response are based on past FDA experience with the various cover sheet submissions and range from 5 to 30 minutes. The hours per response are based on the average of these estimates (18 minutes). The total hours are rounded to the nearest whole number.

Inspection by Accredited Persons Program Under Section 704 of the FD&C Act

Section 704(g) of the FD&C Act provides for accreditation of persons for the purpose of conducting inspections and provides the minimum requirements a person must meet to be accredited to conduct inspections (an Accredited Person (AP)). The burden estimate for requests for accreditation is based on the number of applications we've received. Once an organization is accredited, it will not be required to reapply.

The AP Program permits eligible manufacturers to use APs to perform certain inspections. While all firms remain subject to inspection by FDA, eligible manufacturers have the option of requesting inspection by an AP. A device establishment is eligible for inspection by APs if the establishment meets certain conditions of section 704(g)(6) of the FD&C Act, including that they provide notice of their intention to use an AP to conduct inspections of the establishment.

We estimate there are 4,000 domestic manufacturers and 4,000 foreign manufacturers that are eligible for inclusion under the AP program. Based on informal communications with industry, approximately 10 of these manufacturers may submit a request to use an AP in any given year.

Request for Information Under Section 513(g) of the FD&C Act

Respondents may elect to prepare their 513(g) request for information using CDRH's electronic Submission Template and Resource (eSTAR) voluntary guided submission preparation tool, which was developed to improve submission consistency and enhance efficiency in the review process. The total number of annual responses is based on the average number of 513(g) requests received each year by CDRH and CBER respectively.

Based on a review of the information collection since our last request for OMB approval, we have made modifications to our burden estimate. In our March 2023 change request submission, we erroneously excluded the information collection entitled, ''Notification of the intent to use an Accredited Person.'' We have included the information collection activity to this renewal. The information collection, therefore, reflects a cumulative increase in burden by 10 annual responses and 150 burden hours.

Dated: September 16, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21435 Filed 9–18–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4167]

Agency Information Collection Activities; Proposed Collection; Comment Request; Labeling Requirements for Prescription Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 revision of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with labeling requirements for prescription drugs.

DATES: Either electronic or written comments on the collection of information must be submitted by November 18, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 18, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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 well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include Docket No. FDA–2024–N–4167 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Labeling Requirements for Prescription Drugs.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the

claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

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: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Labeling Requirements for Prescription Drugs

OMB Control Number 0910–0572—Revision

This information collection helps implement statutory and regulatory requirements that govern the labeling of prescription drugs. FDA regulations codified in part 201 (21 CFR part 201), subpart B (§ 201.50 to § 201.58) apply to requisite labeling elements that include a statement of identity; a declaration of net quantity of contents; a statement of dosage; and specific content and formatting of information. The regulations also provide for requesting that FDA waive any requirement under §§ 201.56, 201.57, and 201.80. Since last approval of the information collection, FDA requested, and OMB approved, adding tasks provided for under § 201.25(d), requiring that manufacturers submit a written request for exemption from applicable bar code requirements, and tasks relating to exceptions or alternatives to the labeling requirements of products in the Strategic National Stockpile (SNS) as provided for in § 201.26, to the scope of the activity. Under the Public Health Service Act (PHS Act), the Department of Health and Human Services stockpiles medical products that are essential to the security of the Nation (section 319F–2 of the PHS Act (42 U.S.C. 247d–6b). Information regarding the SNS is available at the following website: *www.phe.gov/about/sns/Pages/default.aspx.*

Relevant information regarding applicable statutory and regulatory requirements are also discussed in topic-specific guidance documents issued consistent with 21 CFR 314.445, 21 CFR 601.29 (guidance documents), and Agency Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time. The following guidance documents discuss activities included in the information collection:

''Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act,'' (July 2013). The guidance document includes instruction on communicating with FDA regarding labeling changes required under section 505(o)(4) (Section IV—Procedures) and is available for download from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-labeling-changes-implementation-section-505o4-federal-food-drug-and-cosmetic-act.*

''Guidance for Industry on Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims,'' (March 2011). The guidance document is intended to help respondents with developing labeling for cardiovascular outcome claims for drugs that are indicated to treat hypertension. The guidance document is available for download from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/hypertension-indication-drug-labeling-cardiovascular-outcome-claims.*

Respondents to the information collection are sponsors of product labeling subject to the applicable labeling requirements. We characterize the information collection activities as recordkeeping, consistent with 5 CFR 1320.3(m), noting that a recordkeeping requirement means a requirement to maintain specified records, including the requirement to retain, notify third parties, the Federal government, or the public regarding such records. Regulations in part 201 govern the statement of ingredients and declaration of net quantity of contents with regard to prescription drug product labeling. The regulations require that firms identify bulk or transport containers with the name of the product contained therein and that containers be accompanied by documentation that identifies the product as meeting applicable compendial standards. New drug product and biological product applicants must: (1) design and create prescription drug labeling containing ''Highlights,'' ''Contents,'' and ''Full Prescribing Information;'' (2) test the designed labeling (for example, to ensure that the designed labeling fits into carton-enclosed products); and (3) submit it to FDA for approval.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Labeling requirements for prescription drugs; §§ 201.56 and 201.57.	414	1.326	549	3,349	1,838,601
Labeling applicable to medical gas containers; §§ 201.161(b) and 201.328.	260	1,663	432,380	0.17 (10 minutes)	73,505
Exemption from barcode requirements § 201.25(d)	2	1	2	24	48
Safety labeling required under section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and rebuttal statement.	36	1	36	6	216
Safety labeling changes; posting approved letter on application holder's website.	351	1	351	4	1,404
Exceptions or alternatives to labeling requirements for human drug product held by SNS; § 201.26.	1	1	1	32	32
Hypertension claims; recommended labeling considerations.	5	1	5	18	90
Total			433,324		1,913,896

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

Based on our evaluation, we have retained the currently approved estimate that 414 applicants will prepare an average of 549 prescription drug labels annually, and assume it will require 3,349 hours to design, test, and submit to FDA as part of a new drug application or a biologics license application.

New medical gas containers must meet applicable requirements found in 21 CFR part 211, as well as specific labeling requirements in § 201.328. Consistent with statutory authority under the Consolidated Appropriations Act, 2017 (Pub. L. 115–31), we have revised the information collection to include burden associated new medical gas labeling requirements under § 201.161(b), established by a final rule published in the **Federal Register** of June 18, 2024 (89 FR 51738). We estimate 260 respondents will incur burden for the design, testing, production, and submission of labeling for new medical gas containers as established in § 201.328 and assume an average of 10 minutes (0.17) is required for these activities.

Based on our evaluation, few requests for exemption from barcode requirements are received and we have therefore made no changes to the currently approved estimate for this activity. Likewise, we have also retained the currently approved estimate for information collection activities associated with safety labeling requirements established in section505(o)(4) of the FD&C Act. Similarly, we retain the currently approved estimate for exceptions to labeling under § 201.26, however this activity was previously approved in OMB control number 0910–0614 and is a new element to the collection, adding 1 response and 32 hours annually.

Finally, we have combined activity elements associated with labeling recommendations regarding drug products that include a hypertension indication as discussed in the applicable guidance, reducing the overall estimate for this element by 4 hours annually.

Dated: September 16, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21436 Filed 9–18–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Funding, Poison Control Centers Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of supplemental award.

SUMMARY: HRSA is awarding supplemental funds in fiscal year 2024 to provide coverage for calls to the toll-free Poison Help line that originate from Puerto Rico. The current program period of performance ends on August 31, 2024.

FOR FURTHER INFORMATION CONTACT: Maureen Perkins, MPH; Team Lead; Poison Control Program; Division of Child, Adolescent and Family Health; Maternal and Child Health Bureau; HRSA, at *mperkins@hrsa.gov* and 301–443–9163.

SUPPLEMENTARY INFORMATION:

Intended Recipient(s) of the Award: New York City Health & Hospitals Corporation.

Amount of Non-Competitive Award(s): One award of $265,188.

Project Period: September 1, 2024, to August 31, 2025.

Assistance Listing (CFDA) Number: 93.253.

Award Instrument: Supplement for Poison Control Services.

Authority: 42 U.S.C. 300d–73 (title XII, 1273 of the Public Health Service Act).

TABLE 1—RECIPIENT AND AWARD AMOUNT

Grant No.	Award recipient name	State	Award amount
H4BHS15477	New York City Health & Hospitals Corporation	NY	$265,188