Supporting Statement for

EXCEPTIONS OR ALTERNATIVES TO LABELING REQUIREMENTS FOR PRODUCTS HELD BY THE STRATEGIC NATIONAL STOCKPILE; INTERIM FINAL RULE

OMB # 0910-0614

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 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 provisions to the appropriate 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 provisions to the appropriate 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 provisions to the appropriate 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 provisions to the appropriate Center Director.

Under the Public Health Security and Bioterrorism Preparedness and Response Act and other relevant statutes, the Department of Health and Human Services (HHS) stockpiles medical products that are essential to the security of the nation (see Public Law 107-188, Title I, section 121 (June 12, 2002). As established in section 3 of the Project BioShield Act of 2004 (section 319F-2 of the

Public Health Service Act (the PHS Act) (42 U.S.C. 247d-6b) , this collection of medical products for use during national health emergencies, known as the Strategic National Stockpile (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).

2. Purpose and Use of the Information Collection

The interim final rule allows the appropriate FDA Center Director to 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 would be 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 rule will facilitate the safety, effectiveness, and availability of appropriate medical countermeasures and 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).

The information collection provisions in §§ 314.70, 601.12, 807.81 and 814.39 have been approved under OMB control numbers 0910-0001 (expires May 31, 2008), 0910-0338 (expires September 30, 2008), 0910-0120 (expires May 31, 2007), and 0910-0231 (expires September 30, 2007), respectively.

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. FDA utilizes electronic information system technologies where applicable. FDA believes the increased use of computer-assisted information technology, such as regulatory submissions in electronic format, 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 exceptions or alternatives to certain labeling requirements applicable to human drugs, biological products, and medical devices that are or would 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, Training, and Manufacturers Assistance, the Center for Drug Evaluation and Research, Office of Training and Communication, 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 has instituted security measures to protect confidential information received and will, to the extent permitted by law, protect the information.

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

In accordance with 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13), FDA published in the Federal Register of December 28, 2007 (72 FR73589) an emergency processing notice requesting public comment on the information collection provisions in the interim final rule.

FDA received several public letters of comment on the interim final rule; however, only one letter of comment addressed the information collection provisions.

The comment stated that the regulation would appear to place burdens on a manufacturer. In one example, the comment stated a company would need to include in an annual report to FDA information on changes in labeling even when the changes were initiated by the government without knowledge of the manufacturer, and the company would therefore need to track activities of the SNS after the product had been distributed. The comment also stated that FDA may require a manufacturer of investigational products to add language to the outer package labeling of an SNS

product after the product is licensed, approved, or cleared.

Under the rule, an exception or alternative granted by an FDA Center Director on his or her own initiative would not require a manufacturer to submit information about the exception or alternative in an annual or periodic report. See, e.g., 21 CFR 314.70(a)(1)(ii) ("However, any *grant of a request* for an exception or alternative under § 201.26 of this chapter must be reported as part of the annual report….") (emphasis added). Moreover, any annual or periodic report submissions reflecting exceptions or alternatives requested and granted under this rule would be submitted under §§ 314.70, 601.12, 807.81, and 814.84, which have been approved under OMB control numbers 0910-0001, 0910-0338, 0910-0120, and 0910-0231. Therefore, FDA does not believe any additional change in burden is necessary.

With respect to the comment regarding the addition of language to outer package labeling of SNS products upon licensure, approval, or clearance, it is possible that such labeling changes may be made in connection with FDA's grant of an exception or alternative under this rule. We note that labeling changes upon product licensure, approval, or clearance are generally required by FDA's labeling regulations under the applicable sections in parts 201, 610, and 801, which have been approved under OMB control numbers 0910-0338, 0910-0572, 0910-0340, 0910-0139, and 0910-0485. In many cases, an exception or alternative granted under this rule would allow information already required under FDA's labeling regulations to be placed in a different location (e.g., outer packaging) or at a later date than would ordinarily be required. To the extent that labeling changes not already required by FDA regulations are made in connection with an exception or alternative granted under this rule, FDA is adjusting the burden estimate. Based on our limited experience with requests for an exception or alternative under this rule, we have not required any additional labeling changes when granting a request. However, FDA is estimating one occurrence annually in the event we 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. As we gain more experience, we will adjust the burden estimates as necessary.

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. Proprietary or trade secret information is deleted from any information released by FDA under the Freedom of Information Act and FDA regulations.

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 728 hours annually.

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)	18	1	18	24	432
610.68(b)(1)(i)	10	1	10	24	240
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					728

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

Although FDA cannot predict the number of future requests, based on limited information within FDA, we estimate that approximately 30 respondents would request annually one exception or alternative to labeling provisions to avoid misbranding of their products in the SNS. The estimate of one request per respondent is based on the anticipated occasional occurrence of a product being misbranded while in the SNS. We are estimating that each respondent would spend from 8 to 24 hours preparing each request. The hours per response are based on 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. FDA is estimating one occurrence annually in the event we 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. As we gain more experience, we will adjust the burden estimates as necessary.

The information collection provisions in §§ 314.70, 601.12, 807.81 and 814.39 have been approved under OMB control numbers 0910-0001 (expires May 31, 2008), 0910-0338 (expires September 30, 2008), 0910-0120 (expires August 31, 2010), and 0910-0231 (expires November 30, 2010), respectively.

Cost to Respondents

The estimated annual cost to respondents is $34, 398.

Activity	No. of Hours	Cost per Hour	Total Cost
Reporting	728	$47.25	$34398

The cost estimate is based on a regulatory affairs specialist, at a pay rate of $47.25/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 $36,600.

Activity	Number of Reviews	Average Hours per Review	Average Cost per Hour	Total Cost
Review & Process	30	20	$61	$36,600

This estimate is based on FDA regulatory review staff with an average pay of $61/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 was 720 hours in 2007. The current increase to 728 burden hours is attributed to the response to the public comment to account for any additional labeling changes not already covered by FDA regulations.

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.