DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0918]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Labeling Requirements: Calorie Labeling of Articles of Food in Vending Machines and Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments

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 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 0910–0381. 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 Labeling Requirements: Calorie Labeling of Articles of Food in Vending Machines and Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments

OMB Control Number 0910–0381—Revision

This information collection supports statutory and regulatory requirements that govern food labeling, and information collection recommendations discussed in associated Agency guidance. Sections 4, 5, and 6 of the Fair Packaging Labeling Act (15 U.S.C. 1453, 1454, and 1455) and sections 201, 301, 402, 403, 409, 411, 701, and 721 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321, 331, 342, 343, 348, 350, 371, and 379e), establish provisions under which 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. Implementing regulations are codified in parts 101, 102, 104, and 105 (21 CFR parts 101, 102, 104, and 105). While regulations in part 101 set forth general food labeling provisions, requirements pertaining to the common or usual name for nonstandardized foods; guidelines for nutritional quality to prescribe the minimum level or range of nutrient composition appropriate for a given class of food; and requirements for foods for special dietary use are found in parts 102, 104, and 105, respectively. The requirements are intended to ensure the safety of food products produced or sold in the United States and enable consumers to be knowledgeable about the foods they purchase and include corresponding information disclosure requirements, along with the reporting and recordkeeping provisions, subject to enforcement by FDA.

In the **Federal Register** of April 12, 2023 (88 FR 22045), we published a 60-day notice soliciting comment on the proposed collection of information. No comments were received. On our own initiative and for efficiency of Agency operations, we are revising the information collection to include burden we attribute to related collection activities described in sections 201(n), 403(a)(1), 403(f), 403(q)(5)(H), and 701(a) of the FD&C Act, codified in §§ 101.8 and 101.11 (21 CFR 101.8 and 101.11), and currently approved under OMB control number 0910–0782. Sections 101.8 and 101.11 provide that respondents with a chain of 20 or more locations will disclose nutritional information of certain foods for consumers of food products for the purpose of making informed dietary choices. Section 101.8 applies specifically to vending machines, and § 101.11 applies to covered establishments such as restaurants. Sections 101.8(d) and 101.11(d) provide for registration for respondents not otherwise subject to these regulations but who wish to voluntarily participate with this information collection activity, for which we developed Form FDA 3757 entitled ''DHHS/FDA Menu and Vending Machine Labeling Voluntary Registration'' to assist respondents in this regard. The form is available for download at *https://www.fda.gov/about-fda/reports-manuals-forms/forms* and entering ''3757'' into the search field. To keep the registration active, a respondent renews their registration every other year within 60 days prior to the expiration of the respondent's current registration with FDA, or it will automatically expire.

We have also developed Agency guidance to communicate our interpretation of the regulatory requirements. The guidance document entitled ''Menu Labeling: Supplemental Guidance for Industry'' (May 2018), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-menu-labeling-supplemental-guidance,* provides a discussion of the regulations in §§ 101.8 and 101.11 in a question-and-answer format. We have recently issued a draft second edition of the guidance document (December 2023), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-menu-labeling-supplemental-guidance-edition-2.* The draft guidance, when finalized, will update the May 2018 guidance to add two new questions and answers regarding voluntarily declaring added sugars as part of additional written nutrition information and voluntarily providing nutrition information consistent with the menu labeling requirements through third-party platforms. Because of the growing popularity of third-party platforms among consumers, such as third-party online ordering websites and delivery applications to order food for pickup and delivery from chain restaurants and similar retail food establishments, we discuss our recommendation that covered establishments provide third-party platforms nutrition information for standard menu items to help consumers make informed and healthy decisions when ordering their meals online using a third-party platform. All Agency guidance documents are issued consistent with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

Description of Respondents: Respondents to the collections of information in part 101 are manufacturers, packers, and distributors of food products, as well as certain food

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.

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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*''