The reporting and third-party disclosure burden estimates are based on our records, which show that there are 5 manufacturers of infant formula and that there have been, on average, 2 infant formula recalls per year for the past 3 years. Based on this information, we estimate that there will be, on average, approximately 2 infant formula recalls per year over the next 3 years.

Thus, we estimate that 2 respondents will conduct recalls annually pursuant to §§ 107.230, 107.240, and 107.250. The estimated number of respondents for § 107.260 is minimal because we seldom use this section; therefore, we estimate that there will be 1 or fewer respondents annually for § 107.260. The estimated number of hours per response is an average based on our experience and information from firms that have conducted recalls. We estimate that 2 respondents will conduct infant formula recalls under § 107.230 and that it will take a respondent 4,450 hours to comply with the requirements of that section, for a total of 8,900 hours. We estimate that 2 respondents will conduct infant formula recalls under § 107.240 and that it will take a respondent 1,482 hours to comply with the requirements of that section, for a total of 2,964 hours. We estimate that 2 respondents will submit recommendations for termination of infant formula recalls under § 107.250 and that it will take a respondent 120 hours to comply with the requirements of that section, for a total of 240 hours. Finally, we estimate that 1 respondent will need to carry out additional effectiveness checks and issue additional notifications, for a total of 625 hours.

Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. No burden has been estimated for the recordkeeping requirement in § 107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice.

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

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
107.230; elements of infant formula recall	2	1	2	50	100
107.260; revision of an infant formula recall	1	1	1	25	25
Total					125

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

Table 2 reports our third-party disclosure burden estimates for §§ 107.230 and 107.260. The estimated burden hours per disclosure is an average based on our experience. The third-party disclosure burden in § 107.230 is the requirement to promptly notify each affected direct-account (customer) about the recall, and if the recalled formula presents a risk to human health, the requirement that the recalling firm must also request that each establishment that sells the recalled formula post a notice of the recall at the point of purchase. We estimate that 2 respondents will conduct infant formula recalls under § 107.230 and that it will take a respondent 50 hours to comply with the third-party disclosure requirements of that section, for a total of 100 hours. The third-party disclosure burden in § 107.260 is the requirement to issue additional notifications where the recall strategy or implementation is determined to be deficient. We estimate that 1 respondent will issue additional notifications under § 107.260 and that it will take a respondent 25 hours to comply with the third-party disclosure requirements of that section, for a total of 25 hours.

Dated: October 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–25105 Filed 10–21–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1104]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; State Petitions for Exemption From Preemption

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 November 21, 2014.

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 0910–0277. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd.; COLE–14526, Silver Spring, MD 20993–0002 *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.

State Petitions for Exemption From Preemption—21 CFR 100.1(d) (OMB Control Number 0910–0277)—(Extension)

Under section 403A(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343–1(b)), states may petition FDA for exemption from Federal preemption of state food labeling and standard of identity requirements. Section 100.1(d) (21 CFR 100.1(d)) sets forth the information a

state is required to submit in such a petition. The information required under § 100.1(d) enables FDA to determine whether the state food labeling or standard of identity requirement satisfies the criteria of section 403A(b) of the FD&C Act for granting exemption from Federal preemption.

In the **Federal Register** of August 7, 2014 (79 FR 46269), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR 100.1(d)	Number of respondents	Number of responses per respondent	Total annual responses	Avg. burden per response	Total hours
Form of petition	1	1	1	40	40

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

The reporting burden for § 100.1(d) is minimal because petitions for exemption from preemption are seldom submitted by states. In the last 3 years, we have received one new petition for exemption from preemption; therefore, we estimate that one or fewer petitions will be submitted annually.

Dated: *October 16, 2014.*

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–25106 Filed 10–21–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1540]

Migraine: Developing Drugs for Acute Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Migraine: Developing Drugs for Acute Treatment.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs for the acute treatment of migraine. This guidance focuses on specific drug development and trial design issues that are unique to the study of drugs for the acute treatment of migraine. This guidance is intended to serve as a focus for continued discussions among the Division of Neurology Products, pharmaceutical sponsors, the academic community, and the public.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 22, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Eric Bastings, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4338, Silver Spring, MD 20993–0002, 301–796–1039.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Migraine: Developing Drugs for Acute Treatment.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs for the acute treatment of migraine. This guidance focuses on specific drug development and trial design issues that are unique to the study of drugs for the acute treatment of migraine. This guidance is intended to serve as a focus for continued discussions among the Division of Neurology Products, pharmaceutical sponsors, the academic community, and the public.

Migraine is a chronic neurovascular disorder characterized by recurrent attacks of often severe headache, typically presenting with nausea, vomiting, and sensitivity to light and/or sound. Pharmacologic approaches to the treatment of migraine include drugs to treat acute migraine attacks as they arise (acute treatment of migraine) and drugs to reduce the frequency of migraine attacks (preventive treatment). This guidance addresses the development program of drugs for the acute treatment of migraine, including trial population, trial design, dose selection, efficacy endpoints, and statistical considerations. The guidance also discusses safety considerations, pediatric studies, and labeling considerations.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on developing drugs for the acute treatment of migraine. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 201, 312, and 314 have been approved under OMB control numbers 0910–0572, 0910–0014, and 0910–0001, respectively.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the