

Annually, FDA projects about 20 focus group studies using 160 focus groups with an average of 9 persons per group, and lasting an average of 1.75 hours each. FDA is requesting this burden for unplanned focus groups so as not to restrict the Agency's ability to gather information on public sentiment of its proposals in its regulatory and communications programs.

Dated: November 23, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-30037 Filed 11-29-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0588]

#### Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements for FDA regulations related to the exceptions or alternatives to labeling requirements for products held by the Strategic National Stockpile (SNS).

**DATES:** Submit either electronic or written comments on the collection of information by January 31, 2011.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792, [Elizabeth.Berbakos@fda.hhs.gov](mailto:Elizabeth.Berbakos@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### 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 (the PHS Act), the Department of Health and Human Services stockpiles medical products that are essential to the health security of the Nation (see section 319F-2 of the 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).

In the **Federal Register** of December 28, 2007 (72 FR 73589), FDA published an interim final rule entitled "Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile." In the interim final rule, FDA issued regulations under §§ 201.26, 610.68, 801.128, and 809.11 (21 CFR 201.26, 610.68, 801.128, and 809.11), which allow the appropriate FDA Center Director to 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 a 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 the interim final rule (72 FR 73589) may be used to satisfy certain reporting obligations relating to changes to product applications under § 314.70 (21 CFR 314.70) (human drugs), § 601.12 (21 CFR 601.12) (biological products), § 814.39 (21 CFR 814.39) (medical devices subject to premarket approval), or § 807.81 (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 since issuance of the interim final rule, FDA estimates an average of two requests annually. FDA is estimating that each respondent will spend an average of 24 hours preparing each request. The hours per response for each submission are 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 interim final rule, FDA is estimating one occurrence annually in the event FDA would require any additional labeling changes not already covered by FDA regulations, and that it would take 8 hours to develop and revise the labeling to make such changes.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR section	Number of respondents	Annual frequency per response	Total annual responses	Hours 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) .....	2	1	2	24	48
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 .....					56

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 23, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2010–N–0576]

**Supplemental Funding Under the Food and Drug Administration’s Convener of Active Medical Product Surveillance Discussions (U13) RFA–FD–09–012; Request for Supplemental Application**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of intent.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a program expansion of its Conference Cooperative Agreement Program (U13), awarded to the Engelberg Center for Health Care Reform at the Brookings Institution (Brookings). The goal of this expansion is to plan and hold meetings and conferences that will ensure broad stakeholder input on FDA programs and initiatives related to disseminating information from active medical product surveillance activities and other sources of product information.

**DATES:** Important dates are as follows:

1. The supplemental application due date is December 13, 2010.
2. The award anticipated start date is January 1, 2011.

3. The opening date is November 30, 2010.

4. The expiration date is December 14, 2010.

**FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT:**

Melissa Robb, Office of Medical Policy, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 51, rm. 6360, Silver Spring, MD 20993–0002, 301–796–2500, e-mail: [Melissa.Robb@fda.hhs.gov](mailto:Melissa.Robb@fda.hhs.gov); or

Camille R. Peake, Division of Acquisition Support and Grants, Food and Drug Administration, 5630 Fishers Lane (HFA–500), Rockville, MD 20857, 301–827–7175, FAX: 301–827–7101, e-mail: [Camille.Peake@fda.hhs.gov](mailto:Camille.Peake@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**