Affordable Care Act'' (83 FR 57592) expand exemptions for religious beliefs and moral convictions for certain entities or individuals whose health plans may otherwise be subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. The final regulations extend the exemption to health insurance issuers that hold religious or moral objections in certain circumstances, as well as to additional categories of group health plan sponsors.

The 2018 final regulations also leave the accommodation process in place as an optional process for objecting entities who wish to use it, and expand the categories of group health plan sponsors that may avail themselves of the accommodation. To avoid contracting, arranging, paying, or referring for contraceptive coverage, an organization seeking to be treated as an eligible organization may self-certify (by using EBSA Form 700), prior to the beginning of the first plan year to which an accommodation is to apply, that it meets the definition of an eligible organization. The eligible organization must provide a copy of its self-certification to each health insurance issuer that would otherwise provide such coverage in connection with the health plan (for insured group health plans or student health insurance coverage). The issuer that receives the self-certification must provide separate payments for contraceptive services for plan participants and beneficiaries (or students and dependents). For a self-insured group health plan, the self-certification must be provided to its third party administrator. An eligible organization may submit a notification to HHS as an alternative to submitting EBSA Form 700 to the eligible organization's health insurance issuer or third party administrator. A health insurance issuer or third party administrator providing or arranging payments for contraceptive services for participants and beneficiaries in plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations must provide a written notice to such plan participants and beneficiaries (or such student enrollees and covered dependents) informing them of the availability of such payments.

Under the 2018 final regulations, eligible organizations can revoke the accommodation process if participants and beneficiaries (or student enrollees and covered dependents) receive written notice of such revocation from the issuer or third party administrator, and such revocation will be effective on the first day of the first plan year that begins on or after thirty days after the date of revocation. Final regulations were published in the **Federal Register** on July 14, 2015 (80 FR 41318) under which qualifying closely held, for-profit entities may avail themselves of the accommodation. Previously, this accommodation had been available only to non-profit eligible organizations. The 2015 final regulations also finalized the 2014 interim final regulations that permit an eligible organization to notify HHS directly that it will not contract, arrange, pay, or refer for all or a subset of contraceptive services. These information collection requirements (ICRs) are intended for use under whichever accommodation process is in effect at the time an entity avails of it (for example, the 2018 final regulations, or the 2015 final regulations). HHS will only implement the ICRs under regulations that are legally in effect at the time the ICRs are used. *Form Number:* CMS–10653 (OMB Control number 0938–1344); *Frequency:* On Occasion; *Affected Public:* Private Sector; *Number of Respondents:* 60; *Number of Responses:* 595,312; *Total Annual Hours:* 72. (For policy questions regarding this collection, contact Usree Bandyopadhyay at 410–786–6650.)

Dated: November 16, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–25316 Filed 11–18–21; 8:45 am]

BILLING CODE 4120–01–P

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, Agency, or we) 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: Submit written comments (including recommendations) on the collection of information by December 20, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0728. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

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 (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 (the 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/regulatory-information/search-fda-guidance-documents/guidance-industry-labeling-certain-beers-subject-labeling-jurisdiction-food-and-drug-administration.* 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 May 21, 2021 (86 FR 27631), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received two comments pertaining to the necessity and practical utility of the information being collected and the accuracy of our burden estimate.

(Comment 1) One comment questioned the necessity and practical utility of treating beer as a ''food'' making it subject to food labeling regulations. A related comment questioned the need to label beer at all.

(Response) As stated in the guidance as well in the above-referenced 60-day notice, the definition of ''food'' under the FD&C Act (see 21 U.S.C. 321(f)), includes ''articles used for food or drink'' and thus includes alcoholic beverages. 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 are administered by FDA. In addition, as provided for under the FPLA, alcoholic beverages that are not covered by the labeling provisions of the FAA Act are subject to the provisions of the FPLA, which is administered by FDA.

Therefore, the beers described in the TTB's Ruling as not being a ''malt beverage'' are subject to the labeling requirements under the FD&C Act and FPLA, and FDA's implementing regulations. In general, FDA requires that food products under its jurisdiction be truthfully and informatively labeled in accordance with the FD&C Act, the FPLA, and FDA's regulations.

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.

(Comment 2) One comment argued that the burden estimate underestimated the number of respondents affected by this collection.

(Response) This collection of information applies to alcoholic beverages not covered by the labeling provisions of the FAA Act. 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.

We estimate 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; statement of identity labeling requirements	12	2	24	0.5 (30 minutes)	12
101.4; ingredient labeling requirements	12	2	24	1	24
101.5; requirement to specify the name and place of business of the manufacturer, packer, or distributor.	12	2	24	0.25 (15 minutes)	6
101.9; labeling requirements for disclosure of nutrition information	12	2	24	4	96
101.7; declaration of net quantity of contents	12	2	24	0.5 (30 minutes)	12
Section 403(w)(1) of the FD&C Act; declaration of food allergens	12	2	24	1	24
Guidance document entitled ''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.

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 101.7 (21 CFR 101.3, 101.4, 101.5, 101.9, 101.22, and 101.7) are equal to, and based upon, the estimated average burden per disclosure approved by 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, we estimate that a respondent will spend 1 hour reading the guidance.

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 101.7 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 15, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–25300 Filed 11–18–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1192]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Generally Recognized as Safe: Notification Procedure

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection associated with provisions of the notification procedure for substances generally recognized as safe (GRAS).

DATES: Submit either electronic or written comments on the collection of information by January 18, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 18, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 18, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as