DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1164]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile

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 (PRA).

DATES: Fax written comments on the collection of information by August 15, 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 0910–0614. 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.

Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile—(OMB Control Number 0910–0614)—Extension

Under the Public Health Service Act (PHS Act), the Department of Health and Human Services stockpiles medical products that are essential to the health security of the nation (see PHS Act, 42 U.S.C. 247d-6b). This collection of medical products for use during national health emergencies, known as the SNS, is to ''provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency.''

It may be appropriate for certain medical products that are or will be held in the SNS to be labeled in a manner that would not comply with certain FDA labeling regulations given their anticipated circumstances of use in an emergency. However, noncompliance with these labeling requirements could render such products misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352).

Under §§ 201.26, 610.68, 801.128, and 809.11 (21 CFR 201.26, 610.68, 801.128, and 809.11), the appropriate FDA Center Director may grant a request for an exception or alternative to certain regulatory provisions pertaining to the labeling of human drugs, biological products, medical devices, and in vitro diagnostics that currently are or will be included in the SNS if certain criteria are met. The appropriate FDA Center Director may grant an exception or alternative to certain FDA labeling requirements if compliance with these labeling requirements could adversely affect the safety, effectiveness, or availability of products that are or will be included in the SNS. An exception or alternative granted under the regulations may include conditions or safeguards so that the labeling for such products includes appropriate information necessary for the safe and effective use of the product given the product's anticipated circumstances of use. Any grant of an exception or alternative will only apply to the specified lots, batches, or other units of medical products in the request. The appropriate FDA Center Director may also grant an exception or alternative to the labeling provisions specified in the regulations on his or her own initiative.

Under § 201.26(b)(1)(i) (human drug products), § 610.68(b)(1)(i) (biological products), § 801.128(b)(1)(i) (medical devices), and § 809.11(b)(1)(i) (in vitro diagnostic products for human use), an SNS official or any entity that manufactures (including labeling, packing, relabeling, or repackaging), distributes, or stores such products that are or will be included in the SNS may submit, with written concurrence from an SNS official, a written request for an exception or alternative to certain labeling requirements to the appropriate FDA Center Director. Except when initiated by an FDA Center Director, a request for an exception or alternative must be in writing and must:

- Identify the specified lots, batches, or other units of the affected product;
- Identify the specific labeling provisions under this rule that are the subject of the request;
- Explain why compliance with the specified labeling provisions could adversely affect the safety, effectiveness, or availability of the product subject to the request;
- Describe any proposed safeguards or conditions that will be implemented so that the labeling of the product includes appropriate information necessary for the safe and effective use of the product given the anticipated circumstances of use of the product;
- Provide copies of the proposed labeling of the specified lots, batches, or other units of the affected product that will be subject to the exception or alternative; and
- Provide any other information requested by the FDA Center Director in support of the request.

If the request is granted, the manufacturer may need to report to FDA any resulting changes to the New Drug Application, Biologics License Application, Premarket Approval Application, or Premarket Notification (510(k)) in effect, if any. The submission and grant of an exception or an alternative to the labeling requirements specified in this rule may be used to satisfy certain reporting obligations relating to changes to product applications under 21 CFR 314.70 (human drugs), 21 CFR 601.12 (biological products), 21 CFR 814.39 (medical devices subject to premarket approval), or 21 CFR 807.81 (medical devices subject to 510(k) clearance requirements). The information collection provisions in §§ 314.70, 601.12, 807.81, and 814.39 have been approved under OMB control numbers 0910–0001, 0910–0338, 0910–0120, and 0910–0231 respectively. On a case-by-case basis, the appropriate FDA Center Director may also determine when an exception or alternative is granted that certain safeguards and conditions are appropriate, such as additional labeling on the SNS products, so that the labeling of such products would include information needed for safe and effective use under the anticipated circumstances of use.

Respondents to this collection of information are entities that manufacture (including labeling, packing, relabeling, or repackaging), distribute, or store affected SNS products. Based on the number of requests for an exception or alternative received by FDA in fiscal years 2012–13, FDA estimates an average of one request annually. FDA estimates an average of 24 hours preparing each request. The average burden per

response for each submission is based on the estimated time that it takes to prepare a supplement to an application, which may be considered similar to a request for an exception or alternative. To the extent that labeling changes not already required by FDA regulations are made in connection with an exception or alternative granted under the final rule, FDA is estimating one occurrence annually in the event FDA would require any additional labeling changes not already covered by FDA regulations. FDA estimates 8 hours to develop and revise the labeling to make such changes. The average burden per response for each submission is based on the estimated time to develop and revise the labeling to make such changes.

In the **Federal Register** of February 18, 2014 (79 FR 9219), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment from the public. The comment was not responsive to the comment request on the four specified aspects of the collection of information and did not provide any data or explanation that would support a change regarding the information collection requirements.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
201.26(b)(1)(i), 610.68(b)(1)(i), 801.128(b)(1)(i), and 809.11(b)(1)(i)	1	1	1	24	24
201.26(b)(1)(i), 610.68(b)(1)(i), 801.128(b)(1)(i), and 809.11(b)(1)(i)	1	1	1	8	8
Total					32

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

Dated: July 10, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–16589 Filed 7–15–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Food and Drug Administration Third Annual Patient Network Meeting; Under the Microscope: Pediatric Drug Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA), Office of Health and Constituent Affairs (OHCA) is announcing a 1-day meeting to explore challenges related to pediatric product development. The meeting will serve as a forum for FDA's stakeholders (patients, caregivers, patient advocates, healthcare professional groups, the general public, academia, and industry) to learn about regulations that encourage pediatric product development; to discuss ways to advance pediatric product development, how health disparities impact pediatric product development, the importance of transparency in pediatric clinical trials, and how analysis of information from failed pediatric clinical trials might improve future designs for pediatric trials; and to identify ways patient input can benefit clinical trial design for pediatric trials.

The 1-day meeting will also provide an opportunity to participate in panel discussions on the challenges related to development of products used to treat pediatric patients, including pediatric patients with rare diseases and explore ways that patients/caregivers, FDA, and industry may work together to incorporate patient input in future pediatric product development and regulatory decisionmaking.

DATES: The public meeting will be held on September 10, 2014, from 8 a.m. to 4:30 p.m. If you wish to attend the 1-day meeting, visit the Patient Network at *http://patientnetwork.fda.gov/3rd-annual-patient-network.* Please register before September 5, 2014. Those who are unable to attend the meeting in person can register to view a live webcast of the meeting. You will be asked to indicate in your registration whether you plan to attend the meeting in person or via the webcast. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. There is no registration fee for this meeting and early registration is suggested because space is limited. We request that non-patient organizations limit the number of representatives to three. For further registration information or problems with the Web site call Steve Morin (see **FOR FURTHER INFORMATION CONTACT**) at 301–796–0161 or email at *patientnetwork@fda.hhs.gov.*

If you need special accommodations due to a disability, please specify those accommodations when registering for this 1-day meeting.

ADDRESSES: The meeting will be held at the Washington Marriott at Metro Center, 775 12th St. NW., Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Steve Morin, Office of Health and Constituent Affairs, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–0161, FAX: 301–847–8623, *patientnetwork@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. The FDA Patient Network

This is the third FDA Patient Network Annual Meeting hosted by OHCA, the Agency's primary liaison with patient and health professional communities. This annual meeting is being hosted as part of the larger FDA Patient Network program. The FDA Patient Network is a resource that seeks to:

- Educate and inform patients and patient advocacy organizations about FDA's:
  - Regulatory authorities and processes;
  - Initiatives;
  - Public meetings;
  - Ways to comment on FDA draft guidances; and
- Provide a venue for patient advocacy involvement within the FDA.

In addition to an annual meeting, the FDA Patient Network consists of: