

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is given that no objections or requests for a hearing were filed in response to the July 6, 2000, final rule. Accordingly, the amendments issued thereby became effective August 8, 2000.

Dated: September 29, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00-25703 Filed 10-5-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 601

[Docket No. 97N-0165]

Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations to reincorporate a regulation that was inadvertently omitted. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective October 6, 2000.

FOR FURTHER INFORMATION CONTACT:

Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION: FDA has discovered that an error has caused an omission in the agency's codified regulations for part 601 (21 CFR part 601). In the **Federal Register** of May 17, 1999 (64 FR 26657), FDA published a final rule that inadvertently omitted § 601.37 when subpart D was revised. Accordingly, § 601.37, which was added in the **Federal Register** of December 2, 1998 (63 FR 66672), is being reincorporated into the regulations and redesignated as § 601.28. In addition,

FDA is removing subpart B and reorganizing subpart C in part 601. Accordingly, current § 601.28 is redesignated as § 601.15. This document corrects those errors. Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment is nonsubstantive.

List of Subjects in 21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 601 is amended as follows:

PART 601—LICENSING

1. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: 15 U.S.C. 1451-1561; 21 U.S.C. 321, 351, 352, 353, 355, 360, 360c-360f, 360h-360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263; sec. 122, Pub. L. 105-115, 111 Stat. 2322 (21 U.S.C. 355 note).

§ 601.12 [Redesignated to subpart C]

2. Section 601.12 *Changes to an approved application* is redesignated from subpart B to subpart C.

Subpart B [Removed and Reserved]

3. Subpart B is removed and reserved.

Subpart C—Biologics Licensing

4. The heading for subpart C is revised to read as set forth above.

§ 601.28 [Redesignated as § 601.15]

5. Section 601.28 is redesignated as § 601.15 in subpart C, and a new § 601.28 is added to subpart C to read as follows:

§ 601.28 Annual reports of postmarketing pediatric studies.

Sponsors of licensed biological products shall submit the following information each year within 60 days of the anniversary date of approval of the license to the Director, Center for Biologics Evaluation and Research:

(a) *Summary.* A brief summary stating whether labeling supplements for pediatric use have been submitted and whether new studies in the pediatric population to support appropriate labeling for the pediatric population have been initiated. Where possible, an estimate of patient exposure to the drug product, with special reference to the

pediatric population (neonates, infants, children, and adolescents) shall be provided, including dosage form.

(b) *Clinical data.* Analysis of available safety and efficacy data in the pediatric population and changes proposed in the labeling based on this information. An assessment of data needed to ensure appropriate labeling for the pediatric population shall be included.

(c) *Status reports.* A statement on the current status of any postmarketing studies in the pediatric population performed by, or on behalf of, the applicant. The statement shall include whether postmarketing clinical studies in pediatric populations were required or agreed to, and if so, the status of these studies, e.g., to be initiated, ongoing (with projected completion date), completed (including date), completed and results submitted to the biologics license application (including date).

Dated: September 29, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00-25705 Filed 10-5-00; 8:45 am]

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DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 4

[T.D. ATF-431; Ref: Notice Nos. 890 and 895]

RIN: 1512-AB86

Labeling of Flavored Wine Products (98R-317P)

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

ACTION: Final rule, Treasury decision.

SUMMARY: The Bureau of Alcohol, Tobacco and Firearms (ATF) is amending the regulations to prohibit the use of any varietal designation, type designation of varietal significance, semi-generic geographic type designation, or geographic distinctive designation in statements of composition for flavored wines and other wine specialty products. The regulations are also being amended to provide that references on labels to such designations in the brand name, product name, or fanciful name are limited to standard grape wines. ATF believes that the final regulations will ensure that consumers are not misled as to the identity of the products they purchase.

ATF's proposal to amend the existing definition of "brand label" for wine will be addressed separately in the near future.

DATES: This rule is effective January 1, 2001.

FOR FURTHER INFORMATION CONTACT: James P. Ficaretta, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW., Washington, DC 20226 (202) 927-8210.

SUPPLEMENTARY INFORMATION:

I. Background

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), vests broad authority in the Director of ATF, as the delegate of the Secretary of the Treasury, to prescribe regulations with respect to the bottling, packaging, and labeling of wine, distilled spirits, and malt beverages. The FAA Act provides that these regulations shall prevent deception of the consumer and provide the consumer with adequate information as to the identity and quality of the product. Regulations that implement the provisions of section 105(e), as they relate to wine, are set forth in title 27, Code of Federal Regulations (CFR), part 4.

The regulations require that all wines sold, shipped, or otherwise introduced into interstate commerce bear labels that contain certain mandatory information. Section 4.32(a)(2) provides that, among other things, wine labels must contain a statement relating to the class, type, or other designation of the wine. If the class of wine is not defined by the regulations, section 4.34(a) requires that a truthful and adequate statement of composition appear on the brand label in lieu of the class designation.

Subpart C of part 4 sets forth the standards of identity for the several classes and types of wine. Section 4.21(a) defines "grape wine" as wine produced by the normal alcoholic fermentation of the juice of sound, ripe grapes. Pure condensed grape must and wine spirits may be added to grape wine. Section 4.21(a) also provides limitations on the amelioration of grape wine. Over-ameliorated grape wine may not be designated as "grape wine." Rather, section 4.21(h) requires that such wine be designated as "substandard wine" or "other than standard wine."

In the case of still grape wine there may appear, in lieu of the class designation, any varietal (grape type) designation (e.g., Chardonnay), type designation of varietal significance (e.g., Muscatel), semi-generic geographic type

designation (e.g., Chablis), or geographic distinctive designation (e.g., Bordeaux). In general, section 4.23 provides that the name of a grape variety may be used as the type designation of a grape wine only if the wine is also labeled with an appellation of origin (e.g., "California Chardonnay") and if not less than 75 percent of the finished wine is derived from grapes of the named variety.

In the case of still grape wine there may also appear, in lieu of the class designation, a type designation of varietal significance. This applies to American wines only. Section 4.28 provides several examples of type designations of varietal significance, such as Muscatel and Scuppernong.

As specified in section 4.24(b), a semi-generic designation is a name of geographic significance that is also the designation of a class or type of wine determined by the Director to be semi-generic. Semi-generic designations are also established by the Internal Revenue Code of 1986 (IRC), 26 U.S.C. 5388(c). Examples of semi-generic names that are also type designations for grape wines are Burgundy, Chablis, and Champagne. A semi-generic name of geographic significance may be used to designate wines of an origin other than that indicated by such name only if there appears in direct conjunction therewith an appropriate appellation of origin disclosing the true place of origin of the wine (e.g., "California Burgundy"), and if the wine so designated conforms to the standard of identity for the product or, if there is no such standard, to the trade understanding of such class or type.

Under section 4.24(b), a geographic distinctive designation is a name of geographic significance that has not been found by the Director to be generic or semi-generic and may be used only to designate wines of the origin indicated by such name. Examples of such nongeneric names which are also distinctive designations of specific grape wines are Bordeaux and Graves.

In addition, grape wine may be vintage dated if it is made in accordance with the standards prescribed in section 4.27(a). Vintage wine is wine labeled with the year of harvest of the grapes, and made in accordance with classes 1, 2, or 3 of section 4.21.

Section 4.21 does not allow for the addition of flavoring material(s) to wines with a standard of identity under subpart C of part 4. For example, a class 1, grape wine containing added flavoring material(s) is not entitled to a standard grape wine designation, appellation of origin, or vintage date since these statements only apply to a "standard" grape wine. Likewise,

"substandard wine" or "other than standard wine" under section 4.21(h)(2) does not specifically include wine to which flavoring material(s) have been added. Substandard wine or other than standard wine includes any wine to which has been added sugar and water solution in an amount that is in excess of the limitations prescribed in the standards of identity for these products.

It has been ATF's long-standing policy that wines to which flavoring material(s) are added do not fall within any of the current standards of identity set forth in the wine regulations. As such, a truthful and adequate statement of composition is required on the brand label for such flavored wine products, pursuant to section 4.34(a).

II. Flavored Wine Products

Flavored wine products are composed differently from wines made in accordance with the standards of identity in subpart C. Flavored wines may be derived from grape wine or other wines, including citrus wine (e.g., orange wine, grapefruit wine), fruit wine (e.g., apple wine, berry wine, pear wine) or other agricultural products (e.g., carrot wine, dandelion wine, honey wine). Such flavored wine products contain the addition of flavoring material(s) and may contain coloring material(s). Flavored wine products may also contain sugar and water in excess of that allowed in standard wine.

As stated above, wines to which flavoring materials are added do not fall within any of the current standards of identity set forth in the wine regulations. As such, a truthful and adequate statement of composition is required on the brand label for such flavored products. The labels on these products have traditionally displayed statements of composition such as "Grape Wine With Natural Flavors" to describe to consumers the composition of these products.

Recently, some domestic wineries have begun using varietal and semi-generic names in the statement of composition on their product labels to describe the base wine portion of their flavored wine products. These flavored wine products most often have an appellation of origin such as California in conjunction with the grape varietal or semi-generic name in the statement of composition (e.g., "California Chardonnay (or Chablis) With Natural Flavors"). We are aware that the recent appearance of these grape varietal and semi-generic names on flavored wine products has caused a great deal of discussion within the wine industry. On February 26, 1998, we wrote to the Wine Institute, a national trade association

representing over 500 California winery and associate members, to respond to their concerns about this matter. Soon after the letter was sent to the Wine Institute, it was placed on our internet website as public information.

III. Consumer Survey

In view of our concerns about the labeling of flavored wine products, we commissioned a consumer survey in July of 1998 to determine consumer interpretations of varietal and semi-generic claims on labels of flavored wine products. Among other things, the survey was designed to assess whether wine consumers distinguish between grape wine and flavored wine products based on information provided on product labels. The survey involved obtaining consumer reactions to examples of two flavored wine products: one product was portrayed as containing a grape wine base that qualified as a varietal wine and another was portrayed as a product containing a grape wine base that qualified as a semi-generic wine. Both products chosen for the survey were depicted in "bag-in-box" containers. Consumers were shown labels bearing only varietal or semi-generic designations and labels bearing a varietal or semi-generic type designation as part of a statement of composition including the term "With Natural Flavors." Consumers were shown boxes bearing the statement of composition on the side panel only, and other boxes with the statement of composition prominently displayed on the front label. None of the labels was identical to the labels of wines currently marketed. The brand names, package designs, and label information were selected by the contractor, U.S. Research Company, in order to best measure consumer perceptions about the overall label presentations and were chosen in order to ensure that the results were not specific to any one particular product or brand of wine.

The survey revealed that even when the "With Natural Flavors" disclosure was prominently displayed on the front panel of the product, a large majority (80%) of the respondents failed to distinguish between grape wine and flavored wine products. The survey also revealed that placing the term "With Natural Flavors" on the label had no impact on consumer understanding of the amount of varietal or semi-generic wine in the product. This is important because over fifty-five percent of the consumers surveyed believed that all or almost the entire product was composed of the varietal or semi-generic wine. Moreover, when asked to interpret the "With Natural Flavors" disclosure, more

than one-third of the consumers surveyed perceived it to convey a positive "no chemicals or additives" message. Seventeen percent indicated that they thought the "With Natural Flavors" disclosure meant that the product was "natural," and only fourteen percent suggested that it indicated that flavors had been added to the product.

IV. Petition—California Association of Winegrape Growers

ATF received a petition, dated September 15, 1999, filed on behalf of the California Association of Winegrape Growers (CAWG), requesting an amendment of the regulations to prohibit the use of any varietal, semi-generic, or geographic name as part of a statement of composition on wine specialty products. Specifically, CAWG requested an amendment of section 4.34(a). This section states that if the class of wine is not defined in the standards of identity in subpart C of part 4, "a truthful and adequate statement of composition shall appear upon the brand label of the product in lieu of a class designation." The petitioner requested that the regulation be amended to add the following wording:

A statement of composition shall include the standard of identity (class and type designation) of the wine used in the product, but shall not be permitted to include, in lieu of the class designation for the wine used in the product, any varietal (grape type) designation, type designation of varietal significance, or semigeneric geographic type designation, or geographic distinctive designation, to which the wine used in the product may otherwise be entitled.

The petitioner contended that the manner in which flavored wine products are labeled, packaged, and marketed deceives consumers into thinking they are consuming varietal wine rather than flavored wine. As stated in the petition,

Varietal-based specialty products appear on retailers' shelves next to or intermingled with traditional still wines, in packaging similar to traditional still wines [750 milliliter or 1.5 liter glass bottles sealed with a cork, or 5 liter "bag-in-box" containers] and with a varietal designation and an appellation of origin traditionally associated with still wines prominently displayed.

The petitioner asserted that over the last 20 years, American wine producers and grape growers have developed an important consumer market for still grape wines with varietal designations and appellations of origin. According to the petitioner, these wines represent a large volume of the domestic wine sold in the United States (64 percent for the 52 week period ending July 18, 1999).

As stated in the petition, "[v]arietal designations and appellations of origin have earned an important place in the wine consumer marketplace as indications of quality wines with certain distinctive tastes and styles."

In support of its petition, CAWG commissioned a survey to study consumers' understanding of the current labeling of flavored wine products that include a varietal name with an appellation of origin in the statement of composition. A total of 800 telephone interviews were conducted. According to CAWG, the results of the survey showed that most respondents believe that wine labels accurately reflect what is in the container and that label information is important to their buying decisions. A little more than 48 percent of the respondents stated that they expected products containing labels with such statements as "California Cabernet Sauvignon with natural flavors" and "California Chardonnay with natural flavors" to be standard grape wines that contain 75 percent wine made from grapes of that variety. The petitioner noted that flavored wine products that include a varietal name in the statement of composition have no minimum varietal content requirement.

CAWG stated that the results of its survey clearly show that the labeling of flavored wine products that include a variety name along with an appellation of origin in the statement of composition is misleading to consumers. The petitioner believes that its proposed amendment "is targeted directly at the misleading nature of current statements of composition on varietal-based specialty products." By prohibiting varietal and semi-generic designations and appellations of origin in the statement of composition, the petitioner contends that consumers will not be misled as to the actual identity of the product. Flavored wine products that have a varietal wine base would have statements of composition in the form "grape wine with natural flavors" or "white wine with natural flavors."

ATF did not propose the amendment requested by CAWG. However, we did solicit comments on the petition. This will be addressed further in the section titled "Notice No. 890."

V. Significance of Wine Labeling Terms

ATF believes that consumers have learned to attach significance to varietal/semi-generic designations, appellations of origin, and vintage dates on grape wines. This belief is based on the fact that for many years the grape wine industry has heavily utilized varietal/semi-generic designations, appellations of origin, and vintage

dating in the marketing of grape wines. Additionally, we have conducted rulemaking projects spanning nearly 14 years identifying American grape variety names (See Treasury Decision ATF-370, 61 FR 522, January 8, 1996). Similarly, Congress has recently amended the IRC to recognize semi-generic names as being distinctive grape wine designations. 26 U.S.C. 5388(c), as added by Public Law 105-34, section 910(a). These efforts illustrate the importance of varietal and semi-generic grape wine designations to both the wine industry and to wine consumers. This was also addressed in the CAWG petition.

ATF believes that consumers are confused about the distinction between an existing standard of identity wine and flavored wine products, especially when grape varietal or semi-generic terms appear on the labels of flavored wine products. Flavored wine products are often located next to varietal wines or semi-generic wines on the shelves of grocery and liquor stores. Also, the promotional and advertising materials accompanying these flavored wine products frequently feature or highlight the varietal or semi-generic component of the finished wine product, even though the finished flavored wine product is not entitled to the varietal or semi-generic designation. We concluded that current statements of composition that include varietal or semi-generic names do not provide consumers with adequate information about the identity and quality of the flavored wine product and are likely to mislead consumers to believe that flavored wine products are the same as wines that meet the requirements for a varietal or semi-generic designation. We also believe that the consumer survey we commissioned and the CAWG consumer survey support that conclusion.

Furthermore, examination of this issue caused us to review our policy relating to statements of composition for all flavored wine products, including those that do not include varietal or semi-generic names, such as those that state "Grape Wine With Natural Flavors," since the finished products are no longer "Grape Wine" but are "Flavored Wine Products" because of the presence of flavors.

VI. Notice No. 890

On December 28, 1999, we published a notice of proposed rulemaking in the **Federal Register** concerning the labeling of flavored wine products (Notice No. 890, 64 FR 72612). We proposed to establish a new class designation, "Flavored Wine Product." Under this designation, a flavored wine product

would be a wine-based alcohol beverage that does not qualify for any of the class or type designations listed in the existing wine regulations because of the addition of flavoring material(s).

As stated in Notice No. 890, we believe that all flavored wine products need to be labeled to indicate to consumers that such products are composed differently from wines entitled to be labeled with a standard of identity under subpart C. We, therefore, proposed to add a Class 10 to the standards of identity for wine to be called "Flavored Wine Product." As proposed, such product would be required to be designated on labels as "flavored wine product," together with a truthful and adequate statement of composition, all of which would be required to appear in the same size, style, and color typeface on the brand label.

At a minimum, we proposed that the statement of composition for flavored wine products must meet the following requirements:

1. Identify Class and/or Type

We proposed to require that the class and/or type of each wine used in the flavored wine product (e.g., "grape wine," "table wine," "peach wine," "honey wine") be identified. A single grape variety, type designation of varietal significance, or semi-generic name could be used if such named grape variety, type designation of varietal significance, or semi-generic name appeared together with an appellation of origin no smaller than a country and the named grape variety, type designation of varietal significance, or semi-generic wine constituted not less than 75 percent by volume of the finished flavored wine product. For *Vitis labrusca* varieties, we proposed that the named grape variety must constitute not less than 51 percent by volume of the finished flavored wine product. Under our proposal, an appellation of origin would not otherwise appear on the label of a product of this class. Similar provisions were proposed for specialty products that do not contain any flavor(s) (§ 4.34(c)).

2. Identify Added Flavoring Material(s)

We proposed to require that if one flavoring material is used in the production of the flavored wine product, the flavoring material must be specifically identified (e.g., "strawberry flavor"). If two or more flavoring materials are used in the production of the flavored wine product, we proposed that each flavoring material may be specifically identified (e.g., peach

flavor," "kiwi flavor," or "peach and kiwi flavors") or the characterizing flavor must be specifically identified and the remaining flavoring material(s) must be generally referenced as "other flavor(s)."

With regard to the term "natural" as used on alcohol beverage labels to describe a flavor, e.g., "With Natural Flavors," we stated in the notice that it is our belief that there is no consensus among consumers as to a meaning for the term "natural." This belief is based upon our experience in regulating the wine industry and on the consumer survey noted above. An example indicated in the survey reflects that fully one-third of respondents considered the term "natural" to indicate that no additives or chemicals are present in the product. This conclusion is clearly erroneous. Therefore, to avoid consumer deception concerning the identity of flavored wine products, we proposed that the term "natural" may not be used anywhere on the flavored wine product labels to describe flavoring materials. When artificial flavoring material(s) are used, they would be so described (e.g., "artificial raspberry flavor").

3. Identify Added Coloring Material(s)

We proposed to require that coloring materials(s) be disclosed in the statement of composition, whether added directly or through flavoring material(s). The coloring materials would be identified specifically (e.g., "caramel," "certified color," "annato," etc.) or as a general statement, such as "artificially colored," to indicate the presence of any one or a combination of coloring material(s). However, FD&C Yellow No. 5 requires specific disclosure in accordance with 27 CFR 4.32(c).

4. Include a Reference to Sugar

We proposed to require that sugar be listed in the statement of composition if sugar is used in the production of the flavored wine product (not including its use in the production of the base wine within the range authorized by the regulations).

5. Include a Reference to Water

We proposed to require that water be listed in the statement of composition, if the water addition, whether added directly to the flavored wine product or by the addition of flavoring material(s), exceeds 5 percent by volume of the finished flavored wine product.

6. Include a Reference to Wine Spirits

We proposed to require, except for flavored wine products made from a

base of a class 6 wine and imported flavored wine products, a reference to the addition of wine spirits in the statement of composition, whether such wine spirits are added in the production of the wine component of the flavored wine product or added in the production of the finished flavored wine product, if the wine spirits are not derived from the same kind of fruit from which the wine component was fermented. Section 4.39(a)(7) prohibits the appearance on a wine label of any statement that the wine contains distilled spirits with one exception. Accordingly, we proposed to amend the exception to cover the reference to distilled spirits in the statements of composition for flavored wine products.

Although in Notice No. 890 we solicited comments on the CAWG petition, we did not propose the amendment requested by the petitioner. We believed that the regulation change proposed by CAWG was more restrictive than ATF's proposals and did not provide the industry with flexibility in labeling their flavored wine products.

Miscellaneous—Amended Definition of “Brand Label”

In Notice No. 890, we also proposed to revise the definition of the term “brand label.” As defined in section 4.10, the “brand label” is the label carrying, in the usual distinctive design, the brand name of the wine. Pursuant to section 4.32, certain mandatory information is required to appear on the brand label, including the brand name, the class, type, or other designation of the product, and the alcohol content.

We believe that the existing definition of the term “brand label” allows certain of the mandatory information to be placed on the container in such a way that it is not readily visible to consumers. We also believe consumers are having difficulty locating important mandatory product label information necessary to be adequately informed as to the identity and quality of wine products, including bag-in-boxes and other new wine containers. In addition, the popularity of flavored wine products and the potential for consumer confusion between such products and other wines that fit specific class designations necessitates a more specific definition of “brand label.”

Accordingly, in Notice No. 890 we proposed to amend the definition of “brand label” to mean the principal display panel that is most likely to be displayed, presented, shown, or examined under normal and customary conditions of display for retail sale, and any other label appearing on the same side of the container as the principal

display panel. The brand label appearing on a cylindrical surface is that 40 percent of the circumference which is most likely to be displayed, presented, shown or examined under normal and customary conditions of display for retail sale.

The proposed definition is based on the definition of “brand label” that is currently in the distilled spirits regulations and is consistent with the principal display panel approach of the Fair Packaging and Labeling Act.

The comment period for Notice No. 890, initially scheduled to close on March 29, 2000, was extended until May 5, 2000, pursuant to Notice No. 895 (65 FR 17839, April 5, 2000).

VII. Analysis of Comments

In response to Notice No. 890, ATF received 152 comments, representing 186 signatures. Comments were submitted by members of Congress, consumers, representatives of State government, members of the industry (representing both domestic and foreign interests), and various organizations (e.g., California Association of Winegrape Growers, the Presidents' Forum, the Wine Institute, the National Association of Beverage Importers, Inc., the Flavor and Extract Manufacturers' Association of the U.S., the American Vintners Association, and the French Wine and Spirits Exporters Federation).

One commenter requested an amendment of the regulations (section 4.39(a)(7)) to allow references to distilled spirits on labels of standard wine if such references are true. The amendment requested by the commenter is beyond the scope of this rulemaking. However, it may be included as part of a future rulemaking proceeding.

Six commenters either supported the proposed regulations or expressed support for specific proposals. For example, two commenters supported ATF's proposal to prohibit the term “natural” from appearing on labels of flavored wine products when describing flavoring materials. One of the commenters also supported our proposal to establish a new standard of identity for flavored wine products (i.e., “flavored wine product”). Two commenters supported ATF's proposal to allow a single grape variety, type designation of varietal significance, or semi-generic name in the statement of composition for a wine specialty product, provided the named grape variety, type designation of varietal significance, or semi-generic wine constitutes not less than 75 percent (51 percent for *Vitis labrusca* varieties) by

volume of the finished wine specialty product.

Of the 141 comments that addressed the labeling of flavored wine products, 136 (97 percent) opposed ATF's proposed regulations. Most commenters agreed with ATF's finding that current statements of composition on flavored wines that include a varietal or semi-generic name are likely to mislead the consumer and do not provide the consumer with adequate information as to the identity and quality of the product. Examples were provided in the comments that support this conclusion. However, the commenters believe that it is not necessary to establish a new standard of identity for flavored wine products in order to resolve the problem. Rather, they support the CAWG petition or a similar proposal that would prohibit the use of varietal and semi-generic names in statements of composition for wine specialty products. Approximately 75 commenters contend that ATF's proposed regulations are too broad, too complex, and would affect the labeling of all wine specialty products. They argue that there is no documented evidence of consumer confusion for many of these products. As one commenter stated:

[We have] been producing and bottling plum wine with natural flavors and grape wines with natural flavors since 1984 with no apparent confusion on the part of our consumers with regard to the product that they are buying.

In addition, many commenters object to ATF's proposal that would allow the use of varietal and semi-generic names as part of the statement of composition on both the new class of flavored wine products and other wine specialty products that are not 100 percent standard grape wine. They maintain that varietal and semi-generic names and related appellations of origin should only be used on products that are 100 percent standard grape wine. With respect to the use of varietal names on wine labels, many commenters stated the following:

The standard for varietal content was carefully developed to maintain the varietal character of the wine, and in the context of products which are 100% grape wine. Therefore, varietal terms should only be used on products which are 100% grape wine.

Three comments objected to the proposed designation of the new standard of identity. They argue that the term “flavored wine product” implies that the product is “lesser than, or subordinate to grape wine,” and “both degrades and cheapens everything that we put in to them.”

Several commenters contend that ATF's proposed regulations are not cost effective and would impose an undue burden on the industry. According to one commenter, the massive relabeling of products required by the proposed regulations will result in substantial costs for the domestic and international wine trade without improving consumers' understanding of wine labeling. Another commenter provided specific information—

[Our] line alone includes eight (8) items, all well established as a result of extensive marketing efforts, which would become non-conforming were the proposed regulatory changes to be enacted. Collectively these eight (8) items represented nearly one quarter (25%) of our sales volume last year, calendar [year] 1999. In addition to the tens of thousands of dollars of investment in artwork, design and marketing, * * * [we have] well over one hundred thousand dollars (\$100,000) invested in labels, silk screened bottles and point-of-sale materials for these eight (8) items.

Several commenters objected to ATF's proposals concerning the statement of composition for flavored wine products. One commenter stated that the proposed regulations are excessive and burdensome and "turn a truthful and adequate statement of composition into a version of ingredient labeling without providing adequate justification for the change." Other commenters shared this view.

Many commenters objected specifically to ATF's proposal to prohibit the use of the term "natural" in the statement of composition for flavored wines and other wine specialty products. They maintain that ATF has had a long-standing policy of allowing wine producers to identify a flavor as being "natural" or "artificial," provided it was a truthful characterization of the flavoring. According to one commenter, adopting the proposed regulation "would reverse that long standing policy, cause thousands of labels to change, and would be totally inconsistent with all other food labeling without justification." Another commenter stated that prohibiting the term "natural" to describe a flavor is significantly different from ATF's policy regarding statements of composition as discussed in its publication "Compliance Matters 97-1." In addition, one commenter indicated that if ATF believes there is confusion among consumers as to a meaning for the term "natural," the term should also be prohibited from appearing in statements of composition for flavored malt beverages and distilled spirits specialty products.

One commenter who expressed opposition to the proposed regulations questioned the methodology used with respect to ATF's consumer survey and the validity of the results of the survey. Based, in part, on the consumer survey, ATF concluded that current statements of composition on labels of flavored wines that include varietal or semi-generic names do not provide consumers with adequate information as to the identity and quality of the product and are likely to mislead consumers to believe that flavored wine products are the same as wines that meet the requirements for a varietal or semi-generic designation. In contrast, the commenter refers to the results of its own consumer survey that "clearly shows that consumers are neither confused nor deceived by Flavored Wines labeled in accordance with BATF's current regulations." ATF maintains that statements of composition on flavored wines that include a varietal or semi-generic name are likely to mislead consumers and do not provide consumers with adequate information as to the identity and quality of the product. ATF further believes that its consumer survey, the consumer survey conducted by the petitioner, and the comments received in response to the notice of proposed rulemaking support this conclusion.

VIII. Amended Definition of "Brand Label"

Thirty comments addressed our proposal to amend the definition of "brand label" for wine. The commenters expressed several concerns with respect to the proposed definition that we believe warrant further study and analysis. However, we do not wish to delay a final decision concerning the labeling of flavored wine products. Therefore, we will address the "brand label" issue separately in the near future.

IX. Final Rule

Based on the comments received in response to Notice No. 890, we have re-examined the proposed regulations concerning the labeling of flavored wines and other wine specialty products. It is clear that most commenters agree with our conclusion that current statements of composition on flavored wines that include a varietal or semi-generic name are likely to mislead consumers and do not provide consumers with adequate information as to the identity and quality of the product. It is equally clear that most commenters do not believe ATF's proposal to create a new class

designation is the best solution to the problem.

ATF is particularly concerned about the financial burden that would be placed on the industry, both domestic and foreign, if the proposed regulations were to be adopted as final. As pointed out in the comments, the proposed regulations would affect all wine specialty products, including those that have been in the marketplace for a long time and do not use a varietal or semi-generic name in the statement of composition. In addition, under the proposed regulations, flavored wines and other wine specialty products would still be able to use varietal and semi-generic names in the statements of composition, provided minimum percentage requirements are met. Based on the comments, we are concerned that consumers seeing these designations on such products may perceive these products to be standard grape wines even if the products were labeled as we proposed.

The purpose of the labeling provisions of the FAA Act is to prevent deception of the consumer and to provide the consumer with adequate information as to the identity and quality of the product. In prescribing regulations, ATF has the responsibility to ensure that the statutory goals are met. However, ATF does not believe that the regulations should be more restrictive than is necessary to meet the statutory goal. On the contrary, ATF believes that we should regulate only where necessary and to the extent required to avoid consumer deception or provide the consumer with adequate information about the product.

Accordingly, ATF is not adopting the regulations as proposed in Notice No. 890. We are, however, amending the regulations in section 4.34(a) to prohibit the use of any varietal designation, type designation of varietal significance, semi-generic geographic type designation, or geographic distinctive designation in statements of composition for flavored wines and other wine specialty products. This amendment is similar to that proposed in the CAWG petition.

In Notice No. 890, we proposed that in addition to the statement of composition portion of the mandatory designation for a flavored wine product, additional statements regarding the components of such a product could appear on a back or side label, but not the brand label. Such statements would have to reference all components listed in the mandatory statement of composition and must include the percentage of each component totaling 100 percent. Furthermore, such

additional statements must be truthful, accurate and specific, within the meaning of section 4.38(f). Many commenters disagreed with our proposal, maintaining that varietal and semi-generic names should only be used on products that are 100 percent standard grape wine. For example, one commenter stated the following:

[T]here should be no provision for showing a varietal designation or a semi generic designation (and related appellation of origin) in any way, including in a statement of composition, anywhere on a label of any wine product that is not a standard grape wine. That includes, of course, any other-than-standard wine, substandard wine and/or flavored wine product.

Another commenter stated that “[v]arietal, semi-generic names and appellations of origin should only be used on Class I, Class II and Class III wines. They should not be used on any other class of wine, nor on any ‘wine specialty products.’” Another comment, representing three Washington State wine organizations, maintained that “[p]ermitting the use of varietal or semi-generic names on products that are not in fact 100% [standard grape] wine will simply add to consumer confusion.”

Accordingly, we are amending the regulations to provide that wine labels may not contain any varietal name, type designation of varietal significance, semi-generic name, or geographic distinctive designation in the brand name, product name, or distinctive or fanciful name, unless the wine is made in accordance with the standards prescribed in classes 1, 2, or 3 (i.e., grape wine, sparkling grape wine, or carbonated grape wine). Any other use of such a designation on other than a class 1, 2, or 3 wine is presumed misleading. This amendment is similar to one proposed by the Wine Institute in its comment on the proposed regulations. The Wine Institute represents over 500 California winery and associate members. We believe this amendment is necessary to ensure that consumers are adequately informed as to the identity and quality of the wine, and to prevent consumer deception.

X. Applications for and Certification of Label Approval

Upon the effective date of this Treasury decision, i.e., January 1, 2001, applications for certificates of label approval must be in compliance with the regulations. In accordance with the provisions of 27 CFR 13.51 and 13.72(a)(2), upon the effective date of this Treasury decision, certificates of label approval that are not in compliance with the regulations will be revoked by operation of regulation.

Certificate holders must voluntarily surrender all certificates that are no longer in compliance and submit applications for new certificates that are in compliance with the new requirements.

How This Document Complies With the Federal Administrative Requirements for Rulemaking

A. Executive Order 12866

We have determined that this final rule is not a significant regulatory action as defined in E.O. 12866. Therefore, a regulatory assessment is not required.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small government jurisdictions. We hereby certify that this final rule will not have a significant economic impact on a substantial number of small entities. Since producers routinely make changes to their labels, we do not believe that the final regulation will result in any additional burdens on the industry. Accordingly, a regulatory flexibility analysis is not required.

C. Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, Public Law 104-13, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this final rule because no requirement to collect information is imposed.

Disclosure

Copies of the notice of proposed rulemaking, all written comments, and this final rule will be available for public inspection during normal business hours at: ATF Public Reading Room, Room 6480, 650 Massachusetts Avenue, NW., Washington, DC.

Drafting Information

The author of this document is James P. Ficaretta, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects in 27 CFR Part 4

Advertising, Consumer protection, Customs duties and inspection, Imports, Labeling, Packaging and containers, Wine.

Authority and Issuance

For the reasons discussed in the preamble, ATF amends 27 CFR part 4 as follows:

PART 4—LABELING AND ADVERTISING OF WINE

Paragraph 1. The authority citation for part 4 continues to read as follows:

Authority: 27 U.S.C. 205.

Par. 2. Section 4.34(a) is amended by adding a sentence after the seventh sentence to read as follows:

§ 4.34 Class and type.

(a) * * * The statement of composition will not include any reference to a varietal (grape type) designation, type designation of varietal significance, semi-generic geographic type designation, or geographic distinctive designation. * * *

Par. 3. Section 4.39 is amended by adding a new paragraph (n) to read as follows:

§ 4.39 Prohibited practices.

(n) *Use of a varietal name, type designation of varietal significance, semi-generic name, or geographic distinctive designation.* Labels that contain in the brand name, product name, or distinctive or fanciful name, any varietal (grape type) designation, type designation of varietal significance, semi-generic geographic type designation, or geographic distinctive designation, are misleading unless the wine is made in accordance with the standards prescribed in classes 1, 2, or 3 of § 4.21. Any other use of such a designation on other than a class 1, 2, or 3 wine is presumed misleading.

Signed: August 4, 2000.

Bradley A. Buckles,

Director.

Approved: September 5, 2000.

John P. Simpson,

Deputy Assistant Secretary, (Regulatory, Tariff and Trade Enforcement).

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DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 541

[BOP-1083-F]

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Inmate Discipline: Prohibited Acts

AGENCY: Bureau of Prisons, Justice.