

Alcohol and Tobacco Tax and Trade Bureau, P.O. Box 14412, Washington, DC 20044-4412.

- *Hand Delivery/Courier*: You may hand-carry your comments or have them hand-carried to the Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Suite 200-E, Washington, DC 20005.

Please submit your comments by the closing date shown above in this notice. Your comments must reference Notice No. 109 and include your name and mailing address. Your comments also must be made in English, be legible, and be written in language acceptable for public disclosure. We do not acknowledge receipt of comments, and we consider all comments as originals.

If you are commenting on behalf of an association, business, or other entity, your comment must include the entity's name as well as your name and position title. If you comment via Regulations.gov, please enter the entity's name in the "Organization" blank of the online comment form. If you comment via postal mail, please submit your entity's comment on letterhead.

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.

C. Confidentiality

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

D. Public Disclosure

On the Federal e-rulemaking portal, Regulations.gov, we will post, and the public may view, copies of this notice and any electronic or mailed comments we receive about it. A direct link to the Regulations.gov docket containing this notice and the posted comments received on it is available on the TTB Web site at <http://www.ttb.gov/wine/wine-rulemaking.shtml> under Notice No. 109. You may also reach the docket containing this notice and its related comments through the Regulations.gov search page at <http://www.regulations.gov>.

All posted comments will display the commenter's name, organization (if any), city, and State, and, in the case of mailed comments, all address information, including e-mail addresses. We may omit voluminous attachments or material that we consider unsuitable for posting.

You and other members of the public may view copies of this notice and any electronic or mailed comments we receive on it by appointment at the TTB Information Resource Center, 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 202-453-2270 to schedule an appointment or to request copies of comments or other materials.

IV. Drafting Information

Lisa M. Gesser and Joanne C. Brady of the Regulations and Rulings Division drafted this notice.

Signed: May 13, 2010.

John J. Manfreda,
Administrator.

Approved: June 22, 2010.

Timothy E. Skud,
Deputy Assistant Secretary (Tax, Trade, and Tariff Policy).

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DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Parts 4, 5, and 7

[Docket No. TTB-2010-0008; Notice No. 111]

RIN 1513-AB79

Disclosure of Cochineal Extract and Carmine in the Labeling of Wines, Distilled Spirits, and Malt Beverages

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

ACTION: Notice of proposed rulemaking.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau is proposing to revise its regulations to require the disclosure of the presence of cochineal extract and carmine on the labels of any alcohol beverage product containing one or both of these color additives. This proposed rule responds to a recent final rule issued by the Food and Drug Administration as well as reports of severe allergic reaction, including anaphylaxis, to cochineal extract and carmine-containing foods. This proposal would allow consumers who are allergic to cochineal extract or carmine to identify and thus avoid alcohol beverage products that contain these color additives.

DATES: Comments must be received on or before January 3, 2011.

ADDRESSES: You may send comments on this notice to one of the following addresses:

- *http://www.regulations.gov*: Use the online comment form for this notice as posted within Docket No. TTB-2010-0008 at "Regulations.gov," the Federal e-rulemaking portal, to submit comments via the Internet;

- *Mail*: Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, P.O. Box 14412, Washington, DC 20044-4412; or

- *Hand Delivery/Courier in Lieu of Mail*: Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Suite 200-E, Washington, DC 20005.

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.

You may view copies of this notice and any comments we receive about it within Docket No. TTB-2010-0008 at <http://www.regulations.gov>. A direct link to this docket is posted under Notice No. 111 on the TTB Web site at http://www.ttb.gov/regulations_laws/all_rulemaking.shtml. You also may view copies of this notice and the comments we receive about it by appointment at the TTB Information Resource Center, 1310 G Street, NW., Washington, DC 20220. Please call 202-453-2270 to make an appointment.

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; or Joanne C. Brady, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, P.O. Box 45797, Philadelphia, PA 19149; telephone (215) 333-7050.

SUPPLEMENTARY INFORMATION:

I. TTB's Authority To Prescribe Alcohol Beverage Labeling Regulations

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), codified at 27 U.S.C. 205(e), sets forth standards for regulation of the labeling of wine (containing at least 7 percent alcohol by volume), distilled spirits, and malt beverages, generally referred to as "alcohol beverage products" throughout this notice. This section gives the Secretary of the Treasury the authority to issue regulations to prevent deception of the consumer, to provide the consumer with "adequate information" as to the identity and quality of the product, to prohibit false or misleading statements, and to provide information as to the alcohol content of the product. Section 105(e) of the FAA Act also

requires that a person obtain a certificate of label approval for all distilled spirits, wine, or malt beverages introduced into interstate or foreign commerce before bottling the product or removing the product from customs custody, in accordance with regulations prescribed by the Secretary.

The labeling provisions of the FAA Act also give the Secretary the authority to prohibit, irrespective of falsity, statements relating to age, manufacturing processes, analyses, guarantees, and scientific or irrelevant matters that are likely to mislead the consumer. In the case of malt beverages, the labeling provisions of the FAA Act apply only if the laws of the State into which the malt beverages are to be shipped impose similar requirements. TTB is responsible for the administration of the FAA Act and the regulations promulgated under it.

II. Background on Cochineal Extract and Carmine

Cochineal extract is an insect-derived color additive that is permitted for use in foods, including alcohol beverage products, and drugs in the United States. The related color additive carmine is permitted for use in foods, including alcohol beverage products, drugs, and cosmetics. The Food and Drug Administration (FDA) has listed these color additives, and conditions for their safe use in foods, in § 73.100 of title 21 of the Code of Federal Regulations (21 CFR 73.100).

On January 30, 2006, FDA published a proposed rule in the **Federal Register** (71 FR 4839) to amend its requirements for cochineal extract and carmine by requiring their declaration on the labels of all food and cosmetic products that contain these color additives. More specifically, for food products, FDA proposed to amend the color additive regulations that permit the use of cochineal extract or carmine in foods (21 CFR 73.100) by adding a new requirement that all foods which contain cochineal extract or carmine specifically declare that fact in the ingredient statement of the food label by using its respective common or usual name, "cochineal extract" or "carmine."

FDA explained that the proposal was issued in response to reports of severe allergic reactions, including anaphylaxis, to cochineal extract and carmine-containing foods and cosmetics. The proposal was also in response to a 1998 citizen petition from the Center for Science in the Public Interest, which asked the FDA to take action to protect consumers who are allergic to cochineal extract and carmine.

The preamble to FDA's proposed rule describes, in detail, several instances and studies in which allergic reactions occurred. One of the referenced articles described allergic reactions (including anaphylaxis) experienced by five patients after ingesting the alcohol beverage product Campari, which, according to FDA's preamble, contained carmine. All five patients were women; three had a history of allergic respiratory disease, one had only non-clinical sensitivity to mugwort, and one was nonatopic (had no history of allergy). The time period between ingestion and onset of allergic reaction was given for four patients and varied from 15 minutes to 30 minutes. Two of the five patients reportedly experienced "severe" anaphylactic reactions. Of these two, one required hospitalization while the other was treated with inhalers and intravenous antihistamine. The remaining three experienced angioedema (tissue swelling). See 71 FR 4842.

The preamble to FDA's proposed rule further explains as follows: "Allergic reactions to cochineal extract and/or carmine in a variety of foods (grapefruit juice, the alcohol beverage Campari, a popsicle, candy, yogurt, and artificial crabmeat) and [certain] cosmetics * * * have been reported in scientific and medical literature since 1961." 71 FR 4839-4840. Since 1994, FDA has received 11 adverse event reports of allergic reactions, including anaphylaxis, experienced by individuals after eating food or drinking a beverage containing cochineal extract or carmine, or using cosmetics colored with carmine.

FDA solicited comments from all interested parties in response to their proposal to require the listing of these color additives. As a result, FDA received a total of 159 responses.

On January 5, 2009, FDA published a final rule in the **Federal Register** (74 FR 207) which addressed the comments submitted and finalized the regulatory changes as proposed by adding a new requirement that all foods containing cochineal extract or carmine specifically declare that fact in the ingredient statement of the food label by using its respective common or usual name, "cochineal extract" or "carmine." The final rule takes effect on January 5, 2011.

In light of FDA's official recognition of evidence linking the presence of cochineal extract and carmine in foods and beverages to a health risk for a small percentage of consumers, TTB believes that it is appropriate to require the disclosure of cochineal extract and carmine on the labels of the alcohol

beverage products that it regulates. While TTB believes that the use of these color additives in the manufacture of alcohol beverage products is relatively rare, at least one such alcohol product contained the color additive carmine, as evidenced by the FDA's rulemaking record.

We also note that similar action has been taken in the past. On October 6, 1983, TTB's predecessor agency, the Bureau of Alcohol Tobacco and Firearms (ATF) published a final rule (T.D. ATF-150, 48 FR 45549), rescinding the ingredient labeling regulations for alcohol beverage products. However, mandatory label disclosure was required for alcoholic beverages containing the color additive FD&C Yellow No. 5. The Bureau found, as a result of its rulemaking effort, that there was evidence establishing that consumers of the few alcohol beverage products containing that color additive could have adverse reactions to the ingredient. Pursuant to T.D. ATF-150, the Bureau specifically stated that it "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 that regard, ATF published a final rule in the **Federal Register** requiring mandatory label disclosure of saccharin for alcoholic beverages containing that artificial sweetener (T.D. ATF-220; December 20, 1985, 50 FR 51851), which was subsequently removed as a requirement by TTB in 2004 (T.D. TTB-12; June 16, 2004, 69 FR 33572). ATF also published a final rule requiring label disclosure of sulfites when present in alcoholic beverages at a level of ten or more parts per million (T.D. ATF-236; September 30, 1986, 51 FR 34706).

In determining whether there is a need to require label disclosure of specific ingredients in alcoholic beverages, ATF traditionally utilized the expertise of the Food and Drug Administration (FDA). In 1987, FDA and ATF entered into a memorandum of understanding (52 FR 45502, November 30, 1987), to clarify the enforcement responsibilities of each agency with respect to alcohol beverages. ATF agreed that "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 would initiate rulemaking proceedings to promulgate labeling regulations for alcoholic beverages consistent with ATF's health policy with respect to alcoholic

beverages.” TTB operates under the same memorandum of understanding with FDA.

Accordingly, TTB proposes to amend the TTB regulations to require that each alcohol beverage product containing the color additive cochineal extract or carmine disclose that information on the product’s label.

III. Format and Placement of Disclosure

TTB proposes that all alcohol beverage products that contain the color additive cochineal extract or carmine must declare the presence of the additive on the brand label or on a back label, prominently and conspicuously, using its respective common or usual name “cochineal extract” or “carmine”. (For example: “Contains: Cochineal Extract” or “Contains carmine as a color additive.”).

IV. Implementation Date

TTB believes that this proposed new regulatory requirement will require revisions to the labels of very few alcohol beverage products. Accordingly, TTB proposes an implementation date of 90 days after the date the final rule is published in the **Federal Register**. Upon implementation of the final rule, the label of an alcohol beverage product subject to the requirement for disclosure of cochineal extract and carmine would have to bear the mandatory statement at the time of its removal from bond or from customs custody in bottles. TTB seeks comments from affected industry members as to whether 90 days is a sufficient amount of time to incorporate these changes.

V. Public Participation

A. Comments Invited

We invite comments from interested members of the public on this proposed rulemaking.

B. Submitting Comments

You may submit comments on this notice by using one of the following three methods:

- **Federal e-Rulemaking Portal:** You may send comments via the online comment form linked to this notice in Docket No. TTB–2010–0008 on “Regulations.gov,” the Federal e-rulemaking portal, at <http://www.regulations.gov>. Direct links to the comment form and docket are available under Notice No. 111 on the TTB Web site at http://www.ttb.gov/regulations_laws/all_rulemaking.shtml. Supplemental files may be attached to comments submitted via Regulations.gov. For information on how to use Regulations.gov, click on the site’s Help or FAQ tabs.

- **U.S. Mail:** You may send comments via postal mail to the Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, P.O. Box 14412, Washington, DC 20044–4412.

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information, including e-mail addresses. We may omit voluminous attachments or material that we consider unsuitable for posting.

You and other members of the public may view copies of this notice, all related petitions, maps and other supporting materials, and any electronic or mailed comments we receive about this proposal by appointment at the TTB Information Resource Center, 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 202–453–2270 to schedule an appointment or to request copies of comments or other materials.

VI. Regulatory Analysis and Notices

A. Regulatory Flexibility Act

We certify under the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. We believe that the proposed rule, if adopted, will not impose, or otherwise cause, a significant increase in reporting, recordkeeping, or other compliance burdens on a substantial number of small entities as very few alcohol beverages are made using cochineal extract or carmine as color additives. 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 submit a comment and explain how the rule would affect it.

B. 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.

C. Paperwork Reduction Act

The revisions to collections of information contained in this notice of proposed rulemaking have been submitted to the Office of Management and Budget (OMB) for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collection of information may be sent by e-mail to Shagufta_Ahmed@omb.eop.gov or by postal mail to Shagufta Ahmed, Office of Management and Budget, Attention: Desk Officer for the Department of the

Treasury, Office of Information and Regulatory Affairs, Room 10235, Washington, DC 20503. A copy should also be sent to the Alcohol and Tobacco Tax and Trade Bureau by any of the methods previously described. Because OMB must complete its review of the collection of information between 30 and 60 days after publication, comments on the information collection should be submitted not later than December 3, 2010. Comments are specifically requested concerning:

- Whether the proposed collections of information are necessary for the proper performance of the functions of the Alcohol and Tobacco Tax and Trade Bureau, including whether the information will have practical utility;
- The accuracy of the estimated burden associated with the proposed revision of the collection of information (see below);
- How to enhance the quality, utility, and clarity of the information to be collected;
- How to minimize the burden of complying with the proposed revision of the collection of information, including the application of automated collection techniques or other forms of information technology; and
- Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The collection of information in this proposed regulation is in 27 CFR Sections 4.32, 5.32, and 7.22, and involves mandatory disclosures of information on labels. This information is required to prevent deception of the consumer and to provide the consumer with adequate information as to the identity and quality of the alcohol beverage product. The likely respondents are businesses or other for-profit institutions, including partnerships, associations, and corporations.

This information constitutes only a portion of the labeling information on alcohol beverages required under authority of the Federal Alcohol Administration Act (FAA Act). OMB has previously approved a collection of information for Labeling and Advertising Requirements Under the FAA Act, under control number 1513-0087. The current burdens of this existing collection are:

- *Estimated Number of Respondents:* 7,071.
- *Estimated Total Annual Burden Hours:* 7,071.

Because the proposed disclosure required under this regulation would affect an extremely small number of respondents, the burden estimate

associated with this collection of information, in light of the collective burden, is minimal and is expected to contribute only a negligible additional burden beyond that already accounted for under control number 1513-0087.

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.

VII. Drafting Information

The principal authors of this document are Lisa M. Gesser and Joanne C. Brady, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau.

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.

For the reasons discussed in the preamble, TTB proposes to amend 27 CFR, chapter 1, parts 4, 5, and 7, as set forth below:

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, unless otherwise noted.

2. In § 4.32, paragraph (d) is added to read as follows:

§ 4.32 Mandatory label information.

* * * * *

(d) *Declaration of cochineal extract or carmine.* There shall be stated on the brand label or on a back label a statement that the product contains the color additive cochineal extract or carmine, prominently and conspicuously, using its respective common or usual name “cochineal extract” or “carmine,” where that

coloring material is used in a product removed on or after February 1, 2011. (For example: “Contains: Cochineal Extract” or “Contains carmine as a color additive” or, if applicable, “Contains: Cochineal Extract and Carmine.”).

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PART 5—LABELING AND ADVERTISING OF DISTILLED SPIRITS

3. 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.

4. In § 5.32, paragraph (b)(6) is added to read as follows:

§ 5.32 Mandatory label information.

* * * * *

(b) * * *
(6) A statement that the product contains the color additive cochineal extract or carmine, prominently and conspicuously, using its respective common or usual name “cochineal extract” or “carmine,” where that coloring material is used in a product removed on or after February 1, 2011. (For example: “Contains: Cochineal Extract” or “Contains carmine as a color additive” or, if applicable, “Contains: Cochineal Extract and Carmine.”).

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PART 7—LABELING AND ADVERTISING OF MALT BEVERAGES

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

Authority: 27 U.S.C. 205.

6. In § 7.22, paragraph (b)(8) is added to read as follows:

§ 7.22 Mandatory label information.

* * * * *

(b) * * *
(8) A statement that the product contains the color additive cochineal extract or carmine, prominently and conspicuously, using its respective common or usual name “cochineal extract” or “carmine,” where that coloring material is used in a product removed on or after February 1, 2011. (For example: “Contains: Cochineal Extract” or “Contains carmine as a color additive” or, if applicable, “Contains: Cochineal Extract and Carmine.”).

Signed: August 24, 2010.

John J. Manfreda,
Administrator.

Approved: August 30, 2010.

Timothy E. Skud,
Deputy Assistant Secretary (Tax, Trade, and Tariff Policy).

[FR Doc. 2010-27733 Filed 11-2-10; 8:45 am]

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