65 or reach the 25th month of disability benefit entitlement. These individuals do not file a separate application for Medicare Part A because their application for Social Security or RRB benefits is also an application for Part A. The form is for individuals who are not eligible for Social Security for RRB benefits, but may qualify for premium-free Medicare Part A based on certain requirements outlined in § 406.11 and 406.15 or for certain disabled individuals who may enroll in premium Medicare Part A based on certain requirements outlined in § 406.20. Individuals may also choose to enroll in Medicare Part B at the same time they apply for Medicare Part A.

The Application for Enrollment in Medicare Part A (CMS–18F5 and CMS–18F5–SP) was designed to capture all the information needed to make a determination of an individual's entitlement to Part A. This Information Collection Request (ICR) adds the collection instruments SSA uses to collect information from individuals who are filing an Application for Hospital Insurance, updates the burden information. CMS will begin reporting for additional collection instruments, including the internet Claim System (iClaim), Modernized Claims System (MCS), and the Consolidated Claims Experience (CCE). *Form Number:* CMS–18F5 (OMB control number: 0938–0251); *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 1,394,264; *Total Annual Responses:* 1,394,264; *Total Annual Hours:* 348,566. (For policy questions regarding this collection contact Carla Patterson at 410–786–1000.)

Dated: December 1, 2020.

William N. Parham, III,

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

[FR Doc. 2020–26756 Filed 12–3–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6397]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling; 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 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 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 information collection provisions for calorie labeling of articles of food in vending machines and nutrition labeling of standard menu items in restaurants and similar retail food establishments.

DATES: Submit either electronic or written comments on the collection of information by February 2, 2021.

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 February 2, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 2, 2021. 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 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 the Docket No. FDA–2017–N–6397 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling; Calorie Labeling of Articles of Food in Vending Machines and Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments.'' 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 extension 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.

Food Labeling; 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 0910–0782—Extension

This information collection supports FDA regulations under part 101 (21 CFR part 101) and the associated collection instrument Form FDA 3757. The Federal Food, Drug, and Cosmetic Act requires the disclosure of certain calorie labeling of articles of food in vending machines, as well as nutrition information for standard menu items in certain restaurants and retail food establishments. Sections 101.8 and 101.11 provides 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. We also offer registration for respondents 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. 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 use the collection of information to help determine compliance with regulatory requirements. Third-party disclosure requirements are used by consumers of food products for the purpose of making informed dietary choices.

Description of Respondents: Respondents to this collection of information are vending machine operators and restaurants or other similar food establishments that are subject to the requirements of part 101 as well as those entities that voluntarily participate with the provisions of this collection of information.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity using form FDA 3757; 21 CFR	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Initial Registration for Vending Machine Labeling; 101.8(d)	13	1	13	2	26
Registration Renewal for Vending Machine Labeling; 101.8(d)	19	1	19	0.5 (30 minutes)	9.5
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 (30 minutes)	2,670
Total					9,823.5

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

TABLE 2—ESTIMATED RECORDKEEPING BURDEN [1]

Activity; 21 CFR	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record (in hours)	Total hours
Initial Burden (Annualized over 3 years)					
Initial Nutrition Analysis; 101.8(c)(2)(i)(A)	69,017	1	69,017	0.25 (15 minutes)	17,254
Annual Burden					
Recurring Nutrition Analysis; 101.8(c)(2)(i)(A)	30,059	1	30,059	0.25 (15 minutes)	7,515
Total					24,769

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity; 21 CFR	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
Calorie Analysis; 101.8(c)(2)(i)	282	11	3,102	1	3,102
Calorie Declaration Signage; 101.8(c)(2)(ii)	3,279	2,122	6,958,038	0.21 (12.5 minutes)	1,461,188
Vending Operator Contact Information; 101.8(e)(1)	3,279	125	409,875	0.025 (1.5 minutes)	10,247
Total					1,474,537

[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.

Dated: November 30, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26695 Filed 12–3–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5739]

Formal Meetings Between the Food and Drug Administration and Abbreviated New Drug Application Applicants of Complex Products Under Generic Drug User Fee Amendments; Guidance for Industry; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is correcting a notice entitled ''Formal Meetings Between the Food and Drug Administration and Abbreviated New Drug Application Applicants of Complex Products Under Generic Drug User Fee Amendments; Guidance for Industry; Availability'' that appeared in the **Federal Register** of November 25, 2020. The document announced the availability for a guidance for industry. The document was published with incorrect information in the Paperwork Reduction Act of 1995 section. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1670, Silver Spring, MD 20993–0002, 240–402–7930, *elizabeth.giaquinto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 25, 2020 (85 FR 75336), in FR Doc. 2020–26050, the following correction is made:

On page 75337, in the third column, under the heading, ''II. Paperwork Reduction Act of 1995'', the paragraph is corrected to read:

''While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget