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Migraine: Developing Drugs for Acute Treatment; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Migraine: Developing Drugs for Acute Treatment.''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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 22, 2014.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

docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: October 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–25048 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–2013–D–0710]

Guidance for Industry on Circumstances That Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection.'' The Food and Drug Administration Safety and Innovation Act (FDASIA) added a provision to the Food, Drug, and Cosmetic Act (the FD&C Act) concerning inspections that makes a drug adulterated. This guidance defines the types of actions, inaction, and circumstances that FDA considers to constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection for the purposes of making a drug adulterated.

DATES: Submit either electronic or written comments on Agency guidance at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Policy and Risk Management, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., rm. 4138, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the 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: Emily M. Leongini, Office of Policy and Risk Management, Office of Regulatory Affairs, Food and Drug Administration, 10902 New Hampshire Ave., Bldg. 32, rm. 4339, Silver Spring, MD 20903, 301–796–5300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection.'' On July 9, 2012, FDASIA (Pub. L. 112–144) was signed into law. Section 707 of FDASIA adds 501(j) to the FD&C Act to make a drug adulterated that ''has been manufactured, processed, packed, or held in any factory, warehouse, or establishment and the owner, operator, or agent of such factory, warehouse, or establishment delays, denies, or limits an inspection, or refuses to permit entry or inspection.'' As required by Section 707, FDA is issuing this guidance to define the types of action, inaction, and circumstances that FDA considers to constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection for the purposes of Section 501(j) of the FD&C Act.

In July 2013, FDA issued a draft guidance for industry of the same title (78 FR 42387, July 15, 2013). In response to docket comments, we revised the guidance to clarify FDA's expectations regarding the types of action, inaction, and circumstances that make a drug adulterated under 501(j) of the FD&C Act. Among other things, we added examples that may constitute reasonable explanations for actions, inactions, or circumstances that could otherwise be considered delaying, denying, or limiting inspection, or refusing to permit entry or inspection.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on ''Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection.'' 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. 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 docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/RegulatoryInformation/Guidances/ucm122044.htm* or *http://www.regulations.gov.*

Dated: October 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–25033 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–0001]

Seventh Annual Sentinel Initiative; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Seventh Annual Sentinel Initiative Public Workshop.'' Convened by the Engelberg Center for Health Care Reform at the Brookings Institution and supported by a cooperative agreement with FDA, this 1-day workshop will bring the stakeholder community together to discuss a variety of topics on active medical product surveillance. Topics will include an overview of the transition from the Mini-Sentinel pilot program to the full Sentinel System and what that means for patients and other critical stakeholders. Additionally, panelists will discuss the future of the Sentinel System and opportunities to expand its medical product surveillance capabilities. This workshop will also engage stakeholders to discuss current and emerging Sentinel projects.