retailers, such as supermarkets and restaurants, subject to statutory and regulatory food labeling requirements. Respondents are from the private sector (including for-profit businesses, not-for-profit institutions, and farms).

Collections of information found in §§ 101.8 and 101.11 also include vending machine operators and restaurants or other similar food establishments that are subject to the requirements of part 101 as well as those entities who voluntarily participate with the provisions through registration with FDA.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity using form FDA 3757; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Initial registration for Vending Machine Labeling; 101.8(d)	13	1	13	2	26
Biennial registration renewal for Vending Machine Labeling; 101.8(d)	20	1	20	*0.5	10
Initial registration for Menu Labeling; 101.11(d)	3,559	1	3,559	2	7,118
Registration renewal for Menu Labeling; 101.11(d)	5,340	1	5,340	*0.5	2,670
Total					9,824

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
* 30 minutes.

TABLE 2—ESTIMATED RECORDKEEPING BURDEN [1]

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Nutrition analysis; 101.11(c)	100,000	1	100,000	1	100,000

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

Our estimate of burden reflects adjustments. We have reorganized the information collection activities into reporting and recordkeeping categories, eliminating a separate summary burden estimate for third-party disclosure. As defined in 5 CFR 1320.3(m), recordkeeping is a requirement to maintain specified records and includes activities such as disclosure of these records to third parties, the Federal government, or the public. We believe that vending machine operators and covered establishments who must demonstrate compliance with statutory and regulatory requirements applicable to food labeling would retain requisite records as a usual and customary business practice. (See 5 CFR 1320.3(b)(2).) At the same time, we have modified our recordkeeping burden estimates to account for effort that may be necessary to retain, as well as to ''transmit or otherwise disclose [the] information,'' to the Federal government and/or third parties (see 5 CFR 1320.3(b)(1)(ix)) as required by the regulations to the extent that they reflect on activities applicable to §§ 101.8 and 101.11. Included in our estimated number of recordkeepers are those who voluntarily elect to register with FDA through submissions in accordance with §§ 101.8(d) and 101.11(d). Cumulatively, these adjustments result in a decrease of 1,399,306 hours and 7,370,090 responses annually to the information collection.

Dated: April 8, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–07661 Filed 4–10–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0026]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; DUVYZAT (givinostat)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that DUVYZAT (givinostat), approved on March 21, 2024, manufactured by Italfarmaco S.p.A., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that DUVYZAT (givinostat), manufactured by Italfarmaco S.p.A., meets the criteria for a priority review voucher. DUVYZAT (givinostat) oral suspension is indicated for the treatment of Duchenne muscular dystrophy in patients 6 years of age or older.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about DUVYZAT (givinostat), go to the ''*Drugs@FDA*''

website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: April 8, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–07657 Filed 4–10–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4849]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Allergen Labeling and Reporting

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: Submit written comments (including recommendations) on the collection of information by May 13, 2024.

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 0910–0792. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Food Allergen Labeling and Reporting

OMB Control Number 0910–0792—Revision

This information collection helps support implementation of statutory requirements pertaining to ingredients derived from major food allergens. The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines the term ''major food allergen'' (section 201(qq) of the FD&C Act (21 U.S.C. 321(qq))) and provides that foods are misbranded unless they declare the presence of each major food allergen on the product label using the name of the food source from which the major food allergen is derived or are exempt from the requirement. Under sections 403(w)(6) and (7) of the FD&C Act (21 U.S.C. 343(w)(6) and (7)), respondents may request an FDA determination that an ingredient is exempt from the labeling requirement of section 403(w)(1) of the FD&C Act. Alternatively, an ingredient may become exempt through submission of a notification containing scientific evidence showing that the ingredient ''does not contain allergenic protein'' or that there has been a previous determination through a premarket approval process under 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'' (section 403(w)(7) of the FD&C Act).

To assist respondents with the information collection in this regard, the document entitled ''Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications'' (June 2015), available on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-allergen-labeling-exemption-petitions-and-notifications,* communicates information we recommend respondents include in petitions submitted under sections 403(w)(6) and (7) of the FD&C Act or notifications submitted under section 409 of the FD&C Act. We use the information submitted in the petition or notification to determine whether the ingredient satisfies the criteria of section 403(w)(6) and (7) of the FD&C Act for granting the exemption. The allergen information disclosed on the label or labeling of a food product benefits consumers who purchase that food product. Because even small exposure to a food allergen can potentially cause an adverse reaction, consumers rely upon food labeling information to help determine their product choices.

On April 23, 2021, the definition of the term ''major food allergen'' was amended by the Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER Act) (Pub. L. 117–11) to include sesame. Accordingly, we are revising the information collection to account for burden attributable to required declarations and/or associated requests for exemption as they pertain to foods that include sesame. We issued the draft guidance document entitled ''Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)'' (November 2022), available on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-questions-and-answers-regarding-food-allergen-labeling-edition-5,* that once finalized, will communicate our current thinking regarding the labeling of food allergens, including sesame in food products regulated under section 403 of the FD&C Act. The guidance was issued consistent with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

Description of Respondents: The respondents to this collection of information are manufacturers and packers of packaged foods sold in the United States subject to the labeling requirements and prohibitions found in section 403 of the FD&C Act.

In the **Federal Register** of December 8, 2023 (88 FR 85640), we published a 60-day notice soliciting comment on the proposed collection of information. Although one comment was received, we believe it was misdirected. The comment pertained to neither the topic of this notice, nor the four information collection topics solicited.

We estimate the burden of this collection of information as follows: