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DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Parts 4, 5, and 7

[Notice No. 62]
RIN 1513-AB08

Major Food Allergen Labeling for Wines, Distilled Spirits and Malt Beverages

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Notice of proposed rulemaking; solicitation of comments.

SUMMARY: In this notice, the Alcohol and Tobacco Tax and Trade Bureau proposes the adoption of mandatory labeling standards for major food allergens used in the production of alcohol beverages subject to the labeling requirements of the Federal Alcohol Administration Act. The proposed regulations set forth in this document also provide procedures for petitioning for an exemption from allergen labeling. The proposed regulations parallel the recent amendments to the Federal Food, Drug and Cosmetic Act contained in the Food Allergen Labeling and Consumer Protection Act of 2004. Under the proposed regulations, producers, bottlers, and importers of wines, distilled spirits, and malt beverages must declare the presence of milk, eggs, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as ingredients that contain protein derived from these foods, on a product label unless an exemption applies to the product in question.

DATES: Comments must be received on or before September 25, 2006.

ADDRESSES: You may send comments to any of the following addresses--

Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, Attn: Notice No. 62, P.O. Box 14412, Washington, DC 20044-4412.

202-927-8525 (facsimile).

nprm@ttb.gov (e-mail).

http://www.ttb.gov/alcohol/rules/index.htm. An online

comment form is posted with this notice on our Web site.
http://www.regulations.gov. Federal e-rulemaking portal;

follow instructions for submitting comments.
You may view copies of any comments we receive about this notice by appointment at the TTB Information Resource Center, 1310 G Street, NW., Washington, DC 20220. To make an appointment, call 202-927-2400. You may also access copies of this notice and any comments online at http://www.ttb.gov/alcohol/rules/index.htm
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See the Public Participation section of this notice for specific instructions and requirements for submitting comments, and for information on how to request a public hearing.

FOR FURTHER INFORMATION CONTACT: Lisa M. Gesser, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, P.O. Box 128, Morganza, MD 20660; telephone (301) 290-1460.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, the presence of food allergens in foods has become a matter of public concern. In response, Congress passed the Food Allergen Labeling and Consumer Protection Act of 2004 to require the declaration in labeling of eight major food allergens in plain, common language on the food and beverage products regulated under the Federal Food, Drug and Cosmetic Act. A House of Representatives committee report also noted that the committee expected the Alcohol and Tobacco Tax and Trade Bureau (TTB) to issue regulations on allergen labeling for alcohol beverage products under TTB's existing authority to regulate alcohol beverage labeling, working in cooperation with the Food and Drug Administration (FDA). In addition, TTB had earlier received a petition concerning ingredient and allergen labeling for alcohol beverages.

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A. FAA Act

TTB is responsible for the administration of the Federal Alcohol Administration Act, 27 U.S.C. 201 et seq., (FAA Act), which governs, among other things, the labeling of wines containing at least 7 percent alcohol by volume, distilled spirits, and malt beverages in interstate and foreign commerce. These products are generically referred to as ``alcohol beverages'' or ``alcohol beverage products'' throughout this document.
In particular, section 105(e) of the FAA Act (27 U.S.C. 205(e)) gives the Secretary of the Treasury authority to issue regulations regarding the labeling of alcohol beverages to provide the consumer with adequate information concerning the identity and quality of such products, to prevent deception of the consumer, and to prohibit false

or misleading statements. Section 105(e) also makes it unlawful for industry members ``to sell or ship or deliver for sale or shipment, or otherwise introduce in interstate or foreign commerce, or to receive therein, or to remove from customs custody for consumption, any distilled spirits, wine, or malt beverages in bottles, unless such products are bottled, packaged, and labeled in conformity'' with regulations prescribed by the Secretary. Regulations setting forth mandatory labeling information requirements for wine, distilled spirits, and malt beverages are contained, respectively, in parts 4, 5, and 7 of the TTB regulations (27 CFR parts 4, 5, and 7).

Most of the mandatory labeling requirements found in parts 4, 5, and 7 flow directly from the stated purpose of section 105(e) of the FAA Act, that is, to ``provide the consumer with adequate information as to the identity and quality of the products, the alcoholic content thereof * * *, the net contents of the package, and the manufacturer or bottler or importer of the product.'' Currently, the TTB labeling regulations contained in parts 4, 5, and 7 require the following information to appear on alcohol beverage labels: Brand name; product identity (class or type); the name and address of the bottler, packer, or importer; the net contents; and the alcohol content of distilled spirits, certain flavored malt beverage products, and wines over 14 percent alcohol by volume. Labels for wines with 14 percent alcohol by volume or less may contain either an alcohol content statement or the type designation ``table'' wine or ``light'' wine (see 27 CFR 4.36(a)). In addition, labels must note the presence of sulfites, FD&C Yellow No. 5, and in the case of malt beverages, aspartame. A health warning statement applicable to all alcohol beverages containing 0.5 percent or more alcohol by volume, is required by the Alcoholic Beverage Labeling Act of 1988, codified at 27 U.S.C. 213-219 and 219a and implemented in the TTB regulations at 27 CFR part 16.

B. Current Health-Risk Ingredient Disclosure on Alcohol Beverage Labels

Our predecessor agency, the Bureau of Alcohol, Tobacco and Firearms (ATF), proposed on several occasions to adopt mandatory ingredient disclosure requirements for alcohol beverages. In each case, ATF ultimately decided not to adopt full ingredient labeling requirements. (See Notice No. 41, 70 FR 22274, April 29, 2005, for a more complete history of those ingredient labeling regulatory initiatives.)

These rulemaking actions included publication of T.D. ATF-150 (48 FR 45549, October 6, 1983), which rescinded the ingredient disclosure regulations that had been published in T.D. ATF-66 (45 FR 40538, June 13, 1980), but never implemented. T.D. ATF-150 did, however, mandate the disclosure of one ingredient, FD&C Yellow No. 5, on alcohol beverage labels. In the preamble to T.D. ATF-150, ATF stated:

* * * there is no clear evidence in the record that any other ingredient besides FD&C Yellow No. 5 poses any special health problem. The Department will look at the necessity of mandatory 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).

In conformity with that case-by-case review policy, ATF subsequently issued regulations requiring the disclosure on labels of sulfites in alcohol beverages (T.D. ATF-236, 51 FR 34706, September 30, 1986) because it was determined that the presence of undeclared sulfites in alcohol beverages posed a recognized health problem to sulfite-sensitive individuals.

In 1987, ATF entered into a Memorandum of Understanding (MOU) with FDA. See 52 FR 45502 (November 30, 1987). In the MOU, ATF made a commitment to consult with FDA regarding the necessity of requiring labeling statements for ingredients in alcohol beverages that pose a recognized public health problem and to initiate rulemaking proceedings to require disclosure of such ingredients where appropriate. The pertinent portion of the MOU states:

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

Pursuant to the policies set forth in the MOU, ATF subsequently issued regulations requiring a declaration on labels when aspartame is used in the production of malt beverages (T.D. ATF-347, 58 FR 44131, August 19, 1993). It should be noted that FD&C Yellow No. 5, sulfites, and aspartame are not considered food allergens because they do not cause IgE (Immunoglobulin E)-mediated responses, but they may cause health problems in certain individuals.

C. Petition From Dr. Christine Rogers

On April 10, 2004, Christine A. Rogers, PhD., a senior research scientist in the Exposure, Epidemiology and Risk Program at the Harvard School of Public Health, petitioned TTB to change the regulations to require labeling of all ingredients and substances used in the production of alcohol beverages.

Dr. Rogers stated that she is allergic to egg protein and that she has had allergic reactions to egg in wine. For that reason, she expressed particular concern with the labeling of allergenic substances in alcohol beverage products. Dr. Rogers noted that allergic symptoms in consumers can include tingling or itching in the mouth, salivation, swelling of tissues, hives, abdominal cramps, vomiting, diarrhea, rapid loss of blood pressure, and death. She explained that allergic reactions to food vary based upon an individual's sensitivity to a particular allergen. The most sensitive allergic individuals are

required to carry epinephrine with them for emergency use in the case of exposure to an offending allergen.

D. Enactment of FALCPA

On August 2, 2004, the President signed into law the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (see title II of Pub. L. 108-282, 118 Stat. 905). FALCPA amends portions of the Federal Food, Drug and Cosmetic Act (FD&C Act, 21 U.S.C. 301 et seq.) to require a food that is, or contains an ingredient that bears or contains, a major food allergen to list

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this information on its label using plain, common language. For example, instead of merely listing ``semolina,'' the label must also list ``wheat'', and instead of merely listing ``sodium casein,'' the label must also list ``milk.'' The FALCPA amendments define ``major food allergens'' as milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as most ingredients containing proteins derived from these foods.

The effect of the FALCPA amendments is to add additional allergen information to the food label. The FALCPA amendments provide two ways for a manufacturer to disclose major food allergens on the label:

- The label can show the name of the food source from which the major food allergen is derived within parentheses in the ingredient list, for example, ``Ingredients: Water, wheat, whey (milk), albumen (eggs), and peanuts''; or
- The label can list the name of the food source from which the allergen is derived in summary form after, or adjacent to, an ingredient list, for example: ``Ingredients: Water, sugar, whey, and albumen. Contains: Milk and egg.''

Section 202 of FALCPA contains a number of congressional findings regarding the health risk posed by allergens. Congress found that approximately 2 percent of adults and 5 percent of infants and young children in the United States suffer from food allergies. Each year, roughly 30,000 individuals require emergency room treatment and 150 individuals die because of allergic reactions to food.

Congress found that the eight foods or food groups identified in FALCPA account for 90 percent of all food allergies. Since there is currently no cure for food allergies, a food-allergic consumer must avoid the food to which he or she is allergic. Congress further found that many consumers may not realize that a labeled food ingredient is derived from, or contains, a major food allergen. The FALCPA amendments fill this gap by ensuring that the food source from which a major food allergen is derived is clearly labeled in plain language.

FALCPA amends food and beverage labeling requirements in the FD&C Act. Pursuant to authority delegated to it by the Secretary of Health and Human Services, FDA is responsible for promoting and protecting the public health through enforcement of the FD&C Act and for ensuring that the nation's food supply is properly labeled. FDA's responsibility for proper labeling of food applies to most domestic and imported food and

beverage products. However, it is TTB's responsibility to issue regulations with respect to the labeling of wine, distilled spirits, and malt beverages under the FAA Act. See the 1987 ATF-FDA MOU and Brown-Forman Distillers Corp. v. Mathews, 435 F. Supp. 5 (W.D. Ky. 1976).

The allergen labeling requirements in FALCPA apply to any food, as that term is defined in section 201(f) of the FD&C Act, other than raw agricultural commodities. As reflected in the 1987 MOU with FDA, TTB is responsible for the promulgation and enforcement of regulations with respect to the labeling of distilled spirits, wines, and malt beverages pursuant to the FAA Act. The House of Representatives Committee on Energy and Commerce called for TTB to work with FDA to promulgate appropriate allergen labeling regulations for alcohol beverages labeled under the FAA Act and TTB regulations, consistent with the 1987 MOU with FDA. The committee report accompanying FALCPA stated:

The Committee expects, consistent with the November 30, 1987 Memorandum of Understanding, that the Alcohol and Tobacco Tax and Trade Bureau (TTB) of the Department of Treasury will pursuant to the Federal Alcohol Administration Act determine how, as appropriate, to apply allergen labeling of beverage alcohol products and the labeling requirements for those products. The Committee expects that the TTB and the FDA will work together in promulgation of allergen regulations, with respect to those products. (H.R. Rep. No. 608, 108th Cong., 2d Sess., at 3 (2004); hereafter ``House committee report.'')

Congress thus recognized TTB's longstanding policy of consulting with FDA in determining what ingredients in alcohol beverages should be disclosed on labels, and called on TTB to work with FDA to promulgate appropriate allergen labeling regulations for alcohol beverages. The clear intent reflected in the House committee report is that TTB issue regulations similar to the FALCPA standards, pursuant to the policies expressed in the MOU with FDA and the authority of the FAA Act.

Under the MOU, the two agencies have over the years collaborated on many food safety issues and continue to exchange a wide variety of information, including relevant consumer complaints concerning the adulteration of alcohol beverages. The agencies consult regularly concerning the use and labeling of potentially harmful ingredients and substances in alcohol beverages. The laboratories of FDA and TTB regularly exchange information concerning methodologies and techniques for testing alcohol beverages.

Consistent with the expectations expressed in the House committee report, TTB consulted with FDA prior to issuing this proposed rule. However, it should be emphasized that while we have proposed this rule in response to, among other things, the expectations set out in the legislative history of FALCPA, TTB's legal authority to issue regulations on allergen labeling of alcohol beverages is based on the FAA Act.

FDA is the agency authorized to implement FALCPA with regard to foods. The House committee has set forth its expectation that TTB will implement allergen labeling for alcohol beverages, as appropriate, and

will work with FDA in this effort. While TTB has generally strived to be consistent with FDA's interpretation of FALCPA, the implementation of regulations regarding major food allergen labeling for alcohol beverages under the FAA Act will necessarily differ in some respects from the requirements of FALCPA.

Accordingly, this proposed rule reflects TTB's interpretation of its authority under the FAA Act, as guided by the language in the committee report. The proposed regulations do not necessarily represent the views of FDA with regard to allergen labeling or the requirements of FALCPA.

II. Rulemaking History and Discussion of Comments

On April 29, 2005, TTB published in the Federal Register (70 FR 22274) Notice No. 41, an advance notice of proposed rulemaking (the ANPRM). The notice was entitled ``Labeling and Advertising of Wines, Distilled Spirits and Malt Beverages; Request for Public Comment.'' We provided a 60-day period for comments from consumers, interest groups, trade associations, industry, and other members of the public on several alcohol beverage labeling issues, including calorie and carbohydrate claims on labels, ``serving facts'' labeling, ``alcohol facts'' labeling, ingredient labeling, allergen labeling, and composite label approaches.

In the ANPRM, we invited comments on specific issues related to allergen labeling, including: Whether our regulations should require allergen labeling to be part of or adjacent to a list of ingredients, similar to the FALCPA requirements; whether an allergen must be labeled in an allergen statement even when the allergen name already appears in the product name; how processing or fining agents should be labeled; whether we should consider threshold levels in allergen labeling; what costs industry may incur from new labeling requirements; and how consumers might benefit from allergen labeling. We also invited submission of any other

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relevant information on the subject of allergen labeling.

During the 60-day comment period, we received several requests from alcohol beverage industry representatives and organizations to extend the comment period for an additional 60 to 90 days beyond the original June 28, 2005, closing date. In support of the extension requests, industry members noted that some of the questions posed in the notice were broad and far reaching from a policy standpoint while others were very technical, requiring research and coordination within the affected industries. In response to these requests, we extended the comment period for an additional 90 days. See Notice No. 48, 70 FR 36359, June 23, 2005. The extended comment period for the ANRPM closed on September 26, 2005.

We received more than 18,000 comments in response to the ANPRM, approximately 50 of which specifically addressed the subject of allergen labeling. Based on the clearly expressed congressional interest in allergen labeling, the particular risks that allergens pose

to human health, FALCPA's effective date of January 1, 2006, and the relatively small number of comments submitted on allergen issues, we have decided to separate the allergen labeling rulemaking from the other issues discussed in the ANPRM. We will review the comments submitted on the other ANPRM issues, with a view to determining whether to proceed with future rulemaking action in those areas, separately from our action on allergen labeling. Accordingly, this document only addresses allergen issues, including the approximately 50 comments on allergens submitted in response to the ANPRM.

We note that of the comments we received on allergens, the vast majority favored mandatory labeling of the major food allergens. Industry members as well as consumer and public health advocates commented in support of major food allergen labeling.

The major trade associations representing the alcohol beverage industry expressed their support for mandatory labeling of major food allergens. The Beer Institute, the Brewers Association, the Distilled Spirits Council of the United States (DISCUS), the National Association of Beverage Importers (NABI), the Presidents' Forum, Spirits Canada, Wine America, and the Wine Institute submitted a consolidated comment (hereafter referred to as ``the trade associations' consolidated comment''), in which they stated that they fully supported the purpose and objectives of FALCPA and stood ready to work with TTB in the implementation of allergen labeling. In a separate comment, the Brewers Association stated that ``mandatory rules regarding the disclosure of major allergens are necessary because certain types of allergens, or at least when present above scientifically determined harmful levels, can pose a significant threat to consumer health.''

Consumer and public health interest groups also submitted comments in support of mandatory labeling of major food allergens. The National Consumers League (NCL) submitted a comment supported by several groups, including the American Public Health Association and the American School Health Association. This comment urged TTB to adopt a uniform, mandatory labeling regime for all alcohol beverages that includes, among other things, an ingredient declaration listing each ingredient by its common or usual name and identifying any major food allergens present in the product. The Center for Science in the Public Interest (CSPI), a nonprofit health education and advocacy organization, submitted a comment in support of the adoption of a mandatory allergen disclosure policy for alcohol beverages consistent with the FALCPA requirements for food and the FDA policies implementing FALCPA.

We also received comments in support of allergen labeling from the American Medical Association, the American Academy of Allergy, Asthma and Immunology, the American College of Allergy, Asthma and Immunology; the Food Allergy and Anaphylaxis Network; the American Council on Science and Health; the American Society of Addiction Medicine; the American Dietetic Association; the American Nurses Association; Shape Up America; and several other public health organizations and health professionals.

Only a few comments questioned the usefulness of requiring allergen information on alcohol beverage labels. Furthermore, there were some disagreements among the commenters about the allergen labeling

implementation issues that we raised in the ANPRM.

The comments we received in response to Notice No. 41 on allergen issues are discussed in more detail below.

A. Comments on Industry Costs Versus Consumer Benefits

In the ANPRM we asked for comments on the issue of what costs mandatory allergen labeling would impose on the industry and, ultimately, the consumer. We also solicited comments on how consumers might benefit from allergen labeling.

Costs

Only a few comments specifically addressed the issue of costs and benefits. Some commenters assumed that any costs associated with mandatory labeling arise from the enactment of FALCPA and the expression of congressional intent regarding allergen labeling of alcohol beverages and that the cost issue was therefore not open for discussion. For example, the trade associations' consolidated comment responded to our solicitation of comments on the cost issue by stating that ``[m]andatory allergen labeling requirements pursuant to the Food Allergen Labeling and Consumer Protection Act were signed into law by the President in August 2004.'' The consolidated comment did not include any estimates of the costs associated with the relabeling of alcohol beverages or with the potential reformulation of such products to avoid allergen labeling.

A few commenters raised general concerns about the costs of allergen labeling, based on their assumption that small wineries would be required to conduct expensive laboratory analyses to determine allergen content. For example, Grove Winery commented in opposition to any additional mandatory labeling requirements, including allergen labeling. The winery stated that the ``laboratory work required for each lot would be a prohibitive cost for small lots and for small family wineries, making it even more difficult to compete with the large wine conglomerates and low cost imports.'' We received three other comments raising similar concerns about the costs of testing wines for allergens, and the potential impact of such costs on small wineries.

On the other hand, Dr. Rogers suggested that the least costly approach for the manufacturer, and the safest for the allergic consumer, would be for the producer to list all allergens used in production. She suggested that this approach would preclude the need for testing, and the disclosure of the presence of an allergen would allow the allergic consumer to make an informed decision.

CSPI and one individual commenter referenced a past cost assessment done by FDA that evaluated relabeling costs for a final rule adding trans fatty acid labeling requirements to foods (see 68 FR 41434, 41477, July 11, 2003). In the study, FDA estimated that the average

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low relabeling cost per ``stock keeping unit'' (SKU) would be about $1,100 and the average high relabeling cost per SKU would be $2,600. An SKU is a specific product sold in a specific size.

CSPI and the individual commenter applied these FDA relabeling cost estimates to the alcohol beverage labeling changes aired for comment in the ANPRM. Applying the estimates to a winery selling 5 types of wine, they computed the average total cost of relabeling to be between $5,500 and $13,000 for the winery. They then applied the estimates to a particular brand of wine, stating that if the winery produced 320,000 9-liter cases (3,840,000 750 ml bottles), ``[e]ach of those bottles would incur a cost of $0.000677--less than 7/100ths of a penny--if the cost were $2,600 per sku.''

The Brewers Association did a survey of its members to find out what costs brewers might incur from the new labeling proposals at issue in the ANPRM. The comment stated that the aggregate average costs for respondents by size ranged from $35,530 per brewer for smaller brewers to $1.5 million per brewer for larger brewers. However, it is noteworthy that these estimates were used to support the Brewers Association's opposition to various proposals for new mandatory labeling requirements in the advance notice, including ingredient labeling, nutritional labeling, and ``Alcohol Facts'' panels. Moreover, while the Brewers Association opposed most of the new mandatory labeling requirements aired for comment in the ANPRM and requested exemptions for small brewers from most new labeling requirements, the association's comment supported mandatory allergen labeling, where allergens are present at levels proven to be harmful to certain consumers, and did not request that small brewers be exempted from mandatory allergen labeling.

One commenter who identified himself as a consumer stated that the costs of mandatory labeling would far outweigh any consumer benefits. He suggested that TTB set guidelines for voluntary allergen labeling, rather than mandatory requirements.

Consumer Benefits

We received several comments that addressed the potential benefits to consumers if TTB required mandatory allergen labeling on alcohol beverages. For example, in her comment, Dr. Rogers described the costs associated with the health risks that the major food allergens pose. She stated, ``Currently, a substantial cost is incurred by the allergic public who suffer 4-6 hours of debilitating illness as a result of allergic reactions from hidden or unknown ingredients. There are also economic costs as a result of medications and emergency room visits associated with these incidents.'' Many other commenters agreed that allergen labeling requirements provide distinct benefits to consumers, including providing critical information for consumers with potentially deadly food allergies.

Several commenters noted that mandatory labeling requirements for major food allergens allow consumers to make informed decisions. Dr. Rogers, for example, stated:

> Currently, besides abstinence, the only way to determine if allergens are present in alcoholic beverages is to either contact the brewer/distiller directly for each bottle consumed, or to engage in the more usual high-risk behavior of ``trial and error.'' The latter approach is complicated by the fact that the onset of an allergic reaction can be similar to or be obscured by the effects of

alcohol ([for example], generalized flushing, lightheadedness).

A consumer explained that some beverages have caused her to break out in a mild rash, and she feels that knowing what ingredients are present in these beverages would help her know what drinks to avoid. A Canadian consumer commented that she has an anaphylactic allergy to eggs, and she stated that she considers it very dangerous to drink alcohol beverages at all due to the fact that no allergen information is currently identified on alcohol beverages.

A comment from the American Academy of Allergy, Asthma and Immunology, the American College of Allergy, Asthma and Immunology, and the Food Allergy and Anaphylaxis Network explained the risks of food allergy anaphylaxis as follows:

As you may know, food allergy is an increasing public health and food safety issue. A fish and shellfish prevalence study showed approximately 6.6 million Americans reporting an allergy to these foods. Combined with a previous study of the prevalence of peanut and tree nut allergy, we now estimate that approximately 11.4 million Americans, or 4% of the population, have a food allergy. This represents a significant increase from estimates just 10 years ago, when scientists believed that food allergy affected less than 1% of the population.

Food-allergic reactions continue to be the leading cause of anaphylaxis (a severe, potentially life-threatening allergic reaction) outside the hospital setting, accounting for an estimated 30,000 emergency room visits, 2,000 hospitalizations, and 150-200 deaths each year in the U.S. alone. (Footnotes omitted.)

This comment also stated that there was currently one research study in the medical literature showing an anaphylactic reaction caused by a major food allergen in an alcohol beverage (wheat beer), and that there were anecdotal reports of reactions from other allergens (such as eggs) in alcohol beverages.

TTB Response

The majority of the commenters who addressed this issue agreed with the congressional findings on the importance of providing consumers with clear information about the presence of major food allergens in foods and beverages. We agree with those commenters who stated that mandatory labeling of the major food allergens provides critical information for individuals with potentially deadly food allergies, allowing those consumers to make informed decisions.

In response to the concerns expressed by some wineries that they would be required to conduct extensive and expensive laboratory analysis to determine allergen content, we note that mandatory allergen labeling does not necessarily require producers to conduct any chemical analyses of their products. Producers are aware of and usually keep extensive records of what materials, including major food allergens, go into the production of an alcohol beverage. The producers therefore would already know when the presence of a major food allergen ought to be declared. Thus, the adoption of mandatory labeling requirements for major food allergens in alcohol beverages would not require expensive

laboratory tests of those alcohol beverages.

Because small producers would not have to engage in laboratory testing of their products in order to comply with mandatory allergen labeling requirements, we do not believe that small businesses would be adversely impacted by such requirements. In any event, we believe that exempting small producers from allergen labeling requirements would be inconsistent with our statutory mandate under the FAA Act to protect the consumer and ensure that alcohol beverage labels provide the consumer with adequate information about the identity of the product. Furthermore, the House committee report that directed TTB to work with FDA to implement allergen labeling for alcohol beverages stated that ``[s]ince there is currently no cure for food allergies, consumers need to be empowered to know whether or not food allergies are present in the food they consume.'' This clear congressional

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concern would not be addressed by a rule that allowed for exemptions for small producers.

In this notice, we are soliciting comments directed specifically to the costs and benefits of mandatory labeling of major food allergens and on ways to reduce the costs to industry, in particular small businesses. We note that the regulatory texts in this proposed rule do not specifically require laboratory tests. Nevertheless, any business that believes it would be adversely impacted by the proposed rule should provide us with specific cost figures. We also are soliciting comments on any alternative approach that would meet the intent of FALCPA while minimizing the costs imposed on industry members. We are also seeking comments on how much time industry requires to comply with such labeling requirements. These issues will be carefully considered in the formulation of a final rule on allergen labeling.

B. Comments on Requiring a Full List of Ingredients

In the ANPRM we asked whether TTB should require that major food allergen labeling on alcohol beverage containers be part of, or adjacent to, a larger list of all ingredients found in the product, similar to the requirements of the FD&C Act as amended by FALCPA.

Several commenters expressed support for mandatory ingredient labeling that would include allergenic ingredients. Dr. Rogers, for example, noted that the major food allergens do not account for all allergic reactions, and she suggested that complete ingredient labeling was important for the following reason:

Although milk, egg, fish, shellfish, tree nuts, peanuts, wheat and soy account for most of the food allergy reactions, there are still a significant number of reactions to other proteins not in this list. Therefore a comprehensive ingredient listing would provide the most useful information to allergic individuals regardless of the particular allergen.

The NCL also supported requiring a full list of ingredients,

stating that such a requirement would create labeling consistency between those alcohol beverage products regulated by TTB and wines that are under 7 percent alcohol by volume, the labeling of which is regulated by FDA. The NCL further asserted that Americans with food allergies are accustomed to looking at a product's ingredient declarations to see whether the product contains the allergen they must avoid.

Many industry commenters, on the other hand, suggested that while major food allergen labeling provides important information to a consumer, a full ingredient disclosure has the potential to mislead consumers. For example, the trade associations' consolidated comment stated that a substantial transformation of the raw materials takes place during the fermentation and distillation process in the production of alcohol beverages. The comment asserted that this transformation means that there is little, if any, relationship between the initial ingredients and the contents of the finished product, which undermines the usefulness of ingredient labeling.

TTB Response

As noted above, ATF explored the issue of requiring a full list of ingredients on several occasions in the past and found it to be a very controversial and complex issue. Based on our preliminary review of all comments received in response to the ANPRM, we recognize that the issue of ingredient labeling remains a controversial subject. In contrast, most of the comments we received in response to the issue of allergen labeling, including those of industry members, favored allergen labeling. In view of the controversy and complexity surrounding the complete ingredient labeling issue, we have determined that broader ingredient labeling should not be included with our rulemaking on major food allergen labeling. We are deferring consideration of broader ingredient labeling for a later, additional rulemaking.

C. Comments on Labeling When the Allergen Appears as Part of a Brand Name

In the ANPRM, we posed the following question:

If the product name appearing on the label of an alcohol beverage container indicates that an allergen is present in the product, is it helpful to the consumer to have the allergen labeled again in a standardized allergen statement elsewhere on the container? To illustrate: if a product is called ``Wheat Beer,'' should it also have a label elsewhere on the container that reads: ``Allergens: wheat''? Why or why not?

We received several comments on this issue. Many commenters stated that it is unnecessary to label a product with a second allergen label if the allergen is listed elsewhere on the label, for example, if it is included in the brand name or product name. The European Spirits Organisation argued that we should be consistent with the European Union approach to this problem, where a separate allergen labeling declaration is not required if the allergen present in the final product is identified in the product name or elsewhere on the label.

They suggested that it should be sufficient for the allergen to appear in the product name.

On the other hand, the Ketel One Vodka company commented that regardless of whether the product name indicates that an allergen is present, the label should properly disclose any major food allergen in a standardized form. Dr. Rogers also suggested that one section of the labeling should be the reliable source of ingredient and allergen information.

TTB Response

We think that some measure of standardization is necessary, and therefore it would be inappropriate to allow an allergen to be listed only in an alcohol beverage product's brand or product name. We believe it is reasonable to assume that consumers would grow accustomed to seeing allergen information in one format on alcohol beverage labels and would look for that format.

Moreover, we think that a consumer could be misled if a brand name contains the allergen name, but does not also list the allergen in the same standard format as is required for an alcohol beverage that does not mention the allergen in its brand name. We also can foresee a situation where the brand name of a product includes a major food allergen, but the major food allergen is not present in the final product. To illustrate, consider two hypothetical products:

1. A beer made by Wheat Creek Brewery called ``Wheat Creek Lager,'' which does not contain wheat; and

2. A wheat beer called ``Creek's Wheat Beer,'' which does contain wheat protein.

While ``wheat beer'' is in fact brewed in part from wheat, the use of the term ``wheat'' in the above examples does not necessarily signify the presence of wheat in the product. Therefore, if we adopted a rule that did not require disclosure of allergens where the allergen was included in the brand name of the product, consumers could not be sure when the brand name is in fact imparting information about the presence of an allergen. The consumer should not have to guess in the above situations whether the product does in fact contain wheat or protein derived from wheat. Instead, consumers should be able to look at the label and determine right away whether the product contains any of the major food allergens, and if so, which ones.

To avoid any potential confusion as to what allergen proteins the product may or may not contain, we believe that the

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best policy is to require disclosure of major food allergens in one standard format, whether or not the brand name or any other part of a product label includes the name of the allergen.

D. Comments Regarding the Labeling of Processing and Fining Agents

In the ANPRM, we posed a number of questions regarding the labeling of processing or fining aids containing allergens.

In response to these questions, a few commenters expressed opposition to required labeling of allergenic processing or fining

agents, arguing that there is a lack of clinical evidence that the trace amounts of allergenic fining agents in wine are harmful. For example, Kendall-Jackson Wine Estates asserted that the fining agents used in wine (such as egg whites and isinglass) are substantially altered during the production process. This comment stated that the tertiary structure of the molecule is changed and precipitated out, making it virtually impossible for an adverse reaction to occur.

An individual who commented as both a parent and a wine chemist stated that he agreed with listing allergens that are added to the wine as part of the formula, but stated that processing aids, such as sodium casein, should not be required to be listed unless evidence establishes that they remain in the wine. He also noted that wine makers use different processing aids every year depending on the wines, and asked whether such wineries would be able to list the processing aid on a label as, for example, ``sodium casein may have been used in clarifying this wine.''

In contrast, many other commenters suggested that it was important to label fining and processing agents. For example, CSPI commented that if not subject to an exemption, consumers will expect fining, processing, and filtering agents to be labeled in the same way as any other major food allergen is labeled under FALCPA. CSPI further noted that under exemption procedures in FALCPA, the burden is on the manufacturer to present scientific evidence that justifies a labeling exemption for a major food allergen that is present in very small amounts. CSPI suggested that we should adopt the same exemption procedures in our regulations and that, unless such fining or processing agents are officially exempted, labeling of these agents should be required.

Dr. Elizabeth TePas, a medical researcher at Massachusetts General Hospital, also stressed the importance of the labeling of fining and processing agents. She stated, ``While most food allergic individuals are not going to react to the minute amounts of allergen found in some alcoholic beverages, those who are extremely sensitive can have life-threatening reactions.'' She suggested that until thresholds are scientifically established and affordable and reliable testing is available, both allergens used as primary ingredients and allergens used as fining and processing agents should be disclosed on the label.

Several other commenters also supported the assertion that individuals can possibly have an adverse reaction to mere traces of an allergen. For example, a comment from the American Academy of Allergy, Asthma & Immunology, the American College of Allergy, Asthma & Immunology, and the Food Allergy & Anaphylaxis Network stated that ingestion of even small amounts of an allergen can elicit adverse reactions.

While a few industry members commented that fining and processing agents are not present in finished products, other industry commenters acknowledged that wine treated with fining and processing agents may contain trace amounts of those fining agents in the final product. For example, the Winemakers Federation of Australia advised that most processing aids, if used and removed according to good manufacturing practice, will leave negligible residual in the final product. This

comment also stated that in Australia, processing aids must be labeled unless they cannot be detected in the final product. The California Association of Winegrape Growers also noted in its comment that wine may contain trace amounts of some fining and filtering aids that were used in production, although the comment opposed a requirement to label such trace amounts in the absence of threshold level guidance from FDA.

Dr. Rogers and Dr. TePas both supported the labeling of fining agents. However, they both commented that it would be helpful for consumers of alcohol beverages to have a way to differentiate between those allergens used as primary ingredients (and therefore present at higher concentrations in the finished product) and those allergens used as fining or processing aids (and therefore present at lower concentrations in the finished product).

However, Dr. Rogers, the European Spirits Organisation, and the trade associations' consolidated comment noted that it is important for consumers to trust that the allergen labeling information on labels is reliable. Dr. Rogers, for example, stated, ``An indication that a particular beverage `may contain egg protein' potentially complicates the issue. It leaves the question open as to whether the allergen is or is not in the beverage.'' She further indicated that such statements may be ignored by consumers based upon prior experience consuming the food product in question without incident. The trade associations' consolidated comment similarly stated: ``Consumers need to trust that the allergen labeling information is reliable and not be subjected to precautionary statements where the statement will be ignored based upon, for example, prior experience consuming the food product in question.''

TTB Response

FALCPA amends the FD&C Act to require that, notwithstanding any other provision of law, a flavoring, coloring, or incidental additive that is or bears or contains a major food allergen must conform to FALCPA's labeling requirements. See 21 U.S.C. 343(w)(4). The FDA regulations define the term ``incidental additive'' to include, among other things, processing aids. See 21 CFR 101.100(a)(3). Accordingly, the proposed rule treats major food allergens used as fining or processing agents in the same way as any other major food allergen used in the production of the alcohol beverage.

In response to one commenter's assertion that fining agents are substantially altered during the production process, making it virtually impossible for an adverse reaction to occur, we have seen no scientific or clinical evidence that supports the assertion that an adverse reaction is ``virtually impossible.'' We welcome the submission of any such evidence as part of this rulemaking.

In response to the comments on different labeling for fining and processing aids, we are proposing that fining and processing aids be labeled in the same way as any other major food allergens used in the production of an alcohol beverage. However, we are specifically soliciting comments on whether fining and processing aids should be labeled with a different statement, for example, ``processed with'' instead of ``contains.''

One commenter asked whether TTB would allow a winery to use a ``may

contain'' label for processing aids, given the fact that a winery may use different processing aids every year for different wines. We believe using a ``may contain'' statement for fining or processing aids that were intentionally added to a product would be unclear and misleading. Instead, the label should clearly indicate what processing

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aids containing major food allergens were actually used in production of the alcohol beverage. It is the producer's obligation to know what processing aids were used for particular products.

E. Comments Regarding the Setting of Thresholds for Each Major Food Allergen

In the ANPRM, we asked several questions regarding the setting of threshold levels for each of the major food allergens.

Several industry commenters suggested that additional study is required to establish threshold levels before TTB requires the labeling of major food allergens, particularly allergens used as fining agents or other processing aids. For example, Ketel One Vodka argued that additional study is required to ascertain how the various levels of major food allergens may affect alcohol beverage consumers, and only once threshold levels are established should producers of alcohol beverages be required to disclose the presence of major food allergens. The California Association of Winegrape Growers also commented that it would be premature for TTB to take any action on allergen labeling until FDA establishes thresholds or provides guidance for the labeling of processing aids based on scientifically meaningful data.

CSPI, however, noted in its comment that in enacting FALCPA, Congress recognized that thresholds for the eight major food allergens had not yet been established by the scientific community. CSPI noted that Congress also rejected an automatic exemption for allergens that may be present in very small amounts. See House committee report at 17 and the Senate Committee on Health, Education, Labor, and Pensions report on FALCPA, S. Rep. No. 226, 108th Cong., 2d Sess., at 7 (2004) (hereafter the Senate committee report).

Two medical researchers also noted the lack of threshold data for the major food allergens. Dr. TePas explained in her comments that ``while there is some data available on the lowest observed adverse effect level (LOAEL) for the major food allergens, data on non-observed adverse effect levels (NOAEL) is scant to absent.'' Dr. Rogers also noted that no scientific consensus on ``safe'' threshold levels currently exists. Her comment suggested that it is not possible to define a minimum threshold that would assure the most sensitive individuals that a reaction would not occur.

Additionally, Dr. TePas suggested that alcohol may lower the threshold for having a reaction when an allergic individual is exposed to an allergen to which they are sensitized, which could impact the NOAEL and LOAEL. Dr. Rogers also stated that some components of alcohol beverages can heighten the allergic response.

TTB Response

FALCPA amends the FD&C Act to require that, notwithstanding any other provision of law, all flavoring, coloring, or incidental additives that bear or contain a major food allergen must be labeled. See 21 U.S.C. 343(w)(4), as amended. The FALCPA amendments, which took effect for foods labeled on or after January 1, 2006, require allergen labeling for foods regulated by FDA without the establishment of any threshold levels for labeling. Furthermore, pursuant to our authority under the FAA Act to ensure that labels provide consumers with adequate information about the identity and quality of alcohol beverage products, the proposed regulations provide that all major food allergens and proteins derived from the major food allergens used in production must be declared on the beverage label, unless the product or class of products is covered by an approved petition for exemption. Accordingly, TTB is not proposing to set thresholds in this notice of proposed rulemaking.

TTB believes that this position will ensure that consumers have adequate information about the potential presence of even trace amounts of major food allergens in alcohol beverage products. As more accurate scientific data become available in the future, we may revisit the threshold issue as appropriate.

F. Comments on Harmonization With Foreign Government Requirements and With Other Federal Agency Requirements

In addition to the specific questions on allergen labeling in the ANPRM, we asked broad questions related to all labeling changes at issue. One of those questions was whether TTB should harmonize its labeling requirements with those of other major producing nations such as the Member States of the European Union (EU), Australia, and Canada, and with the regulatory schemes of other Federal agencies such as FDA. We also asked how such harmonization would be best achieved.

In response to this question, most commenters who addressed this issue, including industry members and consumer advocates, suggested that we should be consistent with FDA on allergen labeling requirements and decisions related to those requirements.

The trade associations' consolidated comment urged us to work in tandem with FDA to implement allergen labeling requirements for alcohol beverages in a manner that meets the objectives of Congress. The consolidated comment also encouraged TTB to pay ``due regard to the actions taken by the [EU] regarding what products do or do not require labeling under the EU Allergen Directive (2003/89/EC).''

On November 25, 2003, the European Commission amended the rules regarding labeling of foodstuffs (including alcohol beverages) to require the mandatory labeling of specified food allergens. The allergens subject to this directive are cereals containing gluten, Crustacean shellfish, eggs, fish, peanuts, soybeans, milk, tree nuts, celery, mustard, sesame seeds, and sulphites at concentrations of more than 10 mg/kg. See Directive 2003/89/EC, amending Directive 2000/13/EC.

In the amendments, the Commission provided an avenue for provisional exclusion of particular ingredients and substances derived from allergens to allow manufacturers or their associations to conduct scientific studies to establish that those ingredients or products are

not likely, under specific circumstances, to trigger adverse reactions. The Commission, after receiving notice of several scientific studies and after consultation with the European Food Safety Authority, provisionally excluded eight uses of major food allergens in alcohol beverages until November 25, 2007. See Commission Directive 2005/26/EC. These eight uses are:

1. Distillates made from cereals containing gluten;
2. Distillates made from whey (milk);
3. Distillates made from nuts;
4. Lysozyme (egg) used in wine;
5. Albumen (egg white) used as a fining agent in wine and cider;
6. Fish gelatin or Isinglass used as a fining agent in beer, cider, or wine;
7. Milk (casein) products used as fining agents in cider and wines; and
8. Nuts used as flavor in spirits.

In their consolidated comment, the major U.S. alcohol beverage industry trade associations urged TTB to ``follow the approach taken by the EU that excludes categories of products that are produced and/or processed in a similar manner, i.e. the exclusions from the allergen labeling requirement are linked to the specific methods of manufacture and/or uses identified in the documentation supporting the exclusions.''

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TTB Response

The proposed rule is generally consistent with the requirements of FALCPA, although, as noted in this document, there are certain areas in which we have proposed to provide for different rules applicable to the labeling of major food allergens used in the production of alcohol beverages. TTB is not proposing a provisional exclusion for any ingredients or substances at this time. We do, however, agree that any exemptions from allergen labeling should apply to categories of products that are produced in an identical manner, and the proposed regulations so provide.

III. Proposed Regulatory Changes

After careful consideration of the comments received on allergen issues in response to the ANPRM, TTB has determined that it should propose rules for the mandatory labeling of major food allergens used in the production of alcohol beverages. Consistent with the guidance expressed in the House committee report and with our statutory mandate under the FAA Act to promulgate regulations ensuring that consumers receive adequate information about the identity and quality of alcohol beverages, we believe that alcohol beverage labels should provide consumers with sufficient information about the use of major food allergens in the production of alcohol beverages so that allergic consumers may make an informed decision as to whether consumption of a particular beverage may pose a risk of an allergic reaction.

The proposed regulatory changes set forth in this document would

amend parts 4, 5, and 7 of the TTB regulations to set forth requirements for mandatory labeling of major food allergens. These changes include the addition of a new paragraph (d) in Sec. 4.32, a new paragraph (b)(6) in Sec. 5.32, and a new paragraph (b)(5) in Sec. 7.22. These sections list mandatory label information for alcohol beverage products, and the added texts in each case direct the reader to a new section added to part 4, 5, or 7. These new sections, Sec. Sec. 4.32a, 5.32a, and 7.22a, set forth specific, detailed requirements for major food allergen labeling of wines, distilled spirits, and malt beverages, respectively. Finally, we propose to add three new sections, Sec. Sec. 4.32b, 5.32b, and 7.22b, to set forth procedures for the submission and approval of petitions for exemption from the new major food allergen labeling requirements. A detailed discussion of the specific proposed regulatory amendments follows.

A. Labeling of Major Food Allergens

1. Definitions

Consistent with the FALCPA amendments, the proposed regulations provide that when allergen labeling is required on an alcohol beverage product, the product must be labeled ``Contains:'' followed by the name of the food source from which each major food allergen is derived, as set forth in the definition of ``major food allergen.''

The definition of the term ``major food allergen'' is consistent with the statutory definition in FALCPA. The proposed regulations define the term ``major food allergen'' as any of the following: ``Milk, egg, fish (for example, bass, flounder, or cod), Crustacean shellfish (for example, crab, lobster, or shrimp), tree nuts (for example, almonds, pecans, or walnuts), wheat, peanuts, and soybeans.'' The term as defined also includes any food ingredient that contains protein derived from one of these eight foods or food groups, subject to certain exceptions explained below.

It should be noted that, consistent with guidance provided by FDA to the food industry, the proposed regulations allow the terms ``soybean,'' ``soy,'' and ``soya'' as synonyms for the term ``soybeans,'' as used in the statute. Furthermore, also consistent with FDA guidance, the singular term ``peanut'' may be substituted for the plural term ``peanuts,'' and singular terms (for example, almond, pecan, or walnut) may be used in place of plural terms to describe the different types of tree nuts.

2. Labeling of Fish Species

FALCPA provides that in the case of tree nuts, the label must list the common name of the specific type of nut (for example, almonds, pecans, or walnuts). In the case of Crustacean shellfish, the label must list the name of the species of shellfish (for example, crab, lobster, or shrimp). Finally, in the case of fish, the FALCPA amendments provide that the name of the species of fish (for example, bass, flounder, or cod) must appear on the label.

The proposed regulations are consistent with the FALCPA amendments with respect to the labeling of tree nuts and Crustacean shellfish. However, for the reasons explained below, the proposed regulations set forth in this document would not require labeling of the specific fish

species. The proposed regulations would instead require simply listing ``fish'' when any type of finfish protein is used in the production of an alcohol beverage.

Isinglass and fish gelatin are often used to clarify wines and beers. Isinglass is a substance obtained from the swim bladders of sturgeon and other fish. Fish gelatin is obtained from the skin of a fish. Fish gelatin most often is made from cod skins but can be made from any species of fish.

Vintners and brewers, when purchasing isinglass or fish gelatin from a manufacturer for fining purposes, often do not know, and have no way of easily finding out, which particular species of fish was used to make the product. Moreover, it may be difficult for industry members to determine by chemical analysis which particular fish species was the source of the isinglass or fish gelatin.

On August 1, 2005, the Flavor and Extract Manufacturers Association of the United States (FEMA) submitted a request to FDA for guidance concerning the labeling of fish species under the FALCPA amendments. In its request for guidance, FEMA asked FDA to allow for use of the term ``fish'' for labeling ``non-nutritive fish ingredients'' used in flavors. FEMA cited clinical and scientific evidence in support of its argument that many fish-allergic individuals will react adversely to more than one species of fish.

TTB recognizes that the FALCPA amendments require the labeling of the particular species of fish used as an ingredient in a food product. However, it is our responsibility to implement allergen labeling regulations that are appropriate for alcohol beverages. It is likely that declarations of the use of fish in the production of alcohol beverages will generally involve the use of isinglass or fish gelatin as a processing aid. Because of the particular difficulty faced by the producer in determining the specific species of fish used in producing the isinglass or fish gelatin, and because at least some consumers may be allergic to more than one species of fish, TTB is persuaded that requiring labeling with the name of the specific type of fish would impose a difficult fact-finding burden on the alcohol beverage industry without offering consumers who may be allergic to more than one species of fish any significant additional information to help them avoid the risk of an allergic reaction. Accordingly, we believe that the goal of the FALCPA amendments with respect to alcohol beverages is adequately met if alcohol beverages produced using finfish protein are labeled merely with ``fish,'' rather than with the name of the fish species.

We would note that the data on this matter are not conclusive, and we are specifically inviting comments on this issue.

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3. Processing and Fining Agents

FALCPA amends the FD&C Act to require that, notwithstanding any other provision of law, a flavoring, coloring, or incidental additive that is or bears or contains a major food allergen must conform to FALCPA's labeling requirements. See 21 U.S.C. 343(w)(4). As previously explained, the FDA regulations define the term ``incidental additive'' to include, among other things, processing aids. See 21 CFR

101.100(a)(3). Therefore, the proposed regulations treat major food allergens used as fining or processing agents in the same way as any other major food allergen used in the production of an alcohol beverage.

4. Threshold Levels

The FALCPA amendments, which took effect for foods labeled on or after January 1, 2006, require allergen labeling for foods regulated by FDA without the establishment of any threshold levels for labeling. Furthermore, pursuant to our authority under the FAA Act to ensure that labels provide consumers with adequate information about the identity and quality of alcohol beverage products, the proposed rule provides that all major food allergens and proteins derived from the major food allergens used in production must be declared on the beverage label, unless the product or class of products is covered by an approved petition for exemption. Accordingly, TTB is not proposing to set thresholds.

TTB believes that this position will ensure that consumers have adequate information about the potential presence of even trace amounts of major food allergens in alcohol beverage products. As more accurate scientific data become available in the future, we may revisit the threshold issue as appropriate.

B. Exceptions From Allergen Labeling Requirements

The proposed regulations contain three exceptions from major food allergen labeling. Two of these exceptions are provided within the definition of ``major food allergen,'' and the third is an exemption through a TTB petition process.

1. Highly Refined Oil

The FALCPA amendments exclude from the definition of ``major food allergen'' any highly refined oil derived from one of the eight foods or food groups listed in that definition and any ingredient derived from such highly refined oil. The Senate committee report at page 7 indicates that the exception for highly refined oils was intended to apply to refined, bleached, deodorized (RBD) oils. Both the House committee report at page 16 and the Senate committee report at page 7 specifically identify peanut oil as one of the highly refined oils covered by the exception. We believe this exception from labeling for highly refined oils is also appropriate in the case of alcohol beverages, and we therefore have included this as an exception from the definition of a major food allergen in the proposed regulatory texts.

2. Exemptions Under the FD&C Act

FALCPA added two processes to the FD&C Act at 21 U.S.C. 343(w)(6) and (7) by which any person may obtain an exemption from the allergen labeling requirements imposed by the statute.

Subsection (w)(6) allows any person to petition the Secretary of Health and Human Services to exempt a food ingredient from the allergen labeling requirements. Under its delegated authority, FDA performs the function of the Secretary in this area. In this situation, the burden is on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that the food ingredient, as derived by the method specified in the

petition, does not cause an allergic response that poses a risk to human health. FDA must approve or deny any such petition within 180 days of receipt or the petition will be deemed denied, unless an extension is mutually agreed upon by FDA and the petitioner.

Subsection (w)(7) allows any person to file a notification containing scientific evidence demonstrating that an ingredient ``does not contain allergenic protein.'' The scientific evidence must include the analytical method used to produce the evidence that the ingredient, as derived by the method specified in the notification, does not contain allergenic protein. Alternatively, the notification may contain a determination from FDA under a premarket approval or notification program provided for in section 409 of the FD&C Act (21 U.S.C. 348) that the ingredient does not cause an allergic response that poses a risk to human health. FDA has 90 days to object to a notification. Absent an objection, the food ingredient is exempt from the FDA labeling requirements for major food allergens.

Many ingredients and food additives used in the production of foods regulated by FDA are also used in the production of alcohol beverages regulated by TTB. Under the two exemption processes described above, certain ingredients and food additives may be exempted from the allergen labeling requirements of the FD&C Act. We believe it is appropriate to allow alcohol beverage industry members to rely on the exemptions from major food allergen labeling requirements allowed under the FD&C Act and FDA procedures. We have therefore included in the proposed definition of ``major food allergen'' an exception for uses of food ingredients that are exempt pursuant to 21 U.S.C. 343(w)(6) or (7).

It is important to note in this regard that alcohol beverage industry members would have to consider two issues when determining whether an ingredient exempted under the FD&C Act is also not subject to TTB allergen labeling requirements under TTB's proposed regulations. First, the ingredient they used or intend to use in a product must be the same ingredient that is exempt under the FD&C Act. Second, the proposed use must be consistent with any conditions of use in the FD&C Act exemption for the ingredient.

3. Petitions for Exemption From TTB Regulations

We also recognize that major food allergens are used in alcohol beverage production in ways that may differ from the way they are used in the production of foods regulated by FDA. For this reason, proposed sections 4.32a, 5.32a, and 7.22a refer in each case to an exception for a product covered by a petition for exemption approved under new section 4.32b, 5.32b, or 7.22b. A petition may pertain to the use of a major food allergen in the production of one specific alcohol beverage product or it may pertain to a class of products using a particular process involving a major food allergen.

As stated above, TTB's jurisdiction extends to the labeling of wines, distilled spirits, and malt beverages. Accordingly, under the proposed regulations, we only will accept a petition seeking an exemption from the labeling of a major food allergen when the material in question is used in the production of an alcohol beverage product regulated by TTB. If an exemption from the FD&C Act allergen labeling

requirements is also desired, the interested party would have to submit a petition or notification to FDA under 21 U.S.C. 343(w)(6) or (7), rather than submit a petition under the applicable TTB regulation.

The use of the TTB petition process under the proposed regulations is similar to that of the petition and notification processes provided for at 21 U.S.C. 343(w)(6) and (7), except that the TTB petition procedure focuses on

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products instead of ingredients. The TTB petition process could be used:

When it is asserted that the product or class of products, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health; or

When it is asserted that the product or class of products, as derived by the method specified in the petition, does not contain allergenic protein, even though a major food allergen was used in production.

The proposed TTB regulations provide for only a petition procedure, rather than both the petition procedure and the notification procedure provided for in the FALCPA amendments to the FD&C Act. We believe that having one petition procedure, rather than separate petition and notification procedures, will simplify the process for industry, and will allow our personnel adequate time to review the evidence presented in each request for an exemption. TTB is not in a position to administer a 90-day notice procedure similar to the notification procedure in subsection (w)(7) of the statute. The proposed regulation petition procedure is therefore similar to the petition procedure in subsection (w)(6) of the statute in that the regulation places the burden on the petitioner to provide evidence in support of the exemption and gives TTB 180 days to respond.

The proposed regulations provide that a petition for exemption from major food allergen labeling must be submitted to the appropriate TTB officer. The appropriate TTB officer to whom petitions would be submitted, if the regulations are adopted, is the Assistant Administrator, Headquarters Operations. Petitions should be sent to the Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Suite 200E, Washington, DC 20220 and should bear the notation: ``Attention: Petition for Exemption from Major Food Allergen Labeling'' to ensure prompt processing.

In addition, the proposed regulations provide that if TTB does not approve or deny the petition for exemption within 180 days of receipt, the petition is deemed denied, unless an extension of time is mutually agreed upon by TTB and the petitioner. The regulations also provide that a determination under this section constitutes a final agency action and that even though a petition is deemed denied because no action was taken within the 180-day period, the petitioner may resubmit the petition at any time. A resubmitted petition will be treated as a new petition.

As a result of FDA's implementation of FALCPA and our proposal of mandatory allergen labeling regulations, TTB and FDA will both be

regulating allergen labeling, with TTB overseeing labeling for alcohol beverages and FDA the labeling for all other products that are foods under the FD&C Act. As noted, TTB and FDA are parties to an MOU signed in 1987. That MOU provides that FDA and TTB will exchange information generally about appropriate labeling for, and the adulteration of, alcohol beverages, including information about methodologies and techniques for testing such beverages. Consistent with these general MOU provisions and both agencies' recognition that, generally, the regulation of allergen labeling should be consistent for alcohol beverages and all other foods, TTB intends to confer with FDA, as appropriate and as FDA resources permit, on petitions submitted under the proposed rule.

Consistent with FALCPA, the proposed rule places the burden on the petitioner to provide adequate evidence in its initial petition submission to justify an exemption from labeling. TTB may require the subsequent submission of product samples and other additional information in support of a petition; however, unless required by TTB, the submission of samples or additional information by the petitioner after submission of the petition will be treated as the withdrawal of the initial petition and the submission of a new petition.

FALCPA provides that FDA shall promptly post to a public site all petitions within 14 days of receipt and shall promptly post the Government's response to each. Our proposed regulations are consistent with FALCPA's requirement to make petitions and responses available to the public, but may go beyond the requirements of FALCPA in some respects. The proposed regulations provide that petitions submitted to TTB, and TTB's response to those petitions, will be posted to the TTB Web site (http://www.ttb.gov). However, TTB will not post lengthy

materials submitted in support of a petition on its Web site; we will, instead, make such materials available to the public in accordance with the procedures set forth in the Freedom of Information Act, 5 U.S.C. 552.

A person who provides trade secrets or other confidential commercial or financial information in either a petition for exemption or in any supporting documentation submitted in connection with such a petition would be able to request that TTB give confidential treatment to that information. The proposed regulations set forth the standards for making such a request. A failure to request confidential treatment at the time the information in question is submitted to TTB would constitute a waiver of confidential treatment.

C. Effective Date and Compliance With the Proposed Regulations

We note that in response to the ANPRM, some commenters urged TTB to require labeling of major food allergens for products labeled on or after January 1, 2006, which is the effective date of the FALCPA amendments. One commenter suggested that consumers will expect to see allergen information on alcohol beverage products at the same time that such information begins appearing on food labels under FALCPA, and that they may be misled by the absence of such information on labels of products that in fact contain major food allergens. Other commenters,

recognizing that it may take some time before a final rule is issued, suggested that TTB allow voluntary labeling of major food allergens pending the completion of rulemaking.

Given that the TTB regulations must be amended in order to implement allergen labeling, we believe it is appropriate to allow the public, including affected industry members, the opportunity to comment on allergen labeling standards before making them mandatory. Accordingly, we are issuing this notice in order to solicit comments on our proposed rules regarding mandatory allergen labeling of alcohol beverage products.

However, we have issued interim regulations to govern the voluntary labeling of major food allergens in alcohol beverage products and procedures for petitioning for an exemption from the standards imposed on those alcohol beverage producers who wish to make voluntary allergen statements on their product labels. These interim regulations, which are effective immediately, are published in the Rules and Regulations section of this Federal Register.

Several industry commenters suggested that we follow the compliance date approach taken in the sulfite labeling rulemaking. See T.D. ATF-236 (September 30, 1986, 51 FR 34706), in which ATF applied the dates for compliance in a three-step fashion over a one year period. However, for labeling of major food allergens, we believe a three-step compliance standard modeled after the sulfite rulemaking is not necessary. We believe that providing one delayed date for compliance, rather than three dates, would be easier to administer and would facilitate industry compliance. However, we are soliciting specific comments on what period of

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time industry needs to comply with allergen labeling requirements.

Although the proposed regulatory texts do not specifically address this issue, we anticipate that TTB would not require an industry member to apply for a new COLA for a product before adding major food allergen declarations to the label. We believe this policy would foster compliance and ease administrative burdens. Under such a policy, a COLA valid at the time the final rule went into effect would not become invalid because of the new regulatory texts. However, industry members may apply for new COLAs if they wish. They also would have an opportunity to obtain guidance from TTB on how to add these additional allergen statements to their labels.

IV. Public Participation

Comments Sought

We request comments from anyone interested in the proposed mandatory allergen labeling regulations set forth in this document. All comments must reference Notice No. 62 and include your name and mailing address. They must be legible and written in language acceptable for public disclosure. Although we do not acknowledge receipt, we will consider your comments if we receive them on or before the closing

date. We regard all comments as originals.

We are specifically soliciting comments on the following issues:

1. What would be the costs associated with mandatory allergen labeling to the industry and, ultimately, the consumer?

2. Does the proposed rule adversely impact small businesses? If so, explain how. If you are a small business and you expect that the proposed rule would have an adverse impact on you, please provide us with specific data on the expected adverse impact.

3. Are there ways in which the proposed regulations can be modified to reduce the regulatory burdens and associated costs imposed on the industry?

4. The proposed rule allows industry members a great deal of flexibility in the placement of mandatory allergen labeling statements. Does this flexibility reduce the costs of compliance? Would this flexibility interfere with the consumer's ability to locate the allergen declaration? Alternatively, should TTB mandate specific placement, type size, and presentation requirements for these labeling statements in addition to the requirements already applicable to all mandatory information on alcohol beverage labels? For example, should the required allergen disclosure statement be set off by a box? Should the statement of major food allergens be combined with existing required disclosures of FD&C Yellow No. 5, sulfites, and aspartame?

5. Do the proposed rules provide adequate information to consumers about the use of fining or processing agents? Should processing or fining agents be subject to a different labeling requirement, for example, a ``processed with'' labeling statement instead of a ``contains'' labeling statement? Would requiring a distinction between primary ingredients and fining and processing agents be informative to the consumer or would it mislead consumers? Would distinct labeling for processing and fining agents allow industry members to impart more specific information about the use of processing and fining aids?

6. Should mandatory allergen labeling statements for alcohol beverages disclose the specific species of fish, or is it sufficient to merely label the allergen as ``fish,'' as TTB proposes?

7. How much time does industry require to comply with mandatory food allergen labeling requirements? What delayed effective date would reduce the regulatory burdens on affected industry members and at the same time ensure the protection of consumers?

Confidentiality

All comments are part of the public record and subject to disclosure. Do not enclose any material in your comments that you consider confidential or inappropriate for public disclosure.

Submitting Comments

You may submit comments in any of five ways:

Mail: You may send written comments to TTB at the address listed in the ADDRESSES section of this document.

Facsimile: You may submit comments by facsimile transmission to 202-927-8525. Faxed comments must--

(1) Be on 8.5- by 11-inch paper;
(2) Contain a legible, written signature; and
(3) Be no more than five pages long. This limitation ensures electronic access to our equipment. We will not accept faxed comments that exceed five pages.

E-mail: You may e-mail comments to nprm@ttb.gov. Comments transmitted by electronic mail must--
(1) Contain your e-mail address;
(2) Reference Notice No. 62 on the subject line; and
(3) Be legible when printed on 8.5- by 11-inch paper.

Online form: We provide a comment form with the online copy of this document on our Web site at http://www.ttb.gov/alcohol/rules/index.htm. Select the ``Send comments via e-mail'' link under

Notice No. 62.

Federal e-Rulemaking Portal: To submit comments to us via the Federal e-rulemaking portal, visit http://www.regulations.gov and

follow the instructions for submitting comments.

You may also write to the Administrator before the comment closing date to ask for a public hearing. The Administrator reserves the right to determine whether to hold a public hearing.

V. Public Disclosure

You may view copies of this proposed rule document and any comments we receive by appointment at the TTB Information Resource Center at 1310 G Street, NW., Washington, DC 20220. You may also obtain copies at 20 cents per 8.5- x 11-inch page. Contact our information specialist at the above address or by telephone at 202-927-2400 to schedule an appointment or to request copies of comments.

We will post this document and any comments we receive on the TTB Web site. All name and address information submitted with comments, including e-mail addresses, will be posted. We may omit voluminous attachments or material that we consider unsuitable for posting. In all cases, the full comment will be available in the TTB Information Resource Center. To access the online copy of this document and the submitted comments, visit http://www.ttb.gov/alcohol/rules/index.htm.

Select the ``View Comments'' link under this document's number and title to view the posted comments.

VI. Regulatory Analysis and Notices

A. Executive Order 12866

We have determined that this proposed rule is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required.

B. Regulatory Flexibility Act

We certify under the provisions of section 3 of the Regulatory

Flexibility Act (5 U.S.C. 605(b)) that this proposed rule will not have a significant economic impact on a substantial number of small entities. Based on the comments we received in response to the advance notice of proposed rulemaking, we believe that the proposed rule will not impose, or otherwise cause, a significant increase in reporting, recordkeeping, or other compliance burdens on a substantial number of small entities. The proposed rule is not expected to have significant

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secondary or incidental effects on a substantial number of small entities.

We specifically solicit comments on the number of small producers, bottlers, and importers of alcohol beverages that may be affected by this proposed rule and the impact of this rule on those small businesses. We ask any small business that believes that it would be significantly affected by this proposed rule to let us know and to tell us how the rule would affect it.

C. Paperwork Reduction Act

This proposed rule includes a new collection of information involving the mandatory declaration of major food allergens on a front or back label and the voluntary submission of petitions for exemption from allergen rulemaking.

This collection of information has been submitted to the Office of Management and Budget (OMB) for review and approval under the Paperwork Reduction Act of 1995 pending receipt and evaluation of public comments. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

The collection of information is in Sec. Sec. 4.32, 4.32a, 4.32b, 5.32, 5.32a, 5.32b, 7.22, 7.22a, and 7.22b. The likely respondents are individuals and business or other for-profit institutions, including partnerships, associations, and corporations.

Estimated total annual reporting and/or recordkeeping burden: 3,700 hours.

Estimated average annual burden per respondent/ recordkeeper: 0.74 hours.

Estimated number of respondents and/or recordkeepers: 5,000.

Estimated annual number of responses: 5,020.

Comments on this collection of information may be sent by e-mail to OMB at Alexander_T._Hunt@omb.eop.gov, or by paper mail to Office of Management and Budget, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503. A copy should also be sent to TTB by any of the methods previously described. Comments should be submitted within the time frame that comments are due regarding the substance of the regulation.

Comments are invited on: (a) Whether the collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;

(b) the accuracy of the agency's estimate of the information collection burden; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the information collection burden on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimate of capital or start up costs and costs of operations, maintenance, and purchase of services to provide information.

VII. Drafting Information

The principal author of this document was Jessica M. Bungard, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau. However, other personnel participated in its development.

List of Subjects

27 CFR Part 4

Administrative practice and procedure, Advertising, Customs duties and inspection, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Trade practices, Wine.

27 CFR Part 5

Administrative practice and procedure, Advertising, Customs duties and inspection, Distilled spirits, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Trade practices.

27 CFR Part 7

Administrative practice and procedure, Advertising, Customs duties and inspection, Imports, Labeling, Malt Beverages, Reporting and recordkeeping requirements, Trade practices.

Amendments to the Regulations

For the reasons discussed in the preamble, TTB proposes to amend 27 CFR parts 4, 5, and 7 as follows:

PART 4--LABELING AND ADVERTISING OF WINE

1. The authority citation for 27 CFR part 4 continues to read as follows:

Authority: 27 U.S.C. 205.

2. In Sec. 4.32, paragraph (d), which is currently reserved, is added to read as follows:

Sec. 4.32 Mandatory label information.

* * * * *

(d) If a major food allergen as defined in Sec. 4.32a is used in the production of a wine, there shall be included on a label affixed to the container a statement as required by that section.

* * * * *

3. Section 4.32a is revised to read as follows:

Sec. 4.32a Major food allergens.

(a) Definitions. For purposes of this section the following terms have the meanings indicated.

(1) Major food allergen. Major food allergen means any of the following:

(i) Milk, egg, fish (for example, bass, flounder, or cod), Crustacean shellfish (for example, crab, lobster, or shrimp), tree nuts (for example, almonds, pecans, or walnuts), wheat, peanuts, and soybeans; or

(ii) A food ingredient that contains protein derived from a food specified in paragraph (a)(1)(i) of this section, except:

(A) Any highly refined oil derived from a food specified in paragraph (a)(1)(i) of this section and any ingredient derived from such highly refined oil; or

(B) A food ingredient that is exempt from major food allergen labeling requirements pursuant to a petition for exemption approved by the Food and Drug Administration (FDA) under 21 U.S.C. 343(w)(6) or pursuant to a notice submitted to FDA under 21 U.S.C. 343(w)(7), provided that the food ingredient meets the terms or conditions, if any, specified for that exemption.

(2) Name of the food source from which each major food allergen is derived. Name of the food source from which each major food allergen is derived means the name of the food as listed in paragraph (a)(1)(i) of this section, except that:

(i) In the case of a tree nut, it means the name of the specific type of nut (for example, almonds, pecans, or walnuts);

(ii) In the case of Crustacean shellfish, it means the name of the species of Crustacean shellfish (for example, crab, lobster, or shrimp); and

(iii) The names ``egg'' and ``peanuts,'' as well as the names of the different types of tree nuts, may be expressed in either the singular or plural form, and the term ``soy'', ``soybean'', or ``soya'' may be used instead of ``soybeans''.

(b) Labeling requirements. All major food allergens (defined in paragraph (a)(1) of this section) used in the production of a wine, including major food allergens used as fining or processing agents, must be declared on a label affixed to the container, except when subject to an approved petition for exemption described in Sec. 4.32b. The major food allergens declaration must consist of the word ``Contains'' followed by a colon and the name of the food source from which each major food

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allergen is derived (for example, ``Contains: egg'').

(c) Cross reference. For labeling requirements applicable to wines containing FD&C Yellow No. 5 and sulfites, see Sec. Sec. 4.32(c) and (e).

4. Section 4.32b is revised to read as follows:

Sec. 4.32b Petitions for exemption from major food allergen labeling.

(a) Submission of petition. Any person may petition the appropriate TTB officer to exempt a particular product or class of products from the labeling requirements of Sec. 4.32a. The burden is on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that the finished product or class of products, as derived by the method specified in the petition, either:

(1) Does not cause an allergic response that poses a risk to human health; or

(2) Does not contain allergenic protein derived from one of the foods identified in Sec. 4.32a(a)(1)(i), even though a major food allergen was used in production.

(b) Decision on petition. TTB will approve or deny a petition for exemption submitted under paragraph (a) of this section in writing within 180 days of receipt of the petition. If TTB does not provide a written response to the petitioner within that 180-day period, the petition will be deemed denied, unless an extension of time for decision is mutually agreed upon by the appropriate TTB officer and the petitioner. TTB may confer with the Food and Drug Administration (FDA) on petitions for exemption, as appropriate and as FDA resources permit. TTB may require the submission of product samples and other additional information in support of the petition; however, unless required by TTB, the submission of samples or additional information by the petitioner after submission of the petition will be treated as the withdrawal of the initial petition and the submission of a new petition. An approval or denial under this section will constitute a final agency action.

(c) Resubmission of a petition. After a petition for exemption is denied under this section, the petitioner may resubmit the petition along with supporting materials for reconsideration at any time. TTB will treat this submission as a new petition for purposes of the time frames for decision set forth in paragraph (b) of this section.

(d) Availability of information. (1) General. TTB will promptly post to its public Web site, http://www.ttb.gov, all petitions received under this section as well as TTB's responses to those petitions. Any information submitted in support of the petition that is not posted to the TTB Web site will be available to the public pursuant to 5 U.S.C. 552, except where a request for confidential treatment is granted under paragraph (d)(2) of this section.

(2) Requests for confidential treatment of business information. A person who provides trade secrets or other commercial or financial information in connection with a petition for exemption under this

section may request that TTB give confidential treatment to that information. A failure to request confidential treatment at the time the information in question is submitted to TTB will constitute a waiver of confidential treatment. A request for confidential treatment of information under this section must conform to the following standards:

(i) The request must be in writing;

(ii) The request must clearly identify the information to be kept confidential;

(iii) The request must relate to information that constitutes trade secrets or other confidential commercial or financial information regarding the business transactions of an interested person, the disclosure of which would cause substantial harm to the competitive position of that person;

(iv) The request must set forth the reasons why the information should not be disclosed, including the reasons the disclosure of the information would prejudice the competitive position of the interested person; and

(v) The request must be supported by a signed statement by the interested person, or by an authorized officer or employee of that person, certifying that the information in question is a trade secret or other confidential commercial or financial information and that the information is not already in the public domain.

PART 5--LABELING AND ADVERTISING OF DISTILLED SPIRITS

1. The authority citation for 27 CFR part 5 continues to read as follows:

Authority: 26 U.S.C. 5301, 7805, 27 U.S.C. 205.

2. In Sec. 5.32, paragraph (b)(6), which is currently reserved, is added to read as follows:

Sec. 5.32 Mandatory label information.

* * * * *

(b) * * *

(6) If a major food allergen as defined in Sec. 5.32a is used in the production of a distilled spirits product, a statement as required by that section.

* * * * *

3. Section 5.32a is revised to read as follows:

Sec. 5.32a Major food allergens.

(a) Definitions.

(1) Major food allergen. Major food allergen means any of the following:

(i) Milk, egg, fish (for example, bass, flounder, or cod), Crustacean shellfish (for example, crab, lobster, or shrimp), tree nuts

(for example, almonds, pecans, or walnuts), wheat, peanuts, and soybeans; or

(ii) A food ingredient that contains protein derived from a food specified in paragraph (a)(1)(i) of this section, except:

(A) Any highly refined oil derived from a food specified in paragraph (a)(1)(i) of this section and any ingredient derived from such highly refined oil; or

(B) A food ingredient that is exempt from major food allergen labeling requirements pursuant to a petition for exemption approved by the Food and Drug Administration (FDA) under 21 U.S.C. 343(w)(6) or pursuant to a notice submitted to FDA under 21 U.S.C. 343(w)(7), provided that the food ingredient meets the terms or conditions, if any, specified for that exemption.

(2) Name of the food source from which each major food allergen is derived. Name of the food source from which each major food allergen is derived means the name of the food, as listed in paragraph (a)(1)(i) of this section, except that:

(i) In the case of a tree nut, it means the name of the specific type of nut (for example, almonds, pecans, or walnuts);

(ii) In the case of Crustacean shellfish, it means the name of the species of Crustacean shellfish (for example, crab, lobster, or shrimp); and

(iii) The names ``egg'' and ``peanuts,'' as well as the names of the different types of tree nuts, may be expressed in either the singular or plural form, and the term ``soy'', ``soybean'', or ``soya'' may be used instead of ``soybeans''.

(b) Labeling requirements. All major food allergens (defined in paragraph (a)(1) of this section) used in the production of a distilled spirits product, including major food allergens used as fining or processing agents, must be declared on a label affixed to the container, except when subject to an approved petition for exemption described in Sec. 5.32b. The declaration must consist of the word ``Contains'' followed by a colon and the name of the food source from which each major food

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allergen is derived (for example, ``Contains: Egg'').

(c) Cross reference. For labeling requirements applicable to distilled spirits products containing FD&C Yellow No. 5 and sulfites, see Sec. Sec. 5.32(b)(5) and (b)(7).

4. Section 5.32b is revised to read as follows:

Sec. 5.32b Petitions for exemption from major food allergen labeling.

(a) Submission of petition. Any person may petition the appropriate TTB officer to exempt a particular product or class of products from the labeling requirements of Sec. 5.32a. The burden is on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that the finished product or class of products, as derived by the method

specified in the petition, either:

(1) Does not cause an allergic response that poses a risk to human health; or

(2) Does not contain allergenic protein derived from one of the foods identified in Sec. 5.32a(a)(1)(i), even though a major food allergen was used in production.

(b) Decision on petition. TTB will approve or deny a petition for exemption submitted under paragraph (a) of this section in writing within 180 days of receipt of the petition. If TTB does not provide a written response to the petitioner within that 180-day period, the petition will be deemed denied, unless an extension of time for decision is mutually agreed upon by the appropriate TTB officer and the petitioner. TTB may confer with the Food and Drug Administration (FDA) on petitions for exemption, as appropriate and as FDA resources permit. TTB may require the submission of product samples and other additional information in support of the petition; however, unless required by TTB, the submission of samples or additional information by the petitioner after submission of the petition will be treated as the withdrawal of the initial petition and the submission of a new petition. An approval or denial under this section will constitute a final agency action.

(c) Resubmission of a petition. After a petition for exemption is denied under this section, the petitioner may resubmit the petition along with supporting materials for reconsideration at any time. TTB will treat this submission as a new petition for purposes of the time frames for decision set forth in paragraph (b) of this section.

(d) Availability of information. (1) General. TTB will promptly post to its public Web site, http://www.ttb.gov, all petitions received

under this section as well as TTB's responses to those petitions. Any information submitted in support of the petition that is not posted to the TTB Web site will be available to the public pursuant to 5. U.S.C. 552, except where a request for confidential treatment is granted under paragraph (d)(2) of this section.

(2) Requests for confidential treatment of business information. A person who provides trade secrets or other commercial or financial information in connection with a petition for exemption under this section may request that TTB give confidential treatment to that information. A failure to request confidential treatment at the time the information in question is submitted to TTB will constitute a waiver of confidential treatment. A request for confidential treatment of information under this section must conform to the following standards:

(i) The request must be in writing;

(ii) The request must clearly identify the information to be kept confidential;

(iii) The request must relate to information that constitutes trade secrets or other confidential commercial or financial information regarding the business transactions of an interested person, the disclosure of which would cause substantial harm to the competitive position of that person;

(iv) The request must set forth the reasons why the information

should not be disclosed, including the reasons the disclosure of the information would prejudice the competitive position of the interested person; and

(v) The request must be supported by a signed statement by the interested person, or by an authorized officer or employee of that person, certifying that the information in question is a trade secret or other confidential commercial or financial information and that the information is not already in the public domain.

PART 7--LABELING AND ADVERTISING OF MALT BEVERAGES

1. The authority citation for 27 CFR part 7 continues to read as follows:

Authority: 27 U.S.C. 205.

2. In Sec. 7.22, paragraph (b)(5), which is currently reserved, is added to read as follows:

Sec. 7.22 Mandatory Label Information.

* * * * *

(b) * * *

(5) If a major food allergen as defined in Sec. 7.22a is used in the production of a malt beverage, a statement as required by that section.

* * * * *

3. Section 7.22a is revised to read as follows:

Sec. 7.22a Major food allergens.

(a) Definitions. For purposes of this section the following terms have the meanings indicated.

(1) Major food allergen. Major food allergen means any of the following:

(i) Milk, egg, fish (for example, bass, flounder, or cod), Crustacean shellfish (for example, crab, lobster, or shrimp), tree nuts (for example, almonds, pecans, or walnuts), wheat, peanuts, and soybeans; or

(ii) A food ingredient that contains protein derived from a food specified in paragraph (a)(1)(i) of this section, except:

(A) Any highly refined oil derived from a food specified in paragraph (a)(1)(i) of this section and any ingredient derived from such highly refined oil; or

(B) A food ingredient that is exempt from major food allergen labeling requirements pursuant to a petition for exemption approved by the Food and Drug Administration (FDA) under 21 U.S.C. 343(w)(6) or pursuant to a notice submitted to FDA under 21 U.S.C. 343(w)(7), provided that the food ingredient meets the terms or conditions, if any, specified for that exemption.

(2) Name of the food source from which each major food allergen is

derived. Name of the food source from which each major food allergen is derived means the name of the food as listed in paragraph (a)(1)(i) of this section, except that:

(i) In the case of a tree nut, it means the name of the specific type of nut (for example, almonds, pecans, or walnuts);

(ii) In the case of Crustacean shellfish, it means the name of the species of Crustacean shellfish (for example, crab, lobster, or shrimp); and

(iii) The names ``egg'' and ``peanuts,'' as well as the names of the different types of tree nuts, may be expressed in either the singular or plural form, and the term ``soy'', ``soybean'', or ``soya'' may be used instead of ``soybeans''.

(b) Labeling requirements. All major food allergens (defined in paragraph (a)(1) of this section) used in the production of a malt beverage product, including major food allergens used as fining or processing agents, must be declared on a label affixed to the container, except when subject to an approved petition for exemption described in Sec. 7.22b. The declaration must consist of the word ``Contains''

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followed by a colon and the name of the food source from which each major food allergen is derived (for example, ``Contains: egg'').

(c) Cross reference. For labeling requirements applicable to malt beverage products containing FD&C Yellow No. 5, sulfites, and aspartame, see Sec. Sec. 7.22(b)(4), (b)(6), and (b)(7).

4. Section 7.22b is revised to read as follows:

Sec. 7.22b Petitions for exemption from major food allergen labeling.

(a) Submission of petition. Any person may petition the appropriate TTB officer to exempt a particular product or class of products from the labeling requirements of Sec. 7.22a. The burden is on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that the finished product or class of products, as derived by the method specified in the petition, either:

(1) Does not cause an allergic response that poses a risk to human health; or

(2) Does not contain allergenic protein derived from one of the foods identified in Sec. 7.22a(a)(1)(i), even though a major food allergen was used in production.

(b) Decision on petition. TTB will approve or deny a petition for exemption submitted under paragraph (a) of this section in writing within 180 days of receipt of the petition. If TTB does not provide a written response to the petitioner within that 180-day period, the petition will be deemed denied, unless an extension of time for decision is mutually agreed upon by the appropriate TTB officer and the petitioner. TTB may confer with the Food and Drug Administration (FDA) on petitions for exemption, as appropriate and as FDA resources permit.

TTB may require the submission of product samples and other additional information in support of the petition; however, unless required by TTB, the submission of samples or additional information by the petitioner after submission of the petition will be treated as the withdrawal of the initial petition and the submission of a new petition. An approval or denial under this section will constitute a final agency action.

(c) Resubmission of a petition. After a petition for exemption is denied under this section, the petitioner may resubmit the petition along with supporting materials for reconsideration at any time. TTB will treat this submission as a new petition for purposes of the time frames for decision set forth in paragraph (b) of this section.

(d) Availability of information. (1) General. TTB will promptly post to its public Web site, http://www.ttb.gov, all petitions received

under this section as well as TTB's responses to those petitions. Any information submitted in support of the petition that is not posted to the TTB Web site will be available to the public pursuant to 5. U.S.C. 552, except where a request for confidential treatment is granted under paragraph (d)(2) of this section.

(2) Requests for confidential treatment of business information. A person who provides trade secrets or other commercial or financial information in connection with a petition for exemption under this section may request that TTB give confidential treatment to that information. A failure to request confidential treatment at the time the information in question is submitted to TTB will constitute a waiver of confidential treatment. A request for confidential treatment of information under this section must conform to the following standards:

(i) The request must be in writing;

(ii) The request must clearly identify the information to be kept confidential;

(iii) The request must relate to information that constitutes trade secrets or other confidential commercial or financial information regarding the business transactions of an interested person, the disclosure of which would cause substantial harm to the competitive position of that person;

(iv) The request must set forth the reasons why the information should not be disclosed, including the reasons the disclosure of the information would prejudice the competitive position of the interested person; and

(v) The request must be supported by a signed statement by the interested person, or by an authorized officer or employee of that person, certifying that the information in question is a trade secret or other confidential commercial or financial information and that the information is not already in the public domain.

Signed: February 16, 2006.
John J. Manfreda,
Administrator.

Approved: March 16, 2006.
Timothy E. Skud,

Deputy Assistant Secretary (Tax, Trade, and Tariff Policy).
[FR Doc. 06-6467 Filed 7-25-06; 8:45 am]

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