FOOD AND DRUG ADMINISTRATION
Exceptions or Alternatives to Labeling Requirements
for Products Held By the Strategic National Stockpile

OMB Control No. 0910-0614

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA) regulations regarding *Exceptions or Alternatives to Labeling Requirements for Products Held By the Strategic National Stockpile*. Accordingly, we are requesting an extension of Office of Management and Budget (OMB) approval of the information collection provisions found in the associated regulations and discussed here:

> **21 CFR 201.26(b)(1)(i) Reporting**: A Strategic National Stockpile (SNS) official or any entity that manufactures (including labeling, packing, relabeling, or repackaging), distributes, or stores a human drug product that is 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.
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> **21 CFR 610.68(b)(1)(i) Reporting**: A Strategic National Stockpile official or any entity that manufactures (including labeling, packing, relabeling, or repackaging), distributes, or stores a biological product that is 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.
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> **21 CFR 801.128(b)(1)(i) Reporting**: A Strategic National Stockpile official or any entity that manufactures (including labeling, packing, relabeling, or repackaging), distributes, or stores a device that is 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.
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> **21 CFR 809.11(b)(1)(i) Reporting**: A Strategic National Stockpile official or any entity that manufactures (including labeling, packing, relabeling, or repackaging), distributes, or stores an in vitro diagnostic product for human use that is 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.

Under the Public Health Service Act (PHS Act), the Department of Health and Human Services (HHS) stockpiles medical products that are essential to the security of the nation (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 have rendered such products misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352).

2. Purpose and Use of the Information Collection

The appropriate FDA Center Director may grant an exception or alternative to certain FDA labeling requirements if compliance with the 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. This facilitates the safety, effectiveness, and availability of appropriate medical countermeasures in the event of a public health emergency.

If the request is granted, the manufacturer may need to report to FDA any resulting changes to the new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or premarket notification (510(k)) in effect, if any. The submission and grant of a request for an exception or alternative to the labeling requirements 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 drugs), 21 CFR 814.39 (medical devices subject to premarket approval), or 21 CFR 807.81 (medical devices subject to premarket notification submission (510(k) clearance) requirements).

3. Use of Improved Information Technology and Burden Reduction

One of FDA's continuing objectives is to improve the speed and quality of its review and approval programs. To make the review process more efficient for industry and FDA, FDA utilizes electronic information system technologies. FDA believes the increased use of computer-assisted information technology enhances the timeliness, effectiveness, and efficiency of the review process and reduces burdensome, nonessential hard-copy handling and storage. FDA is not aware of any other improved technology to reduce the burden.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

This collection of information applies to both small and well as large establishments. Although FDA must apply the statutory and regulatory requirements equally to all enterprises, FDA does provide special help to small businesses. The Center for Biologics Evaluation and Research, Office of Communications, Outreach, and Development, Division of Manufacturer's Assistance and Training, the Center for Drug Evaluation and Research, Office of Communication, Division of Drug Information, and the Center for Devices and Radiological Health, Office of Communication and Education, Division of Industry and Consumer Education provide assistance to small businesses subject to FDA's regulatory requirements.

6. Consequences of Collecting the Information Less Frequently

Less frequent collection of this and other information would not provide the information that FDA needs to facilitate the safety, effectiveness, and availability of appropriate medical countermeasures in the event of a public health emergency.

There are no technical or legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

An entity may be required to submit to FDA proprietary trade secret or other confidential information when submitting a request for an exception or alternative to the labeling requirements. FDA protects confidential information received from manufacturers to the extent permitted by law.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of May 23, 2017 (82 FR 23584). No public comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

The confidentiality of information received by FDA is consistent with the Freedom of Information Act (FOIA) and FDA's published regulations of "Public Information" under 21 CFR Part 20, and 21 CFR 312.130, 314.430, 601.50, 601.51, 807.95, 809.4, 812.38, and 814.122.

11. Justification for Sensitive Questions

Questions of a sensitive nature are not applicable to this collection of information.

12. Estimates of Annualized Burden Hours and Costs

12.a. *Annualized Hour Burden Estimate*

The total annual estimated burden of this collection of information is 32 hours, as reflected in Table 1, below.

Table 1. – Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	No. 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) 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) [Changes]	1	1	1	8	8
Total					32

Respondents to this collection of information are entities that manufacture (including labeling, packing, relabeling, or repackaging), distribute, or store affected products.

Based on the number of requests for an exception or alternative received by FDA in fiscal years 2014 and 2015, FDA estimates an average of one request annually. FDA is estimating that each respondent will spend 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 regulations, 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 information collection provisions in 21 CFR 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.

12.b. *Annualized Cost Burden Estimate*

The estimated annual cost to respondents is $2,208.

Activity	No. of Hours	Cost per Hour	Total Cost
Reporting	32	$69.00	$2,208

The cost estimate is based on a regulatory affairs specialist, at a pay rate of $69.00 per hour, who would be responsible for preparing a submission to FDA. The estimated average hourly pay rate includes benefits but no overhead costs.

13. Estimates of Other Total Annual Costs to Respondents and/or Record Keepers/CapitalCosts

There are no capital costs or operating or maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

The estimated annual cost to FDA is $2,880.

Activity	Number of Reviews	Average Hours per Review	Average Cost per Hour	Total Cost
Review & Process	2	20	$72.00	$2,880

This cost estimate is based on FDA regulatory review staff with an average pay of $72 per hour spending an estimated average of 20 hours to review and process the submissions to FDA. This salary estimate includes benefits but no overhead costs.

15. Explanation for Program Changes or Adjustments

The estimated total annual burden for this information collection in 2014 was 32 hours. Based on a review of more current data we have made no change in our burden estimate for the information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results to publish for this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not seeking approval to exempt display of the OMB Expiration Date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.