Our estimated burden for the information collection reflects an overall increase of 1,217,800 hours. We made this adjustment to correspond with an observed increase in submissions relating to medical devices and an increase in respondents in the medical device industry since last OMB review and approval of the information collection.

Dated: December 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27023 Filed 12–12–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1794]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Drug Labeling Provisions and Over-the-Counter Monograph Drug User Fee Submissions

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 January 12, 2023.

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 0910–0340. 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.

General Drug Labeling Provisions and OTC Monograph Drug User Fee Submissions—21 CFR Part 201

OMB Control Number 0910–0340—Revision

I. Over-the-Counter (OTC) Drug Product Labeling

This information collection supports implementation of general drug labeling provisions, including certain OTC drug product labeling requirements found in FDA regulations in 21 CFR part 201 and in section 502(x) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352(x)), as well as OTC drug product labeling recommendations discussed in FDA guidance documents enumerated below. The requirements and recommendations contained in this authority help ensure that OTC drug product labeling includes information to assist consumers with product selection and with the safe and effective use of products that protect the public health from potential harm that could result from the dissemination of false and misleading statements regarding FDA-regulated products. As described further below, the information collection provisions of one guidance also apply to prescription drug labeling.

A. Principal Display Panel Labeling

Certain information collection provisions address the labeling (third-party disclosures) that drug companies provide on the principal display panel of every OTC drug product in package form—the part of that drug product's label that is most likely to be displayed or examined in a retail sale setting (see 21 CFR 201.60). Information on this panel supports consumers' product selection, as well as identification after purchase. OTC drug product companies must include a declaration of the net quantity of the OTC product contents on the principal display panel (see § 201.62 (21 CFR 201.62)). They also must include a statement of identity (see § 201.61 (21 CFR 201.61)).

FDA has made available a draft guidance for industry entitled ''Statement of Identity and Strength—Content and Format of Labeling for Human Nonprescription Drug Products'' [1] (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/quantitative-labeling-sodium-potassium-and-phosphorus-human-over-counter-and-prescription-drug*) that further addresses content and format of statement of identity information and drug product strength information to be included in the principal display panel labeling of human nonprescription drug products. The guidance provides recommendations to help manufacturers comply with statement of identity labeling requirements under § 201.61 and also provides a recommended alternative to the statement required by that regulation to provide consumers with consistent information about the active ingredients, strength, and dosage form of the product. Consistent information about the active ingredients, strength, and dosage form of the product on the principal display panel may aid consumers in comparing nonprescription drug products and assist consumers in appropriate self-selection of these products and in subsequent identification of the products after purchase.

In estimating burden for statement of identity labeling, we have excluded the burden for disclosing any statement of identity specified in a final OTC monograph order under section 505G of the FD&C Act (21 U.S.C. 355h), because FDA regulations state that for purposes of § 201.61, the statement of identity shall be the term or phrase used in an applicable OTC monograph (see 21 CFR 330.1(c)(1)). By operation of law, OTC monographs are now established by order under section 505G of the FD&C Act, and information collections made under section 505G are exempt from the PRA under section 505G(o) of the FD&C Act.

B. OTC Drug and Prescription Drug Facts Labeling

In addition to labeling that drug companies provide on the principal display panel, companies must also comply with Agency regulations in § 201.66 (21 CFR 201.66), which requires standard content elements and formatting for the ''Drug Facts'' labeling (DFL) of all OTC drug products. This standardized labeling helps consumers understand the information that appears on OTC drug products to help ensure that consumers can use those products safely and effectively. The use of consistent language in labeling headings and subheadings helps consumers comprehend information, and consistent formatting helps consumers more efficiently locate information.

The DFL is where OTC drug product labeling presents certain specific, standardized content required or recommended under other regulations

[1] When final, this guidance will represent FDA's current thinking on this topic.

or guidance documents. For this reason, our burden estimates address these information collections together. One such provision authorizes the optional use of a symbol to convey warnings regarding use of an OTC drug product while pregnant or breast-feeding (see § 201.63(a) (21 CFR 201.63(a)). In addition, the DFL is where OTC drug product labeling presents information (if applicable) on the quantity per dosage unit of certain specific substances. Some consumers need to restrict their total daily intake of these substances because of their impact on the consumers' underlying health conditions. Specific quantitative information must be presented in OTC drug product labeling for phenylalanine/aspartame (§ 201.21(b) (21 CFR 201.21(b))), sodium (§ 201.64(b) (21 CFR 201.64(b))), calcium (§ 201.70(b) (21 CFR 201.70(b))), magnesium (§ 201.71(b) (21 CFR 201.71(b))), and potassium (§ 201.72(b) (21 CFR 201.72(b))).

The quantitative labeling requirements in those regulations cited above are complemented by the draft guidance for industry entitled ''Quantitative Labeling of Sodium, Potassium, and Phosphorus for Human Over-the-Counter and Prescription Drug Products'' [2] (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/quantitative-labeling-sodium-potassium-and-phosphorus-human-over-counter-and-prescription-drug*) (Quantitative Sodium, Potassium, and Phosphorus Labeling Guidance). This draft guidance document provides content and formatting recommendations for presenting quantitative information about sodium, potassium, and phosphorus that can help firms comply with the requirements under §§ 201.64 and 201.72 for conveying information about these substances in OTC drug product labeling. The draft guidance also provides parallel recommendations for drug companies to provide quantitative information about phosphorus in OTC drug product labeling. This quantitative information about sodium, potassium, and phosphorus helps patients who need to limit their overall consumption of any of these substances because of its impact on underlying health conditions, such as heart failure, hypertension, or chronic kidney disease. Quantifying these substances in drug labeling can also help healthcare providers and patients select drug products with lower amounts of these substances when such alternatives are available. The draft guidance recommends approaches to improve consistency in the presentation of this information, including clarifying quantities per dosage unit and rounding consistency. The information collections addressed in the draft guidance with regard to OTC drug products are included with our estimates for preparing the DFL panel of labeling, where this information appears.

The Quantitative Sodium, Potassium, and Phosphorus Labeling Guidance also recommends how drug firms can provide quantitative information on sodium, potassium, and phosphorus in prescription drug labeling to help patients who need to limit their overall consumption of these substances. Prescription drugs are not subject to the OTC labeling regulations, but the content and format of prescription drug labeling is set forth in 21 CFR 201.56 and 201.57 and approved under OMB control number 0910–0572. In the guidance, FDA recommends that when the recommended quantitative information about sodium, potassium, and phosphorus is included in prescription drug labeling, it should be presented within the DESCRIPTION section of that labeling, following the list of inactive ingredients. We estimate that the recommendations of the guidance regarding disclosing quantitative information about sodium, potassium, and phosphorus in prescription drug labeling will have no effect on the overall burden estimate for prescription drug labeling as a whole, which is addressed under OMB control number 0910–0572.

Our estimate of burden for OTC drug labeling that appears within the DFL reflects several considerations. For those OTC drug products that are marketed pursuant to an application approved under section 505 of the FD&C Act (21 U.S.C. 355), we assume a substantial part of the burden of developing labeling is addressed in the submission of the new drug application, which includes submission of the proposed labeling. The information collections associated with new drug applications are approved under OMB control number 0910–0001. For OTC drugs that are legally marketed under section 505G of the FD&C Act that do not have an approved application under section 505 of the FD&C Act, a substantial part of the DFL's content, including applicable Uses (Indications), Warnings, and Directions, is established under section 505G, either by final administrative orders or by section 505G(a)(3) of the FD&C Act. Collections of information made under section 505G of the FD&C Act are exempt from the PRA. Therefore, labeling required by administrative orders under section 505G of the FD&C Act or required by section 505G(a)(3) of the FD&C Act, even if it would ordinarily be a collection of information,[3] is exempt from the PRA and is not considered in our burden estimate for the DFL (see section 505G(o) of the FD&C Act). Finally, we note that the DFL of many individual products already being marketed will remain unchanged within a given year. Thus, our annualized burden estimate encompasses only new products or those otherwise undergoing changes, such as reformulation, or changes in package quantity that necessitate revisions to the DFL, whether those products are marketed under approved applications (*e.g.,* new drug application/abbreviated new drug application) or pursuant to section 505G of the FD&C Act.

Our annualized estimate of burden addresses new products and products for which the DFL and/or net quantity of contents otherwise change in a 12-month period.

C. Labeling Related to Adverse Event Reporting

Section 502(x) of the FD&C Act requires the label of a nonprescription drug product marketed in the United States without an application approved under section 505 of the FD&C Act to include a domestic address or domestic telephone number through which a manufacturer, packer, and distributor may receive a report of a serious adverse event associated with its product(s). To help implement this provision, we developed the guidance for industry entitled ''Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers'' (September 2009) (available at *https://www.fda.gov/media/77411/download*). This guidance document is intended to assist respondents in complying with this statutory labeling requirement and provides recommendations for manufacturers to include an additional labeling statement identifying the purpose of the domestic address or telephone number to improve the usefulness of the labeling for consumers.

[2] When final, this guidance will represent FDA's current thinking on this topic.

[3] Some labeling required by these administrative orders or section 505G(a)(3) of the FD&C Act is not a collection of information at all, but rather, is the public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public (see 5 CFR 1320.3(c)(2))).

D. Submissions To Request Exemptions or Deferrals From OTC Drug Labeling Requirements

FDA regulations in § 201.66(e) authorize FDA to exempt or defer specific requirements in § 201.66 if FDA finds that the requirement is inapplicable, impracticable, or contrary to public health or safety. A manufacturer, packer, or distributor can seek such an exemption or deferral by submitting a written request in accordance with the requirements of § 201.66(e), which address the content of such a written request submission and how and where to submit it. A request for an exemption or deferral must be submitted in triplicate for each OTC drug product and contain certain information allowing the Agency to make an informed decision on the request. FDA uses the submitted information to assess whether the grounds for an exemption or deferral are met. Based on historical experience and from feedback received from respondents who have submitted similar requests, FDA estimates that it will take 24 hours to prepare and submit each submission and that on average annually, the Agency will receive one request for a waiver or exemption from the drug labeling requirement.

In addition, § 201.63(d) states that FDA may grant exemptions from the specific OTC drug product warning for patients who are pregnant or breast feeding that is ordinarily required to appear in labeling by § 201.63(a). To request such an exemption, the regulations call for submission of a citizen petition in accordance with § 10.30 (21 CFR 10.30). The submission of citizen petitions under § 10.30, including those petitions that request this labeling exemption, is approved under OMB control number 0910–0191, and we do not address its burden further in this document.

In the **Federal Register** of September 9, 2022 (87 FR 55440) we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN FOR NEW OTC DRUG PRODUCTS [1]

Information collection activity—labeling	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]
Declaration of Net Quantity of Contents Labeling for Nonprescription Drug Products—§ 201.62.	875	9	7,918	0.5 (30 minutes)	3,959
Statement of Identity Labeling for Nonprescription Drug Products that are not covered by a final OTC Drug Monograph under section 505G of the FD&C Act—§ 201.61.	292	11.5	3,383	2.5	8,457.5
Additional Statement of Identity and Strength information in labeling of nonprescription drug products that are not covered by a final OTC Drug Monograph under section 505G of the FD&C Act (Guidance For Industry (GFI): Statement of Identity and Strength—Content and Format of Labeling for Human Nonprescription Drug Products, section III).	292	11.5	3,383	2.5	8,457.5
Additional Statement of Identity and Dosage Form information in labeling of nonprescription drug products that are covered by a final OTC Drug Monograph under FD&C Act section 505G (GFI: Statement of Identity and Strength—Content and Format of Labeling for Human Nonprescription Drug Products, section III).	292	19	5,614	2.5	14,035
DFL for Nonprescription Drug Products—§ 201.66(c) and (d) (including content within DFL described in §§ 201.21(b), 201.63(a), 201.64(b), 201.70(b), 201.71(b), 201.72(b), or in guidance)..	875	9	7,918	12	95,016
Address and phone number of responsible person added to labeling for nonprescription drug products marketed without an application approved under section 502(x) of the FD&C Act and GFI: Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Q&A—section III).	300	3	900	4	3,600
Total					133,525

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY REPORTING BURDEN FOR OTC DRUG PRODUCTS [1]

Information collection activity—labeling	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Requests for exemptions/deferrals of OTC drug product Drug Facts labeling requirements—§ 201.66(e)	1	1	1	24	24

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

II. OTC Monograph Drug User Fee Program Submissions

This information collection also includes submissions associated with the OTC Monograph Drug User Fee Program. Section 744M of the FD&C Act (21 U.S.C. 379j–72) establishes an OTC monograph drug user fee program (commonly called OMUFA) and authorizes FDA to assess and collect: (1) facility fees from qualifying OTC monograph drug facilities and (2) fees from submitters of qualifying OTC Monograph Order Requests (OMORs). The OMUFA program supports FDA activities related to the regulation of OTC monograph drug products, including provisions of section 505G of the FD&C Act that facilitate innovation and make it easier for FDA to better respond to safety issues when they emerge. We provide information regarding the OMUFA program on our website at *https://www.fda.gov/industry/fda-user-fee-programs/over-counter-monograph-user-fee-program-omufa.*

We developed Form FDA 5009, *Over-The-Counter Monograph User Fee Cover Sheet,* (available at *https://www.fda.gov/about-fda/reports-manuals-forms/forms,* Search for Form FDA 5009) to facilitate the submission of OMUFA fees and to more efficiently administer the OMUFA program. Form FDA 5009 provides FDA with necessary information to determine the total user fee payment amount required and to help the Agency track payments. Respondents to this collection are qualifying finished dosage form manufacturers of OTC monograph drugs and submitters of qualifying OMORs submitted under section 505G(b)(5) of the FD&C Act.

In the **Federal Register** of September 9, 2022 (87 FR 55440) we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 3—ESTIMATED ANNUAL OMUFA REPORTING BURDEN [1]

Form FDA 5009—OMUFA cover sheet	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission associated with facility fees	1,184	1	1,184	0.5 (30 minutes)	592
Submission associated with fees for qualifying OMORs	5	1	5	0.5 (30 minutes)	2.5
Total					594.5

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

Based on data from our electronic Drug Registration and Listing System, we estimate that there will be 1,184 respondents who will provide information in conjunction with facility fee payments annually. In addition, consistent with the ''Over-the-Counter Monograph User Program Performance Goals and Procedures'' commitment letter (available at *https://www.fda.gov/media/106407/download*), we estimate submitters will provide the user fee information using Form FDA 5009 in conjunction with an average of five qualifying OMORs annually. We assume the user fee-related submissions will require an average of 30 minutes to prepare, for a total of 594.5 hours annually.

Dated: December 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27016 Filed 12–12–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0319]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Dear Healthcare Provider Letters: Improving Communication of Important Safety Information

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 January 12, 2023.

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 0910–0754. 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.

Improving Communication of Important Safety Information—21 CFR Part 200

OMB Control Number 0910–0754—Extension

This information collection supports Agency regulations and recommendations found in associated Agency guidance, as discussed below. Under section 705 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 375), the Secretary of the Department of Health and Human Services (the Secretary) may require dissemination of information for drugs in situations that involve, in the Secretary's opinion, ''imminent danger to health, or gross deception of the consumer.'' Implementing regulations are found in § 200.5 (21 CFR 200.5) and outline the general provisions for ''Dear Healthcare Provider'' (DHCP) letters that manufacturers and distributors disseminate about important drug warnings, important prescribing information, and important correction of drug information. The regulations also prescribe certain format and content instructions regarding the dissemination of covered information. Manufacturers or distributors send DHCP letters to physicians and other healthcare providers to communicate an important drug warning, a change in prescribing information, or a correction of misinformation in prescription drug promotional labeling or advertising. We developed the guidance document entitled ''Dear Healthcare Provider Letters: Improving Communication of Important Safety Information'' (January 2014), available at *https://www.fda.gov/media/79793/download,* to provide instructions and recommendations to respondents on implementing the applicable requirements. All Agency guidance documents are issued consistent with our good guidance practice regulations at 21 CFR 10.115.

In addition to the content and format recommendations for each type of DHCP letter, the guidance also includes recommendations on consulting with FDA on: (1) how to develop a DHCP letter; (2) when to send a letter; (3) what type of letter to send; and (4) how to assess the letter's impact.

In the **Federal Register** of June 24, 2022 (87 FR 37871), we published a 60-day notice requesting public comment