Section 316.24(a) specifies a requirement that sponsors respond to deficiency letters from FDA on designation requests within 1 year of issuance of the deficiency letter, unless within that time frame, the sponsor requests an extension of time to respond. Based on past experience, FDA estimates 20 respondents requiring 40 hours of human resources annually.

Section 316.27 specifies content of a change in ownership of orphan-drug designation. Based on past experience, FDA estimates 63 respondents requiring 315 hours of human resources annually. Section 316.30 requires submission of annual reports, including progress reports on studies, a description of the investigational plan, and a discussion of changes that may affect orphan status. Based on number of orphan-drug designations, the number of respondents is estimated as 744 requiring 2,232 hours of human resources annually. Finally, § 316.36 describes information required of sponsor when there is insufficient quantity of approved orphan drug. Based on past experience, FDA estimates two respondents requiring 90 hours of human resources annually.

The information requested will provide the basis for an FDA determination that the drug is for a rare disease or condition and satisfies the requirements for obtaining orphan drug status. Secondly, the information will describe the medical and regulatory history of the drug. The respondents to this collection of information are biotechnology firms, drug companies, and academic clinical researchers.

In the **Federal Register** of June 19, 2017 (82 FR 27836), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section/Form FDA	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Content and format when seeking written recommendations; results of studies; and amendments (§§ 316.10, 316.12, and 316.14)	1	1	1	50	50
Content and format of a request for designation; request for verification of status; amendment to designation	496	1.25	620	135	83,700
Form FDA 3671 or 4035 FDA Orphan Drug Designation Request Form (§§ 316.20, 316.21, and 316.26)	1.25	620	32	19,840	
Notifications of changes in agents (§ 316.22)	70	1	70	2	140
Deficiency letters and granting orphan-drug designation (§ 316.24(a))	20	1	20	2	40
Submissions to change ownership of orphan-drug designation (§ 316.27)	63	1	63	5	315
Annual reports (§ 316.30)	744	1	744	3	2,232
Assurance of the availability of sufficient quantities of the orphan drug; holder's consent for the approval of other marketing applications for the same drug (§ 316.36)	2	3	6	15	90
Total					106,407

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

FDA has experienced increases in: (1) The number of submissions to change ownership of orphan-drug designation (§ 316.27), (2) the number of annual reports (§ 316.30), and (3) assurances of the availability of sufficient quantities of the orphan drug and the holder's consent for the approval of other marketing applications for the same drug (§ 316.36).

Dated: December 6, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26669 Filed 12–11–17; 8:45 am]

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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

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.

DATES: Submit either electronic or written comments on the collection of information by February 12, 2018.

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 12, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of February 12, 2018. 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.'' 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.

- 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.gpo.gov/fdsys/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.

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. 3501–3520), 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

OMB Control Number 0910–0782—Extension

This information collection supports FDA regulations under § 101.8 (21 CFR 101.8) and Form FDA 3757. Under § 101.8(d) vending machine operators not subject to the requirements of section 403(q)(5)(H)(viii) (21 U.S.C. 343(q)(5)(H)(viii)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) may, through an authorized official, voluntarily register with FDA to be subject to those requirements. Those who do voluntarily register must provide FDA with contact information, the address of the location of each vending machine owned or operated by the vending machine operator that is being registered, the preferred mailing address (if different from the vending machine operator address) for purposes of receiving correspondence, and certification that the information submitted is true and accurate, that the person or firm submitting the information is authorized to do so, and that each registered vending machine will be subject to the requirements of § 101.8(c)(2). We have developed Form FDA 3757 entitled, ''DHHS/FDA Menu and Vending Machine Labeling Voluntary Registration,'' to assist respondents in this regard. To keep the establishment's registration active, the authorized official of the vending machine operator must register every other year within 60 days prior to the expiration of the vending machine operator's current registration with

FDA. Registration will automatically expire if not renewed.

It should be noted that an article of food sold from a vending machine whose operator has voluntarily registered with FDA under the regulations is not required to provide calorie declarations for articles of food sold from a vending machine that permits the prospective purchaser to examine the Nutrition Facts label before purchasing the article as provided in § 101.8(b)(1), or otherwise provides visible nutrition information at the point of purchase as provided in § 101.8(b)(2).

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

Reporting Burden

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part 101.8/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
§ 101.8(d); initial registration (Form FDA 3757)	13	1	13	2	26
§ 101.8(d); registration renewal (Form FDA 3757)	19	1	19	0.5 (30 minutes)	9.5
Total	35.5				

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

As reflected in table 1, we retain the currently approved reporting burden estimate for the information collection. At this time, we lack comprehensive data on the number of vending machine operators with fewer than 20 machines that might voluntarily register to comply with the regulations and, as indicated in our final rule of December 1, 2014 (79 FR 71259) establishing the information collection, no vending machine operators have voluntarily registered with FDA. Therefore, while we expect relatively few submissions, we have provided a conservative estimate of the burden respondents may encounter.

We estimate there are approximately 757 vending machine operators with fewer than 20 machines; this number is based on the mean estimate of the low and high counts of firms with less than $50,000 in annual revenue. We estimate that 5 percent of vending machine operators with fewer than 20 machines may voluntarily register to become subject to the final requirements, or 38 operators. We estimate a burden of approximately 2 hours per initial registration, which yields a total burden of 76 hours (38 total operators × 2 hours per response). Annualizing this number over 3 years yields a rounded 13 respondents per year (5 percent × 757 operators/3 years). With an annualized estimate of 13 vending machine operators and one registration per vending machine operator at 2 hours per registration, we estimate the initial hourly burden for these operators is 26 hours.

We expect that renewal registrations after the first year will require substantially less time because operators are expected to be able to affirm or update the existing information in an online account in a way similar to other FDA firm registration systems. Therefore, we estimate that re-registration will take 0.5 hours for each registrant. This indicates that biennial registration would impose a burden of 19 hours (38 operators × 0.5 hours) every 2 years, or 9.5 hours every year (19 operators every year × 0.5 hours).

Recordkeeping Requirements

We have omitted providing a burden estimate associated with generating, providing, or maintaining records associated with calorie analysis and recording because the regulations do not require vending machine operators to maintain such records. However, we have considered the ''time, effort, or financial resources'' expended by covered vending machine operators to declare calories for covered vending machine food and have included the burden in table 2 as part of the third-party disclosure burden. We are particularly interested in hearing from respondents to the information collection regarding calorie declaration signage.

Third-Party Disclosure Requirements

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR Part 101	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
§ 101.8(c)(2)(i); calorie analysis	282	11	3,102	1	3,102
§ 101.8(c)(2)(ii); calorie declaration signage	3,279	2,122	6,958,346	0.21 (12.5 minutes)	1,494,403
§ 101.8(e)(1); vending operator contact information	3,279	125	409,875	.025 (1.5 minutes)	10,248
Total					1,507,753

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

As reflected in table 2, we have retained the currently approved third-party burden estimate for the information collection.

Under the regulations, we calculate three types of third party disclosure burden. The first burden estimate reflects the time and effort we believe necessary for vending machine operators to determine the calorie content of covered vending machine food for the required calorie declarations as described in § 101.8(c)(2)(i). We refer to this as a ''calorie analysis.'' A calorie analysis entails the burden of determining calorie content for covered vending machine food. Most foods sold from vending machines provide the nutrition labeling required by section 403(q) of the FD&C Act and 21 CFR 101.9, including calorie content information, which means that calorie content for many covered vending machine foods is

already available on the Nutrition Facts labels for such foods. In that case, vending machine operators will not need to determine the calorie content of such foods because they can simply declare the calorie information they find on the Nutrition Facts label. Nevertheless, some operators may need to determine calorie information for those vending machine foods that may not bear Nutrition Facts labels or otherwise provide visible nutrition information at the point of purchase in accordance with section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act and § 101.8(b). An operator may obtain the necessary calorie information from nutrient databases, cookbooks, or laboratory analyses. Calorie analysis will most likely only be needed for vended food items such as refrigerated, frozen, can/bowl, or other shelf-stable main meal items, hot cup beverages, and cold cup beverages.

We estimate the mean number of vending machine operators that need calorie analysis to be 847. Annualizing this estimate over 3 years yields 282 operators. We also estimate the range of products available in a typical machine for each of the three most commonly sold product categories that are likely to require a calorie analysis, or 3 percent of food items, 5 percent of hot beverages, and 1 percent of cold cup beverages. We estimate that food machines typically offer between 10 and 25 different items, and both hot beverage and cold cup beverage machines typically offer between 5 and 10 items. From this, we estimate each vending machine operator will require a calorie analysis for 11 items, on average. These estimates are based upon conversations with vending machine operators and our survey of various vending machine models that vend these types of food and beverage, as discussed in our final rule. Based on available data, we estimate the time needed to determine the calorie content of each covered vending machine food to be approximately 1 hour. Our estimate for the burden hours required for new calorie analysis is then 9,317 hours (847 operators × 11 products needing analysis × 1 hour per analysis). Annualizing this value over 3 years yields 3,102 hours (847 operators/3 years × 11 products needing analysis × 4 hours per analysis). (847 operators/3 years = 282 operators per year.) This is reflected in table 2, row 1.

The second burden estimate reflects burden associated with calorie declaration signage as described in § 101.8(c)(2)(ii). Covered vending machine operators with 20 or more vending machines and vending machine operators that voluntarily register to become subject to the Federal requirements must disclose calorie information by providing calorie declaration signs in, on, or adjacent to their vending machines to a third party who will most often be the prospective purchaser or consumer.

We estimate there is an average of 9,838 (9,800 covered non-bulk + 38 voluntary) vending machine operators subject to the regulations (9,838/3 = 3,279 annualized). Our estimate for the average number of non-bulk vending machines that will require declaration signage is based upon data relied upon in our final rule (see references 1, 6 to 8 under Docket No. FDA–2011–F–0171). We estimate there is an average of 5.61 million non-bulk vending machines. Digital signage is an emerging technology, and according to available sources, approximately 0.1 percent of all vending machines in operation currently have electronic video displays capable of providing calorie information, or approximately 4,014 to 5,670 vending machines. Subtracting the number of vending machines with the electronic video from the total machine count yields an average of 5.61 million vending machines that will need signage. We expect the number of vending machines that will require signage to decline over time as manufacturers continue to add the required calorie information to the principal display panel of the package as part of ''front of package labeling,'' and because we anticipate greater use of electronic video displays on vending machines. In addition, to the extent that covered vending machines sell foods that permit prospective purchasers to examine the Nutrition Facts label before purchase or otherwise provide visible nutrition information at the point of purchase in accordance with section 403(q)(5)(H)(viii)(I)(aa) of the FD&C Act and § 101.8(b), this analysis may overestimate the burden estimate for calorie declaration signs.

Vending machine operators can create one sign that contains all of the information for the products offered in the vending machine, and do not have to create individual signs for each item. The number of templates a given firm would need to design to produce signs that comply with the regulations may vary based upon the number of different types of products the firm purveys. In our estimate, we have considered the time it takes for template design, sign creation, sign installation, updates, replacement, and bulk machine signage. Cumulatively we estimate that those 3,279 (annualized) vending machine operators subject to the regulations will expend a total 1,494,403 hours to fulfill the requirements under § 101.8(c)(2)(ii) regarding signage for calorie declarations. This is reflected in table 2 row 2. We note that while we previously provided burden estimates for individual disclosure activities found under § 101.8(c)(2)(ii) in our final rule of December 1, 2014 (79 FR 71259 at 71286), we have consolidated them here into one entry. Because this is the first extension request for this information collection and we have limited available data, we are specifically interested in respondents' experience with the third-party burden associated with the requirements under § 101.8(c)(2)(ii).

Finally, we have provided a burden estimate associated with § 101.8(e)(1) requiring a vending machine operator subject to section 403(q)(5)(H)(viii) of the FD&C Act or a vending machine operator that voluntarily registers to provide contact information. We assume that venders that do not already have a sign or label with their contact information will add their contact information into the initial sign design. We estimate the time it takes to include contact information is 1.5 minutes (0.025 hours) for each sign. We estimate the total initial burden for including contact information on the predesigned templates to be 30,744 hours (9,838 operators × 125 sign formats × 0.025 hours per sign). Annualized over 3 years, this burden becomes 10,248 hours (9,838 operators/3 years × 125 signs × 0.025 hours per sign). (Some States have licensing requirements for vending machine operators, and some of these licensing requirements already require the vending machine operator's license or contact information to be displayed on the vending machine.) If the contact information displayed on a vending machine due to State or local requirements includes some but not all of the contact information required under § 101.8(e)(1), the vending machine operator is required to display the remaining contact information required under § 101.8(e)(1) in a manner specified under § 101.8(e)(1). We do not have an estimate of the number of machines already in compliance; to the extent that some operators are already in compliance, we overestimate the associated burden for third-party disclosure.) This is reflected in table 2, row 3.

Dated: December 5, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26672 Filed 12–11–17; 8:45 am]

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