4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6397]

# Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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, 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: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0782. 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.

Calorie Labeling of Articles of Food in Vending Machines and Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments--21 CFR Part 101

OMB Control Numbers 0910-0782 and 0910-0783--Consolidation

This information collection supports FDA regulations under 21 CFR 101. As published in the *Federal Register* of December 1, 2014 (79 FR 71156 and 71259), regulations at 21 CFR 101.8 and 101.11 were revised to provide for the nutritional analysis of certain foods and for the disclosure of that information on applicable products purchased by consumers. The regulations also provide for the registration of certain individuals who become subject to the requirements, 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, respondents must renew the registration every other year within 60 days prior to the expiration of the establishment's current registration with FDA, or it will automatically expire.

In the *Federal Register* of December 12, 2017 (82 FR 58425), we published a 60-day notice requesting public comment on the proposed information collection. A number of comments were received in response to the notice. The comments were generally supportive of the information collection, but included concerns about the potential effect the ongoing or delayed rulemaking to establish specific packaging requirements (e.g., font-size of labeling, compliance dates) might have on the associated third-party disclosure burden. Other comments

questioned whether FDA needed all data currently being sought by the applicable regulations and suggested the registration schedule be relaxed, especially given the small number of respondents.

We are very appreciative of these comments. At the same time, upon our own review of the information collection, we are seeking to consolidate the burden currently approved under OMB control number 0910-0783 with 0910-0782 because it is intended to account for similar collection activities and is supported by the same collection instrument (Form FDA 3757) identified above. Also, as neither the public comments we received nor our own evaluation suggested we revise our original figures, we are retaining the currently approved estimated burden for the information collection, which is as follows:

Table 1.--Estimated Annual Reporting Burden[1]

| 21 CFR 101.8 and 101.11 Registration Using Form FDA 3757 | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response (in hours) | Total Hours |
|---|---|---|---|---|---|
| § 101.8(d); initial registration | 13 | 1 | 13 | 2 | 26 |
| § 101.8(d); registration renewal | 19 | 1 | 19 | .5 (30 minutes) | 9.5 |
| § 101.11(d) initial registration | 3,559 | 1 | 3,559 | 2 | 7,118 |
| § 101.11(d) registration reviewal | 5,340 | 1 | 5,340 | .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]

| 21 CFR Part 101 | No. of Recordkeepers | Annual Frequency per Recordkeeper | Total Annual Records | Hours per Record | Total Hours |
|---|---|---|---|---|---|
| Initial Burden (Annualized over 3 years) | | | | | |
| § 101.8(c)(2)(i)(A); Initial nutrition analysis | 69,017 | 1 | 69,017 | .25 (15 minutes) | 17,254 |
| Annual Burden | | | | | |
| § 101.8(c)(2)(i)(A); Recurring nutrition analysis | 30,059 | 1 | 30,059 | .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]

| 21 CFR Part 101 | No. of Respondents | No. 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 | 6,958,038 | .21 (12.5 minutes) | 1,461,188 |
| § 101.8(e)(1); vending operator contact information | 3,279 | 125 | 409,875 | .025 (1.5 minutes) | 10,247 |
| Total | | | | | 1,474,537 |

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

These figures are based on our analyses in support of the underlying rulemaking cited above and there is no burden increase since the previous OMB approvals. Because these are newly established information collection provisions, we continue to evaluate the collection burden and solicit public comment, noting that the effective dates and/or compliance dates for certain provisions have not yet been realized.

Dated: March 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-06154 Filed: 3/27/2018 8:45 am; Publication Date: 3/28/2018]