UNITED STATES FOOD & DRUG ADMINISTRATION

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

OMB Control No. 0910-0614

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, the agency) regulations regarding Exceptions or Alternatives to Labeling Requirements for Products Held By the Strategic National Stockpile. 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 render such products misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352). Information regarding the Strategic National Stockpile is available at the following website: www.phe.gov/about/sns/Pages/default.aspx.

We therefore request extension of Office of Management and Budget (OMB) approval of the information collection provisions found in the associated regulations and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

Under 21 CFR §§ 201.26, 610.68, 801.128, and 809.11 (§§ 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 alternate 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. This facilitates the safety, effectiveness, and availability of appropriate medical countermeasures in the event of a

public health emergency. 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 the regulations 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 (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 the regulations may be used to satisfy certain reporting obligations relating to changes to product applications under §§ 314.70, 601.12, 814.39, and 807.81 (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.

3. Use of Improved Information Technology and Burden Reduction

One of our continuing objectives is to improve the efficiency and quality of our review and approval programs. Currently, business activities at FDA are conducted using information system technologies. We believe 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. We are 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 as well as large establishments but imposes no undue burden on respondents. At the same time, the agency assists small businesses through resources available from our website and from small business staff representatives throughout the agency. For reference we invite readers to review the small business resources made available on our website at: https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements. 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), we published a 60-day notice for public comment in the Federal Register of July 2, 2020 (85 FR 39916). One public comment was received, but was not responsive to the four information collection topics solicited and is therefore not addressed in this document.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments, or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted with our Privacy Office to ensure appropriate handling of personally identifiable information (PII). The PII collected identifies the business contact, mailing address, work telephone number, work e-mail address, and work FAX number as part of the written request required to effect an exception or alternative to otherwise applicable labeling requirements. We have determined that although this PII is collected, it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. FDA also minimizes the PII to be collected to protect the privacy of the individuals. Finally, 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

This collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	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.

21 CFR 201.26(b)(1)(i): 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.

21 CFR 610.68(b)(1)(i): 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.

21 CFR 801.128(b)(1)(i): 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.

21 CFR 809.11(b)(1)(i): 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.

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

Based on data from fiscal years 2017, 2018, and 2019, we estimate an average of one request annually. We assume it takes an average of 24 hours to prepare each request based on our experience with the information collection. 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 we would require any additional labeling changes not already covered by applicable regulations. We assume it takes 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.

12b. Annualized Cost Burden Estimate

Activity	No. of Hours	Cost per Hour	Total Cost
Reporting	32	$80.00	$2,560

The cost estimate is based on a regulatory affairs specialist, at a pay rate of $80.00 per hour, who would be responsible for preparing a submission to FDA. The pay rate includes benefits but no overhead costs.

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

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

14. Annualized Cost to the Federal Government

The estimated annual cost to FDA is $3,160.

Activity	Number of Reviews	Average Hours per Review	Average Cost per Hour	Total Cost
Review & Process	2	20	$79.00	$3,160

This cost estimate is based on FDA regulatory review staff with an average pay of $79 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

Based on a review of the information collection, we have made no changes or adjustments to the currently approved burden estimate. We have, however, retitled the information collection elements to reflect the activity versus the regulatory citation reference. Also, although recent consumption of products from the SNS may result in an increase in future submissions, we have not yet received such submissions.

16. Plans for Tabulation and Publication and Project Time Schedule

The information collection will not be published or tabulated.

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

Display of the OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.