

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN<sup>1</sup>—Continued

21 CFR section/activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
701.12—Name and place of business .....	1,518	24	36,432	1	36,432
701.13—Net quantity of contents .....	1,518	24	36,432	1	36,432
Total .....					141,174

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

The hour burden is the additional or incremental time that establishments need to design and print labeling that includes the following required elements: A declaration of ingredients in decreasing order of predominance, a statement of the identity of the product, a specification of the name and place of business of the establishment, and a declaration of the net quantity of contents. These requirements increase the time establishments need to design labels because they increase the number of label elements that establishments must take into account when designing labels. These requirements do not generate any recurring burden per label because establishments must already print and affix labels to cosmetic products as part of normal business practices.

The estimated annual third-party disclosure is based on data available to the Agency, our knowledge of and experience with cosmetic labeling, and our communications with industry. We estimate there are 1,518 cosmetic product establishments in the United States. We calculate label design costs based on stock keeping units (SKUs) because each SKU has a unique product label. Based on data available to the Agency and on communications with industry, we estimate that cosmetic establishments will offer 94,800 SKUs for retail sale in 2017. This corresponds to an average of 62 SKUs per establishment.

One of the four provisions that we discuss in this information collection, § 701.3, applies only to cosmetic products offered for retail sale. However, the other three provisions, §§ 701.11, 701.12, and 701.13, apply to all cosmetic products, including non-retail professional-use-only products. We estimate that including professional-use-only cosmetic products increases the total number of SKUs by 15 percent to 109,020. This corresponds to an average of 72 SKUs per establishment.

Finally, based on the Agency's experience with other products, we estimate that cosmetic establishments may redesign up to one-third of SKUs

per year. Therefore, we estimate that the number of disclosures per respondent will be 21 (31,878 SKUs) for § 701.3 and 24 each (36,432 SKUs) for §§ 701.11, 701.12, and 701.13.

We estimate that each of the required label elements may add approximately 1 hour to the label design process. We base this estimate on the hour burdens the Agency has previously estimated for food, drug, and medical device labeling and on the Agency's knowledge of cosmetic labeling. Therefore, we estimate that the total hour burden on members of the public for this information collection is 141,174 hours per year.

Dated: August 2, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

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

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. **DATES:** Fax written comments on the collection of information by September 7, 2017.

**ADDRESSES:** To ensure that comments on the information collection are received,

OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0614. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### 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 (PHS Act), the Department of Health and Human Services stockpiles medical products that are essential to the health security of the Nation (see 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 render such products misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352).

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 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 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, 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 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.

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 2014 and 2015, FDA estimates an average of one request annually for an exception or alternative received by FDA. FDA estimates 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 average burden per response for each submission is based on the estimated time to develop and revise the labeling to make such changes.

In the **Federal Register** of May 23, 2017 (82 FR 23584), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received.

We therefore estimate the burden of this collection of information as follows:

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

21 CFR Section	Number of respondents	Number 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

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

Dated: August 2, 2017.

**Anna K. Abram,**  
Deputy Commissioner for Policy, Planning,  
Legislation, and Analysis.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Office of Patient Advocacy/Be The Match® Patient Services Survey, OMB No. 0906-0004, Revision**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR must be received no later than October 10, 2017.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting

information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

*Information Collection Request Title:* Office of Patient Advocacy/Be The Match® Patient Services Survey, OMB No. 0906-0004—Revision.

*Abstract:* The National Marrow Donor Program®/Be The Match® is a HRSA contractor dedicated to helping patients and families get the support and information they need to learn about their disease and treatment options, prepare for a blood stem cell transplant, and thrive after a transplant procedure. The information and resources provided help individuals navigate the bone marrow or cord blood transplant process. Participant feedback is essential to understand the needs for transplant support services and educational information across a diverse population. This information is used to determine helpfulness of existing services and resources. Feedback is also used to identify areas for improvement and develop future programs.

*Need and Proposed Use of the Information:* Barriers to access to bone marrow or cord blood transplant related care and educational information are multi-factorial. Feedback from participants is essential to better understand the changing needs for services and information as well as to demonstrate the effectiveness of existing services. The primary use for information gathered through the survey is to determine helpfulness of participants' initial contact with Be The Match® Patient Services Coordinators (PSC) and to identify areas for improvement in the delivery of services. In addition, stakeholders use this evaluation data to make program and resource allocation decisions.

The survey includes items to measure the following: (1) Reason for contacting Be The Match®, (2) if the PSC was able to answer questions and was easy to understand, (3) if the contact helped the participant to feel better prepared to

discuss transplants with their care team, (4) increase in awareness of available resources, (5) timeliness of response, and (6) overall satisfaction.

The proposed changes to the survey instrument include minor changes to both selected survey questions and the instructions. The updated survey questions include simplified language and the references to race and ethnicity are updated to better match preliminary U.S. Census Bureau question format and statements from the U.S. Department of Education. The question format changes will better allow individuals to self-identify their ethnicity and race and permit individuals to select more than one race and/or ethnicity. These changes will not increase respondent burden.

*Likely Respondents:* Respondents will include all patients, caregivers and family members who have contact with Be The Match Patient Services Coordinators via phone or email for transplant navigation services and support. The decision to survey all participants was made based on historic evidence of patients' unavailability due to frequent transitions in health status as well as between home and the hospital for initial treatment and care for complications.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

**TOTAL ESTIMATED ANNUALIZED BURDEN HOURS**

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Be The Match Patient Services Survey .....	420	1	420	0.25	105
Total .....	420	.....	420	.....	105

HRSA specifically requests comments on (1) the necessity and utility of the

proposed information collection for the proper performance of the agency's

functions; (2) the accuracy of the estimated burden; (3) ways to enhance