdictional Conflict, 34 FDC LJ 370, 375 (1979).

<sup>63</sup>Second Edition Peter Barton Hutt, Richard A. Merrill, Food and Drug Law, Cases and Materials 78 (The Foundation Press, Inc. 1991) [hereinafter Hutt, Merrill]

<sup>64</sup>39 Fed. Reg. 27812 (August 1, 1974).

<sup>65</sup>39 Fed. Reg. 26127 (Oct. 8, 1974).

listening to many representatives from the alcoholic beverage industry, consumer groups and other interested persons on the issue of ingredient labeling of alcoholic beverages. In addition BATF reviewed approximately one thousand written comments on the question of ingredient labeling. Upon completion of the public hearings, the BATF then rejected ingredient labeling stating five reasons: (1) the cost of ingredient labeling for alcoholic beverages (to the industry and ultimately to the consumer) would be excessive in relation to the benefit received;... (2) the actual content of alcoholic beverages already is extensively regulated; (3) the labeling of ingredients would be of little value and, in certain cases, even misleading; (4) such requirements might hinder current international trade negotiations; and (5) ingredient labeling is supported by only a small segment of the public.”<sup>67</sup>

As a result of BATF’s announcement the FDA rejected the MOU of 1974 and announced its plan to enforce compliance with the requirements of, and regulations promulgated under the FD&C Act. The FDA announced in the federal register that it sought to impose ingredient labeling requirements on all alcoholic beverages in compliance with section 403(i) of the FDC Act.<sup>68</sup> The FDA simultaneously revoked the Trade Correspondence of 1940 and notified manufactures that the FDA would take regulatory actions to enforce the labeling requirements with respect to all alcoholic beverages shipped in interstate commerce after January 1, 1977. Subsequently, the FDA prepared a booklet demonstrating acceptable beverage labels in early May of 1976<sup>69</sup> and then on June 16, 1976, the FDA and BATF met to discuss the conflicting situation. The FDA discussed with the BATF, who generally concurred with the prospects of entering into a new MOU whereby other than ingredient labeling, the FDA would still defer to BATF and accept labeling as being in compliance with the FD&C Act.<sup>70</sup>

While the United States Brewers Association was not opposed to ingredient labeling, some vintners and

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<sup>67</sup>40 Fed. Reg. 52613 (November 11, 1975).

<sup>68</sup>40 Fed. Reg. 54455 (November 24, 1975).

<sup>69</sup>41 Fed. Reg. 18538 (May 5, 1976).

<sup>70</sup>Cooper , *Supra*, note 62 at 376.

distillers were adamantly opposed to the regulations. In March of 1976 representatives from the distilled spirits and wine industries sought a declaratory judgment that the FDA had no authority to regulate the labeling of alcoholic beverages in Brown-Forman Distillers Corp. v. Matthews (hereinafter Brown Forman).<sup>71</sup> On August 31, 1976 a United States Court in the Western District of Kentucky entered judgment against the FDA, thereby granting the BATF the exclusive jurisdiction over the labeling of alcoholic beverages and shifting the direction of labeling authority away from the FDA indefinitely.

## C.

### The Brown-Forman Decision

Plaintiffs, who included eight US distillers and one winemaker, the Distilled Spirits Council of the United States, the National Association of Alcoholic Beverage Importers, Inc, and the Wine Institute, gained a declaratory judgment in a United States district Court in the Western District of Kentucky stating that neither the FDA nor the Department of Health, Education, and Welfare possessed the jurisdiction or authority to require or regulate the labeling of alcoholic beverages. Albeit the liberal construction traditionally given to the FDC Act<sup>72</sup> and the deference traditionally given to an agency's interpretation of an act enforced by it,<sup>73</sup> the judge concluded that alcoholic beverages were not subject to the labeling provisions of the 1938 Act because Congress "impliedly exempted alcoholic beverages from the misbranding provision of the 1938

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<sup>71</sup>*Brown-Forman Case, Supra*, note 32.

<sup>72</sup>Past Supreme Court decisions have stated the principle of liberal construction should apply to the FD&C Act. *See, e.g.*, *United States v. Dotterweich*, 320 U.S. 277, 280 (1943), where the Supreme Court observed that the FD&C Act's purpose was to "touch the phases of the lives of the people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation. . ." *See also*, *United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969), where the court observed that "remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health. . .". *See also*, *AMP, Inc. v. Cohen*, 393 U.S. 825 (1968).

<sup>73</sup>Because the FDA was charged with enforcement of the word "food", it arguably should have been afforded deference with respect to its defined scope. *See, e.g.*, *Udall v. Tallman*, 380 U.S. 1, 16 (1965). "When faced with a statutory construction, this Court shows great deference to the interpretation given the statute by the officers or agency charged with its administration."

Act.”<sup>74</sup>

After examining the legislative history of the FAA Act and FD&C Act, the statutes themselves, and the actions of the FDA and BATF from 1938-1975 the court concluded that the statutes established conflicting regulatory requirements concerning the labeling of alcoholic beverages. The court indicated that the statutes themselves demonstrated Congress’ intention to place exclusive jurisdiction over the regulation of alcoholic beverage labeling in the Secretary of the Treasury, and through him the BATF, since the FAA Act is specific legislation dealing directly with the alcoholic beverage industry while the FD&C Act is broad in scope and can be argued to apply to alcoholic beverages only because the word food was defined expansively. Judge Gordon reasoned that it was the implied intention of Congress to grant the BATF exclusive labeling jurisdiction over alcoholic beverages and not to grant jurisdiction concurrently between the FDA and BATF thereby prohibiting the FDA from enforcing any requirements or regulations for the labeling of alcoholic beverages.<sup>75</sup>

The FDA’s claim was well supported by the legislative history of the 1938 Act, and past actions of the BATF and FDA (See Parts I and II above). Although Judge Gordon conceded that the FDA could prevent the adulteration of alcoholic beverages, he refused to give FDA jurisdiction over the labeling of alcoholic beverages. The court failed to give a reason why the statute itself does not differentiate between “food” for purposes of misbranding requirements and “food” for purposes of adulteration requirements. Instead Judge Gordon merely concluded that Congress intended to place exclusive jurisdiction over the regulation of alcoholic beverage labeling to the BATF because the FAA Act was very specific legislation.<sup>76</sup>

In holding that BATF had exclusive jurisdiction over labeling, the court refused to accept the idea that Congress’ failure to exclude specifically the labeling of alcoholic beverages from the provisions of the FD&A Act was a decisive indication of Congress’ intention to include labeling authority over alcoholic beverages

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<sup>74</sup>*Brown-Forman Case, Supra*, note 32 at 12.

<sup>75</sup>*Id* at 7.

<sup>76</sup>*Id* at 13.

within the jurisdiction of the FDA. The court relied primarily on the remarks made during the hearings on what eventually became the FD&C Act by a single member of Congress, Congressman Virgil Chapman of Kentucky. Congressman Chapman indicated that he did not believe that alcoholic beverages fell within the labeling sections of the proposed legislation because he thought an amendment was needed to extend the legislation to include whiskey labeling before that subject would be covered. However, Judge Gordon did not take into account the fact that these statements were made during discussions of an early draft of the FD&C Act and instead concluded that Congressman Chapman's words were synonymous with the intentions of Congress.

The statutes themselves supported the FDA's jurisdictional claims as well. For instance, Congress did not specifically exempt alcoholic beverages from the word "food" as defined in the scope of the FD&C Act, as Congress specifically provided for exemptions with such products as meat and meat products in the FD&C Act.<sup>77</sup> Section 392(a) provides that "Meats and meat food products shall be exempt from the provisions of this Act to the extent of the application or the extension thereto of the Meat Inspection Act, approved March 4, 1907, as amended."<sup>78</sup> Nor did Congress list the FAA Act as one of the prior statutes not affected by the passing of FD&C Act in section 392(b), as it did with respect to many other statutes.<sup>79</sup> Finally, no provision in the FD&C Act limits or qualifies the FDA's authority with respect to only enforcing the adulteration provisions of the FD&C Act and not enforcing the labeling sections of the Act..

Instead, the court discounted the fact that the BATF and the FDA assumed that they had concurrent jurisdiction over the regulation of the labeling of alcoholic beverages since 1940. Alternatively, he emphasized that the FDA did not take any major steps towards regulating the labeling of alcoholic beverages over the

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<sup>77</sup>21 U.S.C. § 392 (a).

<sup>78</sup>21 U.S.C.A. §. 601

<sup>79</sup>21 U.S.C. § 392 (b) states, *inter alia*, that: "Nothing contained in this chapter shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of section 351 of public Health Service Act [42 U.S.C.A. § 262] (relating to viruses, serums, toxins, and analogous products applicable to man); the virus, serum, toxin, and analogous products provisions, applicable to domestic animals, of the Act of Congress approved March 4, 1913 21 U.S.C.A. § 151 et seq; the Filled Cheese Act of June 6, 1896, the Filled Milk Act of March 4, 1923 [21 U.S.C.A. § 61 et seq.]; or the Import Milk Act of February 15, 1927 [21 U.S.C.A. § 141 et seq."

past 40 years while at the same time the FDA actively enforced the adulteration provisions of the FD&C Act with regard to alcoholic beverages.<sup>80</sup> Thus, concluded the court, the actions of the FDA during the period beginning with the enactment of the FD&C Act up until the litigation supported the idea that while “Congress intended the FDA to have the authority to enforce the adulteration provisions of the 1938 Act with respect to alcoholic beverages it did not intend the FDA to have concurrent jurisdiction with BATF concerning the labeling of alcoholic beverages.”<sup>81</sup>

Judge Gordon heavily relied on a basic rule of statutory construction that a “specific statute will not be controlled or nullified by a general one.”<sup>82</sup> He disregarded the idea that courts had long recognized the possibility of the FDA having concurrent jurisdictions with both the Treasury Department<sup>83</sup> and the Federal Trade Commission<sup>84</sup> and that the statutory remedies of two agencies could be cumulative and not mutually exclusive. Instead, Judge Gordon pointed out that the 2 statutes were in direct conflict with one another because section 205 (e) of the FAA Act requires that the Secretary of the Treasury prohibit misleading statements on the labels which are likely to mislead the consumer, even though they might not be false, while the FD&C Act requires ingredient labeling regardless of the possibility of misleading the consumer. Thus, according to the court’s analysis, because the ingredient labeling on alcoholic beverages would be misleading at times, the two statutes were in a direct irreconcilable conflict with one another.

Finally Judge Gordon pointed out that the labeling regulations and requirements promulgated by the FDA and BATF would subject the alcohol beverage industry to duplication and inconsistent standards. He refused to accept the FDA’s argument that a memorandum of understanding would be able to resolve this conflict and instead concluded that these irreconcilable differences were hardly a result that Congress would

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<sup>80</sup> *Brown-Forman Case, Supra*, note 32 at 16.

<sup>81</sup> *Id.* at 17.

<sup>82</sup> *Id.* at 13.

<sup>83</sup> *See, e.g., United States v. 1,800.2625 Wine Gallons of Distilled Spirits* 121 F.Supp. 735 (W.D. Mo. 1954).

<sup>84</sup> *See, e.g., United States v. Five Cases . . . Capon Spring Water*, 156 F. 2d 493, 496 (C.A. 2, 1946); *United States v. One Dozen Bottles . . . Bancquet Tablets*, 146 F. 2d 361 (C.A. 4, 1944)

have mandated.<sup>85</sup> Unfortunately, Judge Gordon's ruling which precluded FDA jurisdictional involvement over the labeling of alcoholic beverages, hindered the statutory policies underlying the FDA's rulemaking activities, namely that of consumer protection through the regulation of food.<sup>86</sup>

### **Appeal of Brown-Forman Denied by the Office of Management and Budget**

The FDA Commissioner unsuccessfully tried to seek the required approval to appeal the action from the Department of Justice after BATF agreed to initiate rulemaking to require at least partial ingredient labeling of alcoholic beverages.<sup>87</sup> In a letter on July 20, 1977 the Office of Management and Budget in the Executive Office of the President ordered BATF to develop ingredient labeling jointly with the FDA. In this letter, written to the FDA Commissioner, the Associate Director for Economics and Governments explained the reason for denying appeal:

There appears to be general agreement that the Bureau of Alcohol, Tobacco and Firearms (ATF) currently has the power to require ingredient labeling and could most efficiently and effectively administer new regulations for the alcoholic beverage industry. Therefore, we do not believe that the appeal of Brown-Forman Distillers Corp., v. Mathews is necessary. If the executive branch wishes to require ingredient labeling ATF currently possesses the authority and is the most appropriate regulator. . . . We are therefore requesting ATF to develop proposed partial labeling requirement jointly with the FDA. . . . We anticipate that the affected agencies will move quickly to publish and seek comment on a new proposed rule.<sup>88</sup>

As a result of this request, the BATF came up with a proposal based on "standards of identity" where only those ingredients would be labeled which were not required, but were permitted, by a publicly available BATF-approval standard of identity.<sup>89</sup> The FDA subsequently rejected this incomplete proposal and began

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<sup>85</sup> *Brown-Forman Case, Supra*, note 32 at 15

<sup>86</sup> Cooper, *Supra*, note 62 at 389

<sup>87</sup> Hutt, Merrill *Supra*, note 63 at 78

<sup>89</sup> 44 Fed. Reg. 6740 (February 2, 1979).

to seek legislative and Executive Branch approval to deprive BATF of its labeling jurisdiction.

However, the ruling in Brown-Forman did not prohibit the FDA from indirectly pressuring the BATF to take action with respect to ingredient labeling on alcoholic beverages. The FDA therefore began enlisting the support of the Office of Management and Budget, giving congressional briefings, lobbying, and inciting consumers to the cause of ingredient labeling. These efforts eventually pressured BATF to require ingredient labeling.<sup>90</sup> Subsequently, in February of 1979 in the Federal Register an ingredient labeling regulation was proposed by the BATF with terms very similar to the ones previously rejected by the BATF in 1975.<sup>91</sup>

As a result of this regulation, the plaintiffs from the previous Brown-Forman suit unsuccessfully brought action to find the Commissioner of the FDA in civil contempt of court for violating the court's order enjoining the FDA from imposing or enforcing or attempting to impose or enforce any requirements or regulations for the labeling of distilled spirits or wines.<sup>92</sup> The judge denied the motion, explaining that the court never ordered that the FDA or the Commissioner could not espouse or lobby their labeling cause, so as to eventually bring about action by BATF to label. Therefore the FDA's successful efforts to pressure BATF to require ingredient labeling under the FAA Act did not amount to contempt. With the notice of proposed rule making published, and a judgment permitting FDA's lobbying efforts, it seemed as though the FDA had finally succeeded in its battle over ingredient labeling on alcoholic beverages.

### III.

## The Direction of Alcoholic Beverage Labeling After Brown-Forman

### A.

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<sup>90</sup>Brown-Forman Distillers Corp., v. Califano, Food Drug Cosm. L. Rep. (CCH) ¶ 38, 245 (W.D. Ky. 1979)

<sup>91</sup>44 Fed. Reg. 6740, *Supra*, note 89

<sup>92</sup>Brown-Forman Distiller Corp. v. Califano, *Supra*, note 90.



## The BATF's 1980 Ingredient Disclosure Regulations

In the 1979 notice of proposed rulemaking for ingredient labeling,<sup>93</sup> the BATF described requirements for the partial ingredient labeling of alcoholic beverages which were intended to assist consumers in identification of ingredients contained therein compatible with increasing public awareness. In 1979, after the BATF announcement, the House Committee on Appropriations attempted to prohibit the expenditure of funds in connection with the promulgation of such regulations.<sup>94</sup> However, this limiting amendment proposed by the House was rejected in the Conference report.<sup>95</sup> Additionally, the Senate Committee on Appropriations supported the proposed regulations:

On February 2, 1979, the Bureau published in the Federal Register several proposed regulations, which would require the ingredient labeling of alcoholic beverages. The Committee believes that these regulations, accommodated for the substantive points raised by the industry and other interested parties, should be of benefit to the public.<sup>96</sup>

Then on June 13, 1980, the BATF issued a final rule, T.D. ATF-66, with respect to ingredient disclosure for wine, distilled spirits, and malt beverages,<sup>97</sup> which were to become mandatory on January 1, 1983. The regulations explained that:

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<sup>93</sup>44 Fed. Reg. 6740, *Supra*, note 89.

<sup>94</sup>H.R.REP. NO. 248, 96th Cong., 1st Sess. 10 (1979).

<sup>95</sup>Amendment No. 7: Deletes language proposed by the House and stricken by the Senate which prohibits the use of funds for issuing or carrying out proposed rules on labeling of wine, distilled spirits and malt beverages. H.R.CONF.REP. NO. 471, 96th Cong., 1st Sess. 6 (1979).

<sup>97</sup>45 Fed. Reg. 40538 (June 13, 1980).

“This rule requires ingredient disclosure on labels of wine, distilled spirits, and malt beverages. These regulations, however, provide an exception to this requirement. Under this exception the ingredient list will not be required to appear on the label when the producer, bottler, or importer: (1) elects to make an ingredient list available upon request; (2) places a statement on the front label or a separate strip label notifying the consumer of the availability of an ingredient list and provides the name and, somewhere on the label, a full mailing address in the United States where such an ingredient list can be obtained upon request; and (3) does not place a statement on the label which could be misconstrued to be an ingredient list. This exception gives industry maximum flexibility to provide ingredient information at minimum cost. At the same time, it provides consumers who have the need or desire to avoid various ingredients a means to do so, thus meeting the objective of the regulatory proposal. Because of special health problems, this rule also mandates the disclosure on the label, in all instances, of the presence of FD & C Yellow No. 5 whenever it is used in a product.”<sup>98</sup>

In its final publication the BATF detailed the steps of its Regulatory Analysis, which included an outline of the possible steps that could be taken to deal with the problem of ingredient disclosure, a consumer poll, and a cost-benefit study conducted by the BDM Corporation, a private consultant hired by BATF. The BATF also received 1,873 comments in response to notice of proposed rulemaking from consumers, special interest groups, industry members, doctors, government agencies, and members of Congress.

The BDM study emphasized that very different conclusions could be reached concerning the value of ingredient labeling, depending on the assumptions used. Major findings of the study included: There were important unanswered questions for both costs and benefits, which according to BDM could “lead to widely different conclusions” on the desirability of ingredient labeling. Estimates of expected costs of mandated

ingredient labeling to industry and the Government based on the information submitted, ranged between a low of \$12 million per year to almost \$150 million per year. The major factors that contributed to this range of estimates were the use of a back label, advertisement costs, and markups that might be applied by the industry at different points in the distribution channel. The advertisement costs were submitted directly to BDM by a winery after the comment period and from this submission BDM estimated a total annual \$25 million advertising cost for the entire wine industry. Start-up costs amounted to approximately \$18 million for the entire industry if no additional back labels were used. If additional back labels were used by all producers not presently using back labels, the total potential investment cost for the three industries, as reported by the industries, were in the range of \$35 million.<sup>99</sup>

The BDM study found strong evidence in the medical research literature that indicated “ingredients used in alcoholic beverages can cause adverse health effects in humans.” BDM found that while most of the effects were not necessarily severe, some were severe. The study also reported that adverse effects were not limited to allergic reactions. It was impossible, however, to determine exactly either how many people were affected (the range BDM gave was anywhere from 475,000 to 1,700,000) or how much money in health costs could be saved if ingredients were listed. (A wide range of estimates ranging from approximately one-half million dollars to four hundred million dollars was considered possible, depending on which assumptions were considered the most appropriate.)<sup>100</sup>

However, the BDM study did not contemplate the option that the final regulations included to give manufacturers the option to provide ingredient lists to consumers upon request and to make known the availability of such lists by stating on the label the name and address where such lists could be obtained. The study also did not address the health benefits of ingredient labeling other than prevention of allergic reactions.<sup>101</sup>

Based on the BDM study, the poll of consumers, and the comments and studies submitted in response to

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<sup>99</sup>*Id.*

<sup>100</sup>45 Fed. Reg. 40539 (June, 13 1980)

<sup>101</sup>*Center for Science in the Public Interest v. Department of the Treasury*, 573 F.Supp 1168 (1983) at 1172.

the proposed rulemaking, the Treasury Department stated that it was:

... convinced that the disclosure of ingredients used in the production of alcoholic beverages is of real value. This disclosure will provide consumers with adequate information about the identity and quality of the product, which will enable a consumer to make an informed choice in the purchasing of alcoholic beverages.... However, to minimize the costs while still meeting basic policy objectives, producers, bottlers or importers who elect to make ingredient lists available upon request, notify consumers of their availability, and who avoid implied label statements about ingredients, will not be required to list ingredients on the label.<sup>102</sup>

## BATF's 1981 Rescission of the Ingredient Labeling Requirements

However, this successful advance towards ingredient labeling on alcoholic beverages was short lived. On May 4, 1981, the BATF published another notice of proposed rulemaking, this time notifying the public of its intent to rescind the ingredient labeling regulations.<sup>103</sup> The notice explained that the BATF, as a result of the review of existing regulations called for by Executive Order 12291,... concluded that the regulations were not in accord with the President's mandate, and thus proposed rescission.<sup>104</sup>

Executive Order 12291 was a result of President Reagan's creation on February 17, 1981, and published in the Federal Register.<sup>105</sup> This order directed each Federal agency to establish a management system for Federal regulation that would improve the quality and lessen the burden of Federal regulation. Executive Order 12291 also required agencies, within their legal authority, to establish regulatory goals, set regulatory priorities, review existing regulations, and implement new regulations with the aim throughout government of maximizing the benefits to society while at the same time imposing the least burden to achieve those benefits. Apparently the Department of the Treasury reviewed its final rule regarding ingredient labeling under the criteria of Executive Order 12291 and the comments that it received pursuant to its 1979 notice

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<sup>103</sup>46 Fed. Reg. 24962 (May 4, 1981).

<sup>104</sup>*Id.*

<sup>105</sup>46 FR 13193 (February 19, 1981)

of proposed rule making.<sup>106</sup> The BATF concluded that the ingredient labeling regulations did not meet the criteria of this order, and that the regulations were not truly necessary, cost effective, beneficial, or in keeping with United States international commitments.<sup>107</sup>

Based on these conclusions, the Department issued another notice of proposed rulemaking, but this time proposing the rescission of the ingredient labeling regulations.<sup>108</sup> The closing date for submission of comments was to have been July 6, 1981 and was then extended to August 5, 1981, with a total of 8,068 comments containing 23,352 individual signatures being submitted. Of all comments received, 4,909 comments representing 17,138 individuals supported the proposal to rescind the ingredient labeling regulations. Of these commenters, 693 were American alcoholic beverage industry members or related industries, 144 foreign producers/exporters, six (6) foreign governments, 33 Federal and State officials and organizations, and 4,033 consumers.

Commenters stated the following reasons in support of the proposal to rescind the ingredient labeling regulations: (1) They were unnecessary in that labels currently contained sufficient information without listing the ingredients; (2) The regulations were inflationary in that the increased costs would be passed through the marketing channels to the consumer; (3) The regulations placed American industries at a trade disadvantage compared to other countries; (4) The regulations were not consistent with Executive Order 12291; (5) The commenters supported the President's mandate of less Government regulations, and further stated that the proposal was consistent with this mandate; (6) The health hazard issue was nonexistent.<sup>109</sup>

The BATF received 3,159 comments, representing 6,214 individuals, opposing the rescission of the ingredient labeling regulations. These comments expressed the opinion that it was the consumers' right to know what was contained in alcoholic beverages and the industry should be required to disclose the ingredients contained

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<sup>106</sup>44 FR 6740 (February 2, 1979).

<sup>107</sup>46 Fed. Reg. 24962, *Supra*, note 103.

<sup>108</sup>*Id.*

<sup>109</sup>46 Fed Reg 55094 (November 6, 1981).

in their products.<sup>110</sup> Nevertheless, BATF concluded that the ingredient labeling regulations would result in increased costs to consumers and burdens on industry, which were not commensurate with the benefits that may flow from the additional label information. The BATF further concluded that ingredient labeling would not result in an appreciable benefit to consumers when compared to the existing label information requirements and standards of identity. Because the FAA Act did not require ingredient labeling of alcoholic beverages and vested discretionary authority in the Secretary to prescribe regulations which would provide adequate information as to the identity and quality of the products, the BATF did not think the regulations were necessary.

In the final rule on November 6, 1981, in T.D. ATF-94, the BATF rescinded the ingredient labeling provisions of announced in 1980.<sup>111</sup> The rule explained that the statutory and regulatory provisions that were presently exercised by the BATF were sufficient to protect the consumer and ensure product integrity through the establishment of standards of identity. Under FAA Act regulations, a standard of identity generally identified the basic agricultural ingredient, and further, set forth parameters of production and alcoholic content. Standards of identity for wine and distilled spirits were available to the public and any product not having a standard of identity, had to bear a statement of composition on the label.

Finally the rule explained that all substances used in the production of alcoholic beverages were required to be approved by the FDA, however the rule did not disclose the fact that FDA's approval of certain substances was explicitly conditioned upon disclosure.<sup>112</sup> The FDA and BATF also established specifications and limitations for these substances. Although the BATF included FDA approval in its federal register explanation, the FDA did not directly comment on the first rescission. Moreover, the FDA's position as early as 1978 was a matter of public record, which was that the FDA supported ingredient labeling.

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<sup>110</sup>*Id.*

<sup>111</sup>*Id.*

<sup>112</sup>For instance, the FDA only allowed the additive FD & C Yellow No. 5 be used in a food if the food manufacturers disclosed the existence of the additive on the label (44 Fed.Reg. 37212 (1979)) but the BATF did not require that notice of the additive in a product be disclosed on the alcoholic beverage container's label.

## B.

### Center for Science in the Public Interest Court Decisions

Following the 1981 rescission of the alcoholic beverage ingredient disclosure regulations, the Center for Science in the Public Interest (hereinafter CSPI), a consumer health organization, and two individual consumers brought suit complaining of the rescission under the FAA Act and the Administrative Procedure Act against the Department of the Treasury in Center for Science in the Public Interest v. Department of the Treasury,<sup>113</sup> on February 8, 1983 (hereinafter CSPI I).

The District Court held that the Treasury Department's rule rescinding alcoholic beverage ingredient disclosure regulation was invalid for failure to comply with the Administrative Procedure Act.<sup>114</sup> The district court ruled that the agency had not provided an adequate explanation for its decision rescinding the 1980 regulations, and had given undue weight to cost concerns. The court required Treasury within thirty days thereof to set a new date, not later than one year for ingredient disclosure from the date of the order, for the 1980 ingredient disclosure regulation to become effective. The BATF complied with the court's order in announcing that the 1980 ingredient disclosure regulation would become effective on February 8, 1984, subject to possible judicial or administrative intervention.<sup>115</sup>

Thereafter, the BATF chose to reexamine the ingredient disclosure issue and renew the rulemaking process in light of the criticisms of the district court. On June 17, 1983, the Department issued a notice of proposed rule making proposing to reconsider prior decisions concerning ingredient disclosure on labels of alcohol beverages.<sup>116</sup> Comments were solicited on all phases of the proposed regulation, and particularly on the use of FD & C Yellow Dye No. 5, and on the lead time for implementing a new regulation if the BATF decided

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<sup>113</sup>Center for Science in the Public Interest v. Department of the Treasury, *Supra*, note 101.

<sup>114</sup>5 U.S.C. §§ 551-706 (1976 & Supp. V 1981).

<sup>115</sup>48 Fed. Reg. 10309 (March 11, 1983)

<sup>116</sup>48 FR 27782, (June 17, 1983).

to issue one. The FDA did comment during this rulemaking proceeding, by filing a comment in favor of ingredient labeling in a letter written by Joseph P. Hile, the Associate Commissioner of Regulatory Affairs, FDA to BATF on July 20, 1983.<sup>117</sup>

After considering all comments the BATF on October 6, 1983, promulgated a new rule, T.D. ATF-150.<sup>118</sup> The new rule rescinded the 1980 ingredient disclosure regulations, but required the labeling of FD & C Yellow Dye No. 5 by October 6, 1984, stating that the FDA had previously commented that it had determined that there was enough reason for concern about possible adverse reaction to FD&C Yellow No. 5 to require its specific identification on the labels of all foods in which it was used.<sup>119</sup> The BATF found that no other ingredient posed a special health problem, or that justified a label requirement, but stated that the agency would consider on a case-by-case basis any ingredient alleged to cause a potential problem.

The BATF explained that the entire issue on ingredient labeling for alcohol beverages centered on the labeling authority in the FAA Act for the Secretary to require adequate information as to the identity and quality of the products. With respect to the health issues, the BATF noted that no ingredients used in alcohol beverages were unsafe generally or, other than alcohol itself, posed any general health hazard and that producers could only use ingredients which were approved by the FDA. The BATF pointed out that uncertainties existed as to how many people were affected by allergic reactions to alcohol beverages and concluded that there was neither evidence of a substantial consumer interest in the information, nor clear evidence that the information would provide substantially useful information to consumers generally. For the above reasons, the BATF reasoned that alcoholic beverages did not have to disclose ingredient lists on the bottle in order to be adequately labeled.<sup>120</sup>

Meanwhile, the part of the district court's decision which ordered the BATF to fix the date for the effec-

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<sup>117</sup>Center for Science in the Public Interest v. Department of Treasury, 797 F.2d 995, 55 USLW 2122, 254 U.S.App D.C. 328 (D.D.Cir. Aug 05, 1986)

<sup>118</sup>48 Fed. Reg. 45549, (October 6, 1983).

<sup>119</sup>21 CFR 74.705. FDA's rule established specific label disclosure of FD&C Yellow No. 5.

<sup>120</sup>48 Fed. Reg. 45549, *Supra*, note 118.



tiveness of the comprehensive labeling requirement as not later than February 8, 1984, was appealed by BATF on August 31, 1983. BATF contended that the court order amounted to a usurpation of BATF's statutory authority. This was the only issue raised on appeal by the BATF and they took no appeal from the remainder of the court decision, *i.e.*, that the BATF's rescission of the regulation had been inadequately explained and had given undue weight to costs. However, the Wine Institute and Distilled Spirits Council of the United States appealed this remainder of the decision.

However, three weeks before the appeal could be heard, BATF proposed and finalized ATF- 150, a new rulemaking which rescinded the ingredient labeling requirements on alcoholic beverages of the 1980 regulation.<sup>121</sup> The plaintiffs from the original action again brought suit in front of the same judge from the original action, complaining of the new recession.<sup>122</sup> Therefore, the court of appeals accordingly dismissed BATF's appeal of the mandatory effective date from the first action as moot.<sup>123</sup> The court of appeals also dismissed the appeals of two intervenors, which were directed at overturning the district court's decision on the merits, and refused to vacate the remainder of the District Court's decision.<sup>124</sup>

Again CSPI brought suit, challenging the validity of T.D. ATF-150 and contending primarily that the BATF's rescission violated the FAA Act,<sup>125</sup> that it was arbitrary and capricious and an abuse of discretion in violation of the Administrative Procedure Act.<sup>126</sup> The District Judge found that a substantial number of the same issues of law and fact were implicated and as a result of the CSPI I ruling gave them preclusive effect. These issues included: (1) One of the purposes of § 205(e) of the FAA Act was meant to give consumers information to allow them to make decisions that might affect their health, albeit the fact that it is only a consumer's statute in the narrow sense; (2) While costs would always be an important consideration,

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<sup>121</sup>48 Fed.Reg. 27782 (proposed rule), *Supra*, note 116; 48 Fed.Reg. 45549 (final rule), *Supra*, note 118.

<sup>122</sup>Center for Science in the Public Interest v. Department of Treasury, 1985 WL 9649 (D.D.C. Oct 30, 1985) (NO. CIV.A. 84-2079)

<sup>123</sup>Center for Science in the Public Interest v. Regan, 727 F.2d 1161, 234 U.S.App.D.C. 62 D.C.Cir.Feb 07, 1984

<sup>124</sup>*Id.*, at 1165-66.

<sup>125</sup>27 U.S.C. § 205(e), *Supra*, note 45.

<sup>126</sup>5 U.S.C. § 706(2)(a).

rescission of the Ingredient Disclosure Rule of 1980 could not be based primarily on costs to the industry; (3) Alcoholic beverage ingredients could cause adverse health effects in sensitive individuals; (4) BATF improperly relied on FDA approval of ingredients as a reason for rescinding the Ingredient Disclosure Rule of 1980; (5) BATF improperly relied on their standards of identity for alcoholic beverages<sup>127</sup> as a basis for rescinding the Ingredient Disclosure Rule of 1980 because standards of identity did not provide consumers with adequate information about ingredients.<sup>128</sup>

The District Court noted that, although going into somewhat greater detail, the reasons advanced in support of T.D. ATF-150 were basically the same as those underlying the original recessionary rule. These reasons included that the costs were disproportionately high when compared with the benefits to be derived and consumers were adequately protected under the existing regulations. The Court concluded that T.D. ATF-150 represented a predetermined 'mindset' to reinstate a previous position which was held unlawful and that the BATF again violated the FAA Act and had taken action which was arbitrary, capricious, and an abuse of discretion in violation of the Administrative Procedure Act.<sup>129</sup>

On appeal however, the Court of Appeals noted that although BATF's efforts to explain its turnabout had "hardly been exemplary," it did meet the standard of reasoned decision making and therefore that enough of BATF's reasoning withstood scrutiny.<sup>130</sup> The district court was without power to preclude agency reconsideration and initiation of further rule making to correct deficiencies. BATF's rescission of the 1980

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<sup>127</sup>Standards of identity according to the BATF, "generally identif[ied] the basic agricultural ingredients and further, [set forth parameters of production of alcoholic content." In 46 Fed. Reg. 55094 (November 6, 1981). The standards of identity for wine and distilled spirits are codified at 27 C.F.R. §§ 4.21 and 5.22 respectively and they do not exist for beer or other malt beverages.

<sup>128</sup>Center for Science in the Public Interest v. Department of Treasury, 1985 WL 9649 (D.D.C. Oct 30, 1985) (NO. CIV.A. 84-2079), *Supra*, note 122 at 3.

<sup>129</sup>*Id.*

<sup>130</sup>Center for Science in the Public Interest v. Department of Treasury, 797 F.2d 995, 55 USLW 2122, 254 U.S.App D.C. 328 (D.D.Cir. Aug 05, 1986), *Supra*, note 123.

ingredient disclosure regulation was affirmed and the decision of the District Court accordingly reversed on August 5, 1986.<sup>131</sup> Therefore, the BATF was not required to reinstate the regulation and the challenges to BATF's decision to not require ingredient labeling on alcoholic beverages was finally put to an end after eleven years of disputes.<sup>132</sup>

#### IV.

#### **The Current Scope of Alcoholic Beverages Regulations by the FDA and the BATF**

The BATF is now the sole agency responsible to issuing regulations governing the labeling of wine, distilled spirits, and malt beer in accordance with 27 CFR 4, 5, and 7 respectively. Pursuant to section 5 of the FAA Act, BATF is vested with the authority to promulgate regulations to make sure that they provide the consumer with adequate information concerning the identity and quality of such products.<sup>133</sup>

Although the FDA will be indefinitely barred from imposing labeling requirements on the alcoholic beverage industry, the FDA still holds exclusive responsibility for labeling on wine and cider with less than 7 percent alcohol by volume. Also, the FDA can still espouse or lobby their labeling cause, so as to eventually bring about direct or indirect action by BATF, as it has done with warning labels requirements. Moreover, the FDA works concurrently with the BATF with respect to disclosure of certain substances when determined by the FDA to pose a recognized health risk. The BATF has utilized the scientific and public health expertise of the FDA in approving ingredients in alcoholic beverages and in identifying adulterated alcoholic beverages which are deemed to be mislabeled.<sup>134</sup>

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<sup>131</sup> *Id.*

<sup>132</sup> Beginning with the BATF's rejection of ingredient labeling on November 11, 1975. 40 Fed. Reg. 52613 (November 11, 1975) through to the Appeals Court's decision in this matter on August 5, 1986.

<sup>133</sup> 27 U.S.C. § 205(e), *Supra*, note 45.

<sup>134</sup> Industry Circular Number 93-8, Health Claims in the Labeling and Advertising of Alcoholic Beverages, August 2, 1993

A.

### **Diluted Wines and Ciders with less than 7% Alcohol by Volume**

Although the BATF regulates all beer products regardless of their alcohol contents,<sup>135</sup> it only regulates wine products that contain percent alcohol by volume or more. Wine is defined in the FAA Act, containing not less than 7 and not more than 24 percent alcohol by volume, and thus BATF labeling regulations apply only to wines containing alcohol within the specified range.<sup>136</sup> Only those alcoholic beverages subject to or complying with the packaging or labeling requirements imposed by the FAA Act are exempt from the requirements of the Fair Packaging and Labeling Act.<sup>137</sup> Therefore, although the court in Brown- Forman<sup>138</sup> held that BATF has exclusive jurisdiction over the labeling of alcoholic beverages, the FDA still holds exclusive responsibility for labeling on wine and cider with less than 7% alcohol by volume. The FDA Compliance Policy Guides, Guide 7101.05 FDA explains that because wine is considered having more than 7% or more alcohol by volume in the FAA Act, wines and ciders with less than 7% alcohol by volume are subject to the packaging and labeling requirements of both the FD&C Act and Sec. 10 (a)(4) of the Fair Packaging and Labeling Act.

The FDA also issued a Compliance Policy Guide (CPG) 7101.04 for dealcoholized wine labeling. Dealcoholized wines are prepared by removing alcohol from them and are also subject to the labeling provisions of the FD&C Act. CPG 7101.04 also provided guidance on acceptable statements of identity and certain optional label statements for dealcoholized wine. While this policy did not constitute legal requirements, FDA will use it as guidance when considering whether to recommend legal action against these products.<sup>139</sup>

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<sup>135</sup>51 Fed. Reg. 39666 (October 30, 1986). The term malt beverage is defined in the FAA Act as a beverage made by alcoholic fermentation of specific materials in 27 U.S.C. 211(a)(7). Malt beverages are not characterized by specific alcohol content. All malt beverages meeting the definition of the FAA Act are within the purview of the BATF statute, regardless of alcohol content.

<sup>136</sup>27 U.S.C. 211(a)(6)

<sup>137</sup>Fair Packaging and Labeling Act, § 10 (a)(4)

<sup>138</sup>*Brown-Forman Case, Supra*, note 32.

<sup>139</sup>54 FR 38559-01 (September 19, 1989)

Attempts to amend the FAA Act to extend BATF jurisdiction to wine products containing as little as .5% alcohol have been unsuccessful.<sup>140</sup>

## B.

### Warning Label Requirements

In order to address the problem of fetal alcohol syndrome, the FDA Commissioner wrote to the BATF Director on November 15, 1977 requesting that the BATF “initiate immediately whatever procedures are necessary to require the placement on the labeling of alcoholic beverages of a warning against consumption of excessive amounts of alcohol by pregnant women. . . I hope that BATF, which now has exclusive responsibility for such labeling, will move promptly to address this serious health risk.”<sup>141</sup> On January 13, 1978, in response to this request, BATF requested comments on this proposal, by issuing an advanced notice of proposed rule making in the Federal Register.<sup>142</sup> However, over one year later, the BATF issued a progress report on January 25, 1978, which rejected warning labels for a public awareness campaign to alert consumers of the possible dangers.<sup>143</sup> In 1979, the Senate passed a bill requiring warning labels on all alcoholic beverages,<sup>144</sup> but the House of Representatives failed to pass this bill. In 1986, a similar bill introduced into Congress

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<sup>140</sup>Hutt, Merrill, Food and Drug Law, Cases and Materials, *Supra*, note 63 at 35.

<sup>141</sup>Affidavit of Sam D. Chilcote, Jr., sworn to March 19, 1979 in *Brown-Forman Distiller Corp. v. Califano*, *Supra*, note 90 at ¶ 22.

<sup>142</sup>43 Fed. Reg. 2186 (January 13, 1978).

<sup>143</sup>44 Fed. Reg. 8288 (January 25, 1978).

<sup>144</sup>Senator Thurmond’s bill, S. 1642 purported to give the FDA the power to require hazard labeling on alcoholic beverages.

failed to pass.<sup>145</sup>

This initial request by the FDA was finally executed when Title VIII of the Anti-Drug Abuse Act of 1988,<sup>146</sup> amended the FAA Act by designating the existing sections of the FAA Act as Title I, and by adding at the end a new title, Title II– Alcoholic Beverage Labeling. This title, cited as the Alcoholic Beverage Labeling Act of 1988 required that a specific health warning statement appear on the labels of all containers of alcoholic beverages and authorized the Secretary of the Treasury to implement them and enforce them. The original bill began with both the United States House and the Senate having bills which would have required five separate warning labels to be rotated regularly on the containers of each brand of alcoholic beverage made by a manufacturer.<sup>147</sup> Under the proposed House bill,<sup>148</sup> the FDA would have had the power to enforce these requirements and issue necessary regulations. However, the proposed Senate bill,<sup>149</sup> which was the bill which ultimately became the Anti-Drug Abuse Act of 1988<sup>150</sup> gave the BATF the power to enforce these requirements.

Accordingly, as part of its statutory mandate, on February 14, 1990 the BATF issued a final rule.<sup>151</sup> The regulations require that the following health warning statement appear on the labels of all containers of alcoholic beverages sold or distributed in the United States:

GOVERNMENT WARNING: (1) ACCORDING TO THE SURGEON GENERAL, WOMEN SHOULD NOT DRINK ALCOHOLIC BEVERAGES DURING PREGNANCY BECAUSE OF THE RISK OF BIRTH DEFECTS. (2) CONSUMPTION OF ALCOHOLIC BEVERAGES IMPAIRS OUR ABILITY TO DRIVE A CAR OR OPERATE HEAVY MACHINERY, AND MAY CAUSE HEALTH PROBLEMS.

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<sup>145</sup>Kruger, Mitigating Alcohol Health Hazards Through Warning Labels and Public Education, 63 Wash L. Rev. 979, 979 (1988).

<sup>146</sup>102 Stat. 4181 (1988), 27 U.S.C. § 213 *et seq.*

<sup>147</sup>S. 2047, 100th Cong., 2d Sess., 134 CONG. REC. S663, S663 (daily ed. Feb. 4, 1988).

<sup>148</sup>H.R. 4441, 100th Cong., 2d Sess., 134 CONG. REC. H2472-06 (daily ed. Apr. 21, 1988).

<sup>149</sup>*Id.*

<sup>150</sup>Kruger, *Supra*, note 145 at 982.

<sup>151</sup>55 Fed Reg. 5414 (February 14, 1990).

For purposes of title II, the term alcoholic beverage included any beverage which contained no less than one-half of one percent (.5%) of alcohol by volume. Thus, the term included not only distilled spirits products, malt beverages, wines, but wine coolers as well. The rule's stated purpose was to promote the public health and safety and it became effective and mandatory on November 14, 1990.

C.

### **Adulterated Provision of FD&C Act**

Pursuant to FD&C Act, the FDA has authority to take action with respect to adulterated food products, including both domestic and imported alcoholic beverages, to help assure that only safe ingredients are used in the products.<sup>152</sup> 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 additive.<sup>153</sup> The 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 the FDA to refuse entry of imported products that appear to be adulterated.

A Memorandum of Understanding between the FDA and BATF was published in the federal register on November 30, 1987 (hereinafter the MOU of 1987).<sup>154</sup> The stated purpose of the MOU was to clarify and to delineate the enforcement responsibilities of each agency with respect to alcoholic beverages considered adulterated under the FD&C Act and to confirm BATF's policy with respect to the labeling of ingredients and substances in alcoholic beverages that pose a public health problem. The agreement between the BATF and the FDA is still in effect and states, among other things, that: (1) BATF will be responsible for the promulgation and enforcement of regulations with respect to the labeling of distilled spirits, wine, and malt

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<sup>152</sup>21 U.S.C. 301, § 402

<sup>153</sup>*Id.*

<sup>154</sup>52 Fed Reg. 45502 (November 30, 1987)

beverages pursuant to the FAA Act. If the FDA has determines 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, BATF will initiate rulemaking proceedings to promulgate labeling regulations for alcoholic beverages consistent with BATF's health policy with respect to alcoholic beverages; (2) FDA will, upon BATF's request, provide BATF with a health hazard evaluation with respect to any substance found in alcoholic beverages. BATF agreed to provide FDA with any data or analyses it may have with respect to the substance in question; (3) BATF will prepare, in consultation with FDA, comprehensive formal procedures and guidelines for implementing voluntary recalls of adulterated alcoholic beverages which will be developed in light of the FDA procedures and guidelines for such recalls and must be implemented by BATF after review and comment by FDA; (4) The BATF 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; (5) When the FDA learns or is advised that an alcoholic beverage is or may be adulterated, it will contact BATF; (6) When the BATF learns or is advised that an alcoholic beverage is or may be adulterated, it 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 BATF with a written health hazard evaluation of each product involved in a recall situation or potential recall situation. The BATF will provide the 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, BATF will advise the responsible firm as to an appropriate course of action which might include a voluntary recall; (7) In situations involving a recall of an adulterated alcoholic beverage that pose a significant risk to the public health, BATF will consult with FDA before issuing any press release. (8) FDA and BATF will continue to exchange a wide variety of



information, including relevant consumer complaints concerning the adulteration of alcoholic beverages.<sup>155</sup> The MOU of 1987 confirms that the labeling and quality of alcoholic beverages are regulated by the BATF, which will in turn be responsible for the promulgation and enforcement of regulations with respect to the labeling of alcoholic beverages pursuant to the FAA Act. The FDA presently recognizes this directly on the FDA website as well.<sup>156</sup> Since the promulgation of the MOU of 1987, the BATF has issued some regulations requiring labeling disclosure of certain ingredients in alcoholic beverages.

#### D.

##### Case by Case Mandatory Ingredient Labeling Disclosure

The first mandatory ingredient disclosure came in T.D. ATF-150, which required the specific disclosure of FD&C Yellow No. 5 on the label of all alcohol beverages.<sup>157</sup> The BATF referred to the fact that the FDA had established specific label disclosure of FD&C Yellow No. 5 on the labels of all foods in which it is used due to the concern about possible adverse reaction to it.<sup>158</sup> The rule explained that there was an identifiable benefit, which outweighed the cost or burden that the specific ingredient labeling requirement may cause. Specifically, a sufficient number of consumers had serious allergic reactions to FD&C Yellow No. 5 who would then be able to find out from the label that the ingredient was used in the alcohol beverage.. However, the BATF made sure to point out that the benefit did not outweigh the cost with respect to general ingredient labeling which would require changes to every label of every alcohol beverage regardless of the value of the information.<sup>159</sup>

Pursuant to T.D. ATF-150, the BATF specifically stated it would “look at the necessity of mandatory

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<sup>155</sup> *Id.*

<sup>156</sup> <http://www.fda.gov/comments/noregs.html> What the FDA does not Regulate.

<sup>157</sup> 48 Fed Reg 45549 *Supra*, note 118.

<sup>158</sup> 21 CFR 74.705.

<sup>159</sup> 48 Fed Reg. 45549, *Supra*, note 118.

labeling of other ingredients on a case-by-case basis through its own rulemaking initiative, or on the basis of petitions for rulemaking under 5 U.S.C. § 553(e) and 27 CFR 71.41(c). The BATF also determined that there was no clear evidence in the record, at that time, that any other ingredient being used in the production of alcohol beverages posed a recognized health problem.

In the years following T.D. ATF-150, the BATF had published a final rule in the Federal Register requiring mandatory label disclosure of saccharin for alcoholic beverages containing the artificial sweetener in December 1985 in T.D. ATF 219.<sup>160</sup> The final rule required the following statement on labels of alcohol beverages which used the artificial sweetener saccharin: Use of this product may be hazardous to your health. This product contains saccharin which has been determined to cause cancer in laboratory animals.<sup>161</sup>

The BATF noted that although the FDA regulations did not preclude the use of saccharin in the production of alcohol beverages,<sup>162</sup> the Saccharin Study and Labeling Act<sup>163</sup> mandated that if saccharin was present in a food, then the above warning had to also appear on the label of that product so that all consumers would be informed about the potential health risks associated with its use. Therefore in recognition of this congressional mandate and pursuant to section 5(e)(2) of the FAA Act, which relates to providing the consumer with adequate information, the BATF determined that any alcohol beverage product which contained saccharin (including sodium saccharin, calcium saccharin and ammonium saccharin) must bear on its label a health warning statement identical to that set forth in the Saccharin Study and Labeling Act.

The BATF also published a final rule, on September 30, 1986 in T.D. ATF-236, requiring label disclosure of sulfites when present in alcoholic beverages at a level of ten or more parts per million based on health concerns.<sup>164</sup> The BATF elaborated that it would defer to the FDA's judgment when determining if a specific

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<sup>160</sup>T.D. ATF-220; 50 Fed. Reg. 51851 (December 20, 1985).

<sup>161</sup>*Id.*

<sup>162</sup>21 CFR 180.37 (21 U.S.C. 348, 371),

<sup>163</sup>21 U.S.C. §403(o), *Supra*, note 38. This requirement was repealed by the FDA in January 2001 and no longer requires food products containing saccharin to bear the warning statement. 2000 Amendments. Subsec. (o). Pub.L. 106-554, § 1(a)(1) [Title V, § 517] Dec. 21, 2000, 114 Stat. 2763, 2763A-73, struck out subsection (o), which related to saccharin for immediate consumption.

<sup>164</sup>T.D. ATF-236; 51 Fed. Reg. 34706 (September 30, 1986).

ingredient posed a recognized health warning, thereby requiring it to be disclosed on the label.<sup>165</sup> The final rule explained that:

The Commissioner of Food and Drugs has determined that undeclared sulfites pose a risk to public health. In the Federal Register of July 9, 1986, the Department of Health and Human Services and the U.S. Food and Drug Administration published a final rule establishing 10 parts per million as the threshold for declaration of sulfites in the labeling of foods, nonalcoholic beverages, and wine products containing less than seven percent of alcohol by volume.<sup>166</sup>

The BATF explained that since the FDA had determined that the presence of undeclared sulfites in foods and beverages posed a recognized health problem, then the declaration of sulfites in the labeling of alcoholic beverages would be necessary in order to inform sulfite-sensitive individuals of the presence of sulfites in alcoholic beverages. In the final rule, the BATF also gave much weight to a comment sent to the BATF during the Advance Notice of Proposed Rule Making from Sanford A. Miller, Ph.D., Director, Center for Food Safety and Applied Nutrition:

FDA is in agreement with Notice No. 566 and supports the proposed rulemaking. As we have stated on previous occasions, FDA believes that individuals who are hypersensitive or simply wish to avoid or favor certain food ingredients should receive adequate notice of the presence of these ingredients in food. We believe that your Notice No. 566 accomplishes that for sulfiting agents.

Then in 1984, as a result of the FDA's experience with allergic reactions to FD&C Yellow No. 6, aspartame, and sulfites, the FDA established an ad hoc advisory committee to review hypersensitivity to sulfites and later, to all foods constituents.<sup>167</sup> When the FDA published a final rule in the Federal Register on November 19, 1986<sup>168</sup> requiring mandatory disclosure of FD&C Yellow No. 6 on labels of food products because of evidence of possible allergic-type reactions to the color additive, the BATF subsequently proposed specific

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<sup>165</sup>49 Fed. Reg. 37510, (September 24, 1984). In the preamble of T.D. ATF-182 BATF stated that, "if at some future date the U.S. Food and Drug Administration were to determine that the sulfiting of foods and beverages presents a risk to public health and requires labeling disclosure, ATF would promptly propose the disclosure in labeling of sulfur dioxide and sulfiting agents."

<sup>167</sup>49 Fed. Reg. 15021 (April 16, 1984).

<sup>168</sup>51 Fed. Reg. 41765 (November 19, 1986).

label disclosure for this product as well. The FDA believed that a label declaration would inform the public of the presence of color additives in food or drugs and would enable individuals who may be allergic to FD&C Yellow No. 6 to minimize their exposure to that ingredient. Although the BATF's proposed rule noted the official recognition of evidence linking the presence of FD&C Yellow No. 6 in food and beverages to allergic-type responses in a small percentage of consumers,<sup>169</sup> the BATF never pursued the mandatory disclosure requirements and FD&C Yellow No.6 does not presently have a disclosure requirement. In a semiannual regulatory agenda in 1992, the BATF announced the withdrawal of the proposed rule, citing further study is required.<sup>170</sup>

In August of 1993, the BATF issued a final rule requiring a disclosure statement for aspartame on malt beverage labels, when the product contained aspartame in accordance with regulations issued by the FDA.<sup>171</sup> The rule explained that the FDA had approved the use of the additive aspartame in certain food products and in 1992, FDA issued a final rule to allow for the addition of aspartame in malt beverages of less than 7 percent alcohol by volume and containing fruit juice.<sup>172</sup> The evidence considered by the FDA showed a need to alert certain individuals with specific medical conditions to the presence of phenylalanine in products containing aspartame.

## V.

### **Conclusion: The Future of Ingredient Labeling on Alcoholic Beverages**

When the FD&C Act was amended by the Nutritional Labeling and Education Act, thereby requiring addi-

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<sup>169</sup>52 Fed. Reg. 33603 (September 4, 1987).

<sup>170</sup>57 Fed. Reg. 17169-01 (April 27, 1992).

<sup>171</sup>58 Fed. Reg. 44131 (August 19, 1993).

<sup>172</sup>57 Fed. Reg. 3701 (January 30, 1992).

tional nutritional labeling for food products, the labeling requirements for alcoholic beverages were exempted from it.<sup>173</sup> Attempts to amend the FD&C Act and extend the jurisdiction of alcoholic beverages labeling to the FDA have included two bills introduced in 1993 and then reintroduced in 1996 to the House by Congresswoman Schroeder in The Alcohol Ingredient Labeling Act of 1993<sup>174</sup> and The Alcohol Ingredient Labeling Act of 1996, respectively.<sup>175</sup> The legislations proposed to amend section 403 of the FD&C Act to deem a malt beverage, wine, or distilled spirit mislabeled unless it had a label disclosing: (1) the alcoholic content; (2) the number of drinks (defining drink as 6 ounces of alcohol); (3) its ingredients and calories; (4) the common name of each ingredient, including additives; and (5) a toll-free number for help with a drinking problem.<sup>176</sup>

The bill was introduced on March 18, 1993 and was immediately referred to the House Energy and Commerce Committee. In the 103<sup>rd</sup> Congress, this legislation received the support of groups ranging from the Academy of Pediatrics, to the General Conference of Seventh-Day Adventists, to the National Parent Teacher Association, to the Latino Council on Alcohol and Tobacco.<sup>177</sup> The bill eventually had 20 cosponsors, but the last action taken with respect to the bill was on October 5, 1994 with the deletion of a cosponsor's name. The 1996 proposal was introduced on March 19, 1996 and it was referred to the House Commerce Committee. The last major action taken with respect to the bill was on March 29, 1996 when it was referred to the subcommittee of the House on Health and Environment.<sup>178</sup> Unfortunately Congresswoman Schroeder left Congress in 1996 and no other initiatives have been taken with respect to ingredient labeling on alcoholic beverages.

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<sup>173</sup>Pub. L. No. 101-535 (1990)

<sup>174</sup>1993 Cong US HR 1420 103<sup>rd</sup> Congress, 1<sup>st</sup> Session

<sup>175</sup>1996 Cong US HR 3115 104<sup>th</sup> Congress, 2d Session

<sup>176</sup>*Extension of Remarks in the House of Representatives*, 142 Cong. Rec. E378-04, Statement of Patricia Schroeder, 104<sup>th</sup> Congress, 2<sup>nd</sup> Session (March 19, 1996)

<sup>177</sup>*Id.*

<sup>178</sup>1999 Congressional Record S. 431 106th Congress, First Session

In February of 1999, Senator Thurmond introduced a bill called the Alcoholic Beverage Labeling Act of 1999, to amend the Alcohol Beverage Labeling Act of 1988 to transfer authority over alcoholic beverage labeling from the Department of Treasury to the Department of Health and Human Services and through it to the FDA.<sup>179</sup> The pending bill recognized that the FDA had more experience in labeling requirements.<sup>180</sup> In the Senator's proceeding he asserted that the Treasury and BATF:

[H]ad proved themselves incapable of managing the responsibility of alcohol labeling when they decided to favor the aggressive lobbying tactics of the wine industry over the public health concerns of such groups as the Center for Science in the Public Interest, the American Medical Association, the American Cancer Society, and the American Heart Association. The issues of public health and labeling require a level of experience and expertise that Treasury and BATF apparently do not possess.<sup>181</sup>

Unfortunately on the same day that the bill was introduced, it was referred to the Committee on Commerce, Science, and Transportation, which was the last action taken with respect to it.

In accordance with the Brown-Forman decision, the Congressional mandates thus far, and the MOU of 1987, one viable approach towards getting ingredient disclosure and one day heading towards nutritional requirements on the labels of alcoholic beverages would be through a rule passed by the BATF. The BATF had issued an advanced notice of proposed rule making in 1993 to consider amending their regulations and requiring nutrition labeling for alcoholic beverages.<sup>182</sup> They received many comments from the alcohol industry opposing the concept based on high cost and consumer disinterest.<sup>183</sup> However, after extending the comment deadline twice, the BATF, without explanation announced in its semiannual regulatory agenda that its advance notice of proposed rulemaking on nutrition labeling for alcoholic beverages had been withdrawn in 1995.<sup>184</sup> The BATF has not passed any rules or advanced notices of proposed rule making requiring

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<sup>179</sup> *Id.*

<sup>180</sup> *Id.*

<sup>182</sup> 58 Fed. Reg. 42517 (August 10, 1993).

<sup>183</sup> Food Labeling News, *Industry and Consumers Clash on Alcohol Nutrition Labeling*, Vol. 2, No. 20, February 17, 1994.

<sup>184</sup> 60 Fed. Reg. 23766-02 (May 8 1995).

ingredient or nutritional labeling for alcoholic beverages since then.

While the ruling in Brown-Forman precluded further FDA direct involvement in the labeling of alcoholic beverages, the adulteration and food safety provisions of section 402(a) of the FD&C Act still do apply to alcoholic beverages. This will remain the state of the law but for intervention by Congress, the President or the judiciary.<sup>185</sup> Congress could take action drafting a statute that affords FDA with jurisdiction over labeling on alcoholic beverages, or by a direct Congressional mandate amending the FD&C Act or the FAA Act to require alcoholic beverages labeling. In the alternative, the President may issue an executive reorganization plan which could include the transfer of an “agency functions... to the jurisdiction and control of another agency”,<sup>186</sup> thereby transferring labeling jurisdiction to the FDA, who may be in a better situation to protect the consuming public than is the BATF. Most likely the catalyst for change will come from consumer groups, such as CSPI or the American Diabetes Association who will use their access to Congress, the FDA, and the BATF to propose bills to vastly expand the FDA’s jurisdiction over the labeling of alcoholic beverages.<sup>187</sup> Regardless of who instigates reform, FDA jurisdiction over the ingredient and nutritional labeling will greatly benefit consumers by giving them the information they need to make responsible choices about their consumption of alcoholic beverages.

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<sup>185</sup>If the President issues a favorable executive reorganization plan, he would propose the plan to Congress, and it would become effective unless during a sixty day grace period either House resolves against the plan, in accordance with 5 U.S.C. Sec. 906(a), in Cooper, *Supra*, note 62 at 387.

<sup>186</sup>5 U.S.C. § 903 (a)(1)

<sup>187</sup>Hancock, *Supra*, note 23 at 285