difference could lead to liability concerns (*e.g.,* for a pharmacy manager who makes representations to an outsourcing facility about how a drug will be used) and scope of practice concerns (if a doctor concludes he or she should not be bound by the representations).

FDA Response to Issue Two: For certain drugs, one of the conditions to qualify for exemptions under section 503B is that there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug. If a pharmacy manager does not wish to document on the order that such a drug will only be administered after an appropriate prescriber determination, the manager could ask the prescriber to provide documentation. If a prescriber, or person able to make a representation for a prescriber, refuses to confirm that a compounded drug produces a clinical difference for a patient, the compounded drug may be considered ''essentially a copy'' of the commercially-available product. The outsourcing facility may decide in this scenario to not compound the drug.

Issue Three: At least one commenter recommended that the guidance requires practitioners to provide additional details regarding the patient population in need of a compounded drug as part of the prescriber determination of clinical difference, and that both a hospital and practitioner should produce statements of clinical difference.

FDA Response to Issue Three: FDA's draft guidance states that when an outsourcing facility intends to rely on a prescriber determination to establish that a compounded drug is not essentially a copy of an approved drug, the outsourcing facility should ensure that the determination is documented on the prescription or order for the compounded drug. This means the determination is referenced in the statute at section 503B(d)(2), which FDA cannot change through guidance. FDA cannot give exhaustive guidance regarding what such documentation may contain, but we did provide appropriate examples. Under the guidance, both a prescribing practitioner and a person able to make a representation for the practitioner, such as, potentially, a hospital pharmacy manager, would be able to produce a statement of clinical difference.

Issue Four: At least one commenter asked about the acceptability of specific means of applying a determination statement to a product order.

FDA Response to Issue Four: FDA does not believe a particular format is needed for a prescriber determination of clinical difference, provided that the determination clearly identifies the relevant change made to the compounded product and the clinical difference that the change will produce for patient(s), as determined by the prescriber.

As none of the comments suggested that we revise our estimated burden for the information collection, we have retained our original estimate as follows:

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

Type of reporting recommendations in guidance	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Consultation between the outsourcing facility and prescriber or health care facility, and the notation on the prescription or order documenting the prescriber's determination of clinical difference.	40	100	4,000	0.05 (3 minutes)	200
Checking FDA's drug shortage list and documenting on the prescription that the drug is in shortage.	30	100	3,000	0.03 (2 minutes)	100

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

We estimate that annually a total of approximately 40 outsourcing facilities (''number of respondents'' in table 1, line 1) will consult a prescriber to determine whether he or she has made a determination that the compounded drug has a change that produces a clinical difference for an individual patient as compared to the comparable approved drug and that outsourcing facilities will document this determination on approximately 4,000 prescriptions or orders for compounded drugs (''total annual disclosures'' in table 1, line 1). We estimate that the consultation between the outsourcing facility and the prescriber or health care facility contact adding a notation to each prescription or order that does not already document this determination will take approximately 3 minutes per prescription or order.

We estimate that a total of approximately 30 outsourcing facilities (''number of respondents'' in table 1, line 2) will document this information on approximately 3,000 prescriptions or orders for compounded drugs (''total annual disclosures'' in table 1, line 2). We estimate that checking FDA's drug shortage list and documenting this information will take approximately 2 minutes per prescription or order.

Dated: March 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–06169 Filed 3–27–18; 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; 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 April 27, 2018.

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	Number of respondents	Number 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	Number 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	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	6,958,038	.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 3–27–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and, (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: 2019 National Survey on Drug Use and Health OMB No. 0930–0110—Revision

The National Survey on Drug Use and Health (NSDUH) is a survey of the U.S. civilian, non-institutionalized population aged 12 years old or older. The data are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, the Office of National Drug Control Policy (ONDCP), federal government agencies, and other organizations and researchers to establish policy, to direct program activities, and to better allocate resources.

While NSDUH must be updated periodically to reflect changing substance use and mental health issues, and to continue producing current data, only the following minor changes are planned for the 2019 NSDUH: (1) Adding a brief series of questions on medication-assisted treatment (MAT) for opioids and alcohol; and, (2) including other minor wording changes to improve the flow of the interview, to increase respondent comprehension, or to be consistent with text in other questions.

The series of MAT questions seeks to identify medications prescribed by health professionals to help reduce or stop the use of opioids and alcohol. Including these questions in NSDUH will allow SAMHSA to provide the first known national-level estimates on the use of MAT for opioid use disorder and alcohol use disorder.

As with all NSDUH surveys conducted since 1999, including those prior to 2002 when the NSDUH was referred to as the National Household Survey on Drug Abuse, the sample size of the survey for 2019 will be sufficient to permit prevalence estimates for each of the 50 states and the District of Columbia. The total annual burden estimate is shown below in Table 1.

TABLE 1—ANNUALIZED ESTIMATED BURDEN FOR 2019 NSDUH

Instrument	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours
Household Screening	137,231	1	137,231	0.083	11,390
Interview	67,507	1	67,507	1.000	67,507
Screening Verification	4,116	1	4,116	0.067	276
Interview Verification	10,126	1	10,126	0.067	678
Total	137,231		218,980		79,851

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 15E57B, 5600 Fishers Lane, Rockville, MD 20857 *OR* email a copy to *summer.king@samhsa.hhs.gov.*