

Dated: November 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0268]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 14, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–0728. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration

OMB Control Number 0910–0728—
Extension

The definition of “food” under the Federal Food, Drug, and Cosmetic Act

(FD&C Act) (see 21 U.S.C. 321(f)), includes “articles used for food or drink” and thus includes alcoholic beverages. As such, alcoholic beverages are subject to the FD&C Act’s adulteration and misbranding provisions and implementing regulations related to food. For example, manufacturers of alcoholic beverages are responsible for adhering to the registration of food facilities requirements in 21 CFR part 1 and to the good manufacturing practice regulations in 21 CFR part 110. There are also certain requirements for nutrition labeling on menus, menu boards, and other written materials for alcohol beverages served in restaurants or similar retail food establishments in 21 CFR part 101. However, as reflected in a 1987 Memorandum of Understanding between FDA and the Alcohol and Tobacco Tax and Trade Bureau (TTB), TTB is responsible for the dissemination and enforcement of regulations with respect to the labeling of distilled spirits, certain wines, and malt beverages issued in the Federal Alcohol Administration Act (FAA Act). In TTB Ruling 2008–3, dated July 7, 2008, TTB 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. Accordingly, TTB stated in its ruling that such products (other than saké, which is classified as a wine under the FAA Act), are not subject to the labeling, advertising, or other provisions of TTB regulations issued under the FAA Act.

In cases where an alcoholic beverage is not covered by the labeling provisions of the FAA Act, the product is subject to ingredient and other labeling requirements under the FD&C Act and the implementing regulations that we administer. In addition, as provided for under the Fair Packaging and Labeling Act (FPLA), alcoholic beverages that are not covered by the labeling provisions of the FAA Act are subject to the provisions of the FPLA, which we administer.

Therefore, the beers described in TTB’s ruling as not being a “malt beverage” are subject to the labeling requirements under the FD&C Act and FPLA, and our implementing regulations. In general, we require that food products under our jurisdiction be truthfully and informatively labeled in accordance with the FD&C Act, the FPLA, and FDA’s regulations. Furthermore, 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.

Persons with access to the internet may obtain the guidance entitled, “Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration,” located at <https://www.fda.gov/FoodGuidances>. This guidance is intended to assist manufacturers on how to label bottled or otherwise packaged beers that are subject to our labeling laws and regulations.

Our food labeling regulations under parts 101, 102, 104, and 105 (21 CFR parts 101, 102, 104, and 105) were issued under the authority of sections 4, 5, and 6 of the FPLA (15 U.S.C. 1453, 1454, and 1455) and under sections 201, 301, 402, 403, 409, 411, 701, and 721 of the FD&C Act (21 U.S.C. 321, 331, 342, 343, 348, 350, 371, and 379e). Most of these regulations derive from section 403 of the FD&C Act, which provides that a food product shall be deemed to be misbranded if, among other things, its label or labeling fails to bear certain required information concerning the food product, is false or misleading in any particular, or bears certain types of unauthorized claims. The disclosure requirements and other collections of information in the regulations in parts 101, 102, 104, and 105 are necessary to ensure that food products produced or sold in the United States are in compliance with the labeling provisions of the FD&C Act and the FPLA.

The primary user of the information to be disclosed on the label or labeling of food products is the consumer that purchases the food product. Consumers will use the information to assist them in making choices concerning their purchase of a food product, including choices related to substances that the consumer must avoid to prevent adverse reactions. This information also enables the consumer to determine the role of the food product in a healthful diet. Additionally, FDA intends to use the information to determine whether a manufacturer or other supplier of food products is meeting its statutory and regulatory obligations. Failure of a manufacturer or other supplier of food products to label its products in compliance with section 403 of the FD&C Act and parts 101, 102, 104, and 105 of FDA’s food labeling regulations may result in a product being misbranded under the FD&C Act, subjecting the firm and product to regulatory action.

Description of Respondents: The respondents to this collection of

information are manufacturers of beers that are subject to our labeling laws and regulations.

In the **Federal Register** of June 29, 2018 (83 FR 30738), FDA published a 60-day notice requesting public comment on the proposed collection of

information. Two comments were received. One comment was unrelated to the Paperwork Reduction Act and is not addressed. The second comment was in favor of the practical utility and necessity of labeling the ingredients of

beer for transparency to the consumer. We are appreciative of these comments. At this time, we do not plan on adjusting our current estimate.

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

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
§§ 101.3 and 101.22; principal display and display panel.	12	2	24	0.5 (30 minutes)	12
§ 101.4; designation of ingredients	12	2	24	1	24
§ 101.5; name of manufacturer; packer; distributor	12	2	24	0.25 (15 minutes)	6
§ 101.9; nutrition labeling	12	2	24	4	96
§ 101.7 (formerly 101.105); quantity of contents ...	12	2	24	0.5 (30 minutes)	12
Section 403(w)(1) of the FD&C Act	12	2	24	1	24
Review of Guidance Document: "Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration".	12	1	12	1	12
Total					186

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. Our estimate of the number of respondents is based on the number of regulatory submissions 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 annual number of respondents to be 12 and the annual number of disclosures to be 24. Thus, we adopt TTB's estimate of 12 annual respondents, and an annual number of disclosures per respondent of 2 in table 1.

Our estimates of the average burden per disclosure for each collection provision are based on our experience with food labeling under the Agency's jurisdiction. The estimated average burden per disclosure for §§ 101.3, 101.4, 101.5, 101.9, 101.22, and 101.105 in table 1 are equal to, and based upon, the estimated average burden per disclosure approved by OMB in OMB control number 0910-0381. We further estimate 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.

Thus, we estimate that 12 respondents will each label 2 products annually, for a total of 24 labels. We estimate 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 our labeling regulations and the requirements of section 403(w)(1) of the FD&C Act, for a total of 174 hours (24 labels × 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, we estimate the total hour burden of the proposed collection of information to be 186 hours (174 hours + 12 hours = 186 hours).

The guidance also refers to previously approved collections of information found in our 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 number 0910-0381. Allergen labeling of these beers under section 403(w)(1) of the FD&C Act, which was added by the Food Allergen Labeling and Consumer Protection Act of 2004, has been approved under OMB control number 0910-0792.

Dated: November 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-3931]

Nonmetastatic, Castration-Resistant Prostate Cancer: Considerations for Metastasis-Free Survival Endpoint in Clinical Trials; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Nonmetastatic, Castration-Resistant Prostate Cancer: Considerations for Metastasis-Free Survival Endpoint in Clinical Trials." This draft guidance provides recommendations to sponsors regarding the use of metastasis-free survival (MFS) as an endpoint in clinical trials for nonmetastatic, castration-resistant prostate cancer (nmCRPC) development programs for drug or biological products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

DATES: Submit either electronic or written comments on the draft guidance by January 14, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.