Exceptions or Alternatives to Labeling Requirements for Products Held By the Strategic National Stockpile

OMB # 0910-0614

SUPPORTING STATEMENT

Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting Office of Management and Budget (OMB) approval of the information collection provisions listed below:

21 CFR Section	Category	Description
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 provisions to the appropriate FDA Center Director.
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 provisions to the appropriate FDA Center Director.
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 provisions to the appropriate FDA Center Director.
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 provisions to the appropriate FDA Center Director.

Under the Public Health Service 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 (the act) (21 U.S.C. 352).

This collection of information is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

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 this rule 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 specified in this rule 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 drugs), § 814.39 (21 CFR 814.39) (medical devices subject to premarket approval), or § 807.81 (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

FDA is the only agency that requires the request for an exception or alternative to certain labeling requirements applicable to human drugs, biological products, and medical devices that are or will be included in the SNS. No other component of FDA or other government agencies requires similar information or data to be submitted. This information is not available from any other source.

5. Impact on Small Businesses or Other Small Entities

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 (CBER), 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, Division of Small Manufacturers, International and Consumer Assistance 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, FDA published a 60-day notice for public comment in the Federal Register of November 30, 2010 (75 FR 74062). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift was provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

The confidentiality of information received by FDA would be consistent with the Freedom of Information Act and FDA's regulations under 21 CFR Part 20, 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 information collection.

12. Estimates of Annualized Burden Hours and Costs

The total annual estimated burden imposed by this collection of information is 56 hours.

12.a. Annualized Burden Estimate

Table 1. – Estimated Annual Reporting Burden

21 CFR Section	No. 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) 809.119(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

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 since the 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 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 regulations, 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.

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.

12.b. Annualized Cost Burden to Respondents

The estimated annual cost to respondents is $3,360.

Activity	No. of Hours	Cost per Hour	Total Cost
Reporting	56	$60.00	$3,360

The cost estimate is based on a regulatory affairs specialist, at a pay rate of $60.00 per hour, who would be responsible for preparing a submission. The estimated average hourly pay rate includes benefits but no overhead costs.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

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

14. Annualized Cost to the Federal Government

The estimated annual cost to FDA is $4,200.

Activity	Number of Reviews	Average Hours per Review	Average Cost per Hour	Total Cost
Review & Process	3	20	$70.00	$4,200

This estimate is based on FDA regulatory review staff with an average pay of $70 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 negative numbers that appear in the 'Due to Agency Discretion' and 'Due to Adjustment in Agency Estimate' column are due to:

#1: The estimated total annual burden for this information collection was 728 hours in 2007. The current decrease to 56 burden hours is attributed to the number of annual submissions received since the regulations became effective.

#2: the electronic database systems - ICRAS and ROCIS (used by the Department of Health and Human Services (HHS) and Office of Management and Budget (OMB) automatically defaults the deleted Information Collection (IC) line items into the 'Due to Agency Discretion' column.

Once an Information Collection (IC) line item is deleted; the electronic database systems, used by HHS and OMB, does not allow FDA to modify without the 'annual number of responses and 'annual hour burden' automatically defaulting to a program change and causing a negative number. The negative numbers are a result of the database systems keeping a record of all information since 2007.

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 the display of the expiration date of the OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Not applicable.