

mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that DEMADDEX (torsemide) injection, 20 mg/2 mL (10 mg/mL) and 50 mg/5 mL (10 mg/mL), was withdrawn for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list DEMADDEX (torsemide) injection, 20 mg/2 mL (10 mg/mL) and 50 mg/5 mL (10 mg/mL), in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to DEMADDEX (torsemide) injection, 20 mg/2 mL (10 mg/mL) and 50 mg/5 mL (10 mg/mL), may be approved by the agency if all other legal and regulatory requirements for the approval of ANDAs are met. If FDA determines that labeling for this drug product should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: August 7, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9-19641 Filed 8-14-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0268]

Draft Guidance for Industry: Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled "Guidance for Industry: Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration." This guidance, when finalized, will

provide industry with information on how to label beers that are subject to FDA's labeling laws and regulations. This draft guidance is being issued in light of the recent ruling by the Alcohol and Tobacco Tax and Trade Bureau (TTB) (formerly The Bureau of Alcohol, Tobacco, and Firearms (ATF)) clarifying that certain beers do not meet the definition of a "malt beverage" under the Federal Alcohol Administration Act (FAA Act). Because these beers are not subject to the labeling provisions of the FAA Act, they are subject to the labeling provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA). FDA, in this draft guidance, also reminds manufacturers that the labeling of wine beverages containing less than 7 percent alcohol by volume, such as wine coolers, diluted wine beverages, dealcoholized or partially dealcoholized wine and ciders, is also subject to FDA labeling requirements. FDA is also announcing an opportunity for public comment on the proposed collection of certain information by the agency.

DATES: Submit written or electronic comments on the draft guidance at any time. Submit written or electronic comments on the proposed collection of information by October 16, 2009.

ADDRESSES: Submit written comments on this draft guidance, including comments regarding the proposed collection of information, to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the draft guidance, including comments regarding the proposed collection of information, to <http://www.regulations.gov>. Submit written requests for single copies of the draft guidance to Office of Nutrition, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS-800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance:
Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2371.

With regard to the proposed collection of information: Jonna Capezuto, Office of Information Management

(HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3794.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the draft guidance entitled "Guidance for Industry: Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration." This guidance, when finalized, will provide industry with information on how to label beers that are subject to FDA's labeling laws and regulations. FDA, in this draft guidance, also reminds manufacturers that the labeling of wine beverages containing less than 7 percent alcohol by volume, such as wine coolers, diluted wine beverages, dealcoholized or partially dealcoholized wine and ciders, is also subject to FDA labeling requirements (Ref. 1).

As reflected in the 1987 Memorandum of Understanding between FDA and TTB's predecessor agency, the ATF (Ref. 2), TTB is responsible for the issuance and enforcement of regulations with respect to the labeling of distilled spirits, wines, and malt beverages under the FAA Act.

TTB recently clarified that certain beers, which are not made from both malted barley and hops but are instead made from substitutes for malted barley (such as sorghum, rice or wheat), or are made without hops do not meet the definition of a malt beverage under the FAA Act (see TTB Ruling 2008-3) (Ref. 3). TTB stated in its ruling that such products (other than sake, which is classified as a wine under the FAA Act) are not subject to the labeling, advertising, and other provisions of the TTB regulations issued under the FAA Act. Therefore, these beers are subject to the labeling requirements under FDA's laws and regulations. However, as explained in the TTB ruling, some TTB labeling requirements such as the Government Health Warning Statement under the Alcoholic Beverage Labeling Act and certain marking requirements under the Internal Revenue Code continue to apply to these products.

This draft guidance is intended to assist manufacturers in labeling beers that are subject to FDA's labeling laws and regulations. In general, FDA requires that food products under its labeling jurisdiction be truthfully and informatively labeled in accordance with the FD&C Act and the FPLA, and FDA's implementing regulations. These FDA labeling requirements are explained in the draft guidance document.

FDA is issuing this draft guidance as a level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and

assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration (OMB Control Number 0910–NEW)

This draft guidance is intended to assist manufacturers in labeling beers that are subject to FDA's labeling laws and regulations. All labeling regulations discussed in this draft guidance have been previously approved by OMB in accordance with the PRA under OMB Control No. 0910–0381. The regulations approved under OMB Control No. 0910–0381 include §§ 101.3, 101.4, 101.5, 101.9, 101.22, and 101.105 (21 CFR 101.3, 101.4, 101.5, 101.9, 101.22, and 101.105). The proposed information collection seeks to add manufacturers of certain beers that do not meet the definition of a "malt beverage" under the FAA Act as new respondents to these labeling regulations. The proposed information collection also seeks OMB approval of allergen labeling of these beers under section 403(w)(1) of the FD&C Act (21 U.S.C. 343(w)(1)), which was added by the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).

Section 101.3 of FDA's food labeling regulations requires that the label of a food product in packaged form bear a statement of identity, (i.e., the name of the product), including, as appropriate, the form of the food or the name of the food imitated. Section 101.4 prescribes

the requirements for the declaration of ingredients on the label or labeling of food products in packaged form, including using the common or usual name of each ingredient. Section 101.5 requires that the label of a food product in packaged form specify the name and place of business of the manufacturer, packer, or distributor and, if the food producer is not the manufacturer of the food product, its connection with the food product. Section 101.9 requires that nutrition information be provided for all food products intended for human consumption and offered for sale, unless an exemption in § 101.9(j) applies to the product. Section 101.22 contains labeling requirements for the disclosure of spices, flavorings, colorings, and chemical preservatives (§ 101.22(j)) in food products. Section 101.105 specifies requirements for the declaration of the net quantity of contents on the label of a food in packaged form.

Under the FD&C Act, as amended by the FALCPA, the food source name of any "major food allergen" present must be declared (section 403(w)(1) of the FD&C Act, (21 U.S.C. 343(w)(1))). Section 201(qq) of the FD&C Act, (21 U.S.C. 321(qq)), defines "major food allergen" as milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as any food ingredient that contains protein derived from one of them, with the exception of highly refined oils.

Description of respondents: The respondents to this collection of information are manufacturers of beers that are subject to FDA's labeling laws and regulations.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Citation	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
21 CFR 101.3 and 101.22	12	2	24	.5	12
21 CFR 101.4	12	2	24	1	24
21 CFR 101.5	12	2	24	0.25	6
21 CFR 101.9	12	2	24	4	96
21 CFR 101.105	12	2	24	0.5	12
Section 403(w)(1) of the Federal Food, Drug, and Cosmetic Act	12	2	24	1	24
Guidance Document, "Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration"	12	1	12	1	12

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

Citation	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total					186

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's estimate of the number of respondents in table 1 is based on the number of regulatory submissions submitted to TTB for beers that do not meet the definition of a "malt beverage" under the FAA Act. Based on its records of submissions received from manufacturers of such products, TTB estimates the number of respondents to be 12 and the number of submissions annually to be 25. Thus, FDA adopts TTB's estimate of 12 respondents, and an annual frequency per response of 2, in table 1 of this document.

FDA's estimate of the hours per response for each regulation is based on FDA's experience with food labeling under the agency's jurisdiction. The estimated hours per response for §§ 101.3, 101.4, 101.5, 101.9, 101.22, and 101.105 in table 1 of this document are equal to, and based upon, the estimated hours per response approved by OMB in OMB Control No. 0910-0381. FDA further estimates that the labeling burden of section 403(w)(1) of the FD&C Act, which specifies requirements for the declaration of food allergens, will be 1 hour based upon the similarity of the requirements to that of § 101.4. Finally, FDA estimates that a respondent will spend 1 hour reading the guidance document, once finalized.

Thus, FDA estimates that 12 respondents will each label two products annually, for a total of 24 labels. FDA estimates that the manufacturers will spend 7.25 hours (0.5 hours + 1 hour + 0.25 hour + 4 hours + 0.5 hour + 1 hour = 7.25 hours) on each label to comply with FDA's labeling regulations and the requirements of section 403(w)(1), for a total of 174 hours (24 labels x 7.25 hours = 174 hours). In addition, 12 respondents will each spend 1 hour reading the guidance document, for a total of 12 hours. Thus, FDA estimates the total hour burden of the proposed collection of information to be 186 hours (174 hours + 12 hours = 186 hours).

Before the proposed information collection provisions contained in this draft guidance become effective, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions. An agency may not conduct or sponsor, and

a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in §§ 101.3, 101.4, 101.5, 101.9, 101.22, and 101.105 have been approved under OMB Control No. 0910-0381.

III. Comments

Interested persons may submit written or electronic comments regarding this draft guidance document, including comments regarding the proposed collection of information. Written comments should be submitted to the Division of Dockets Management (see **ADDRESSES**). Electronic comments should be submitted to <http://www.regulations.gov>. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at <http://www.fda.gov/FoodGuidances>.

V. References

We have placed the following references on display in the Division of Dockets Management (see **ADDRESSES**). The references may be seen between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses, but it is not responsible for any subsequent changes to the Web site addresses after this document publishes in the **Federal Register**.

1. FDA Compliance Policy Guide (CPG) 7101.04 (Dealcoholized Wine and Malt Beverages- Labeling), available at <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074430.htm> and CPG 7101.05 (Labeling—Diluted Wines and Cider with Less Than 7% Alcohol), available at <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074431.htm>.

2. Memorandum of Understanding 225-88-2000 between FDA and Bureau of Alcohol, Tobacco and Firearms, available at <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116370.htm>.

3. TTB Ruling 2008-3 dated July 7, 2008, available at <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116370.htm>.

Dated: August 11, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9-19640 Filed 8-14-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of Federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Development of a New Carbohydrate Antibody to GalNac1-3Gal

Description of Technology: The present invention provides a monoclonal antibody that binds