reporting frequency when submitting a PBRER. FDA expects approximately 29 applicants to make these submissions, and we estimate that the time for submitting the additional information described in the previous paragraph would be on average approximately 2 hours for each waiver request.

In the Federal Register of May 23, 2017 (82 FR 23578), 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

<table>
<thead>
<tr>
<th>Additional information and/or lock point and/or a different reporting frequency</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicants that have a PSUR waiver for an approved application</td>
<td>55</td>
<td>3.4</td>
<td>187</td>
<td>1</td>
<td>187</td>
</tr>
<tr>
<td>Applicants that do not have a PSUR waiver for an approved application</td>
<td>29</td>
<td>2.3</td>
<td>67</td>
<td>2</td>
<td>134</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>321</td>
</tr>
</tbody>
</table>

1 There are no capital or operating and maintenance costs associated with the information collection.


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

[FR Doc. 2017–16647 Filed 8–7–17; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[DOCKET NO. FDA–2017–N–1848]

Agency Information Collection Activities; Submission of Office of Management and Budget Review; Comment Request; Cosmetic Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) 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 (PRA).

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. All comments should be identified with the OMB control number 0910–0599. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, 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.

Cosmetic Labeling Regulations—21 CFR Part 701

OMB Control Number 0910–0599—Extension

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) and the Fair Packaging and Labeling Act (the FPLA) require that cosmetic manufacturers, packers, and distributors disclose information about themselves or their products on the labels or labeling of their products. Sections 201, 301, 502, 601, 602, 603, 701, and 704 of the FD&C Act (21 U.S.C. 321, 352, 361, 362, 363, 371, and 374) and sections 4 and 5 of the FPLA (15 U.S.C. 1453 and 1454) provide authority to FDA to regulate the labeling of cosmetic products. Failure to comply with the requirements for cosmetic labeling may render a cosmetic adulterated under section 601 of the FD&C Act or misbranded under section 602 of the FD&C Act.

FDA’s cosmetic labeling regulations are published in part 701 (21 CFR part 701). Four of the cosmetic labeling regulations have information collection provisions. Section 701.3 requires the label of a cosmetic product to bear a declaration of the ingredients in descending order of predominance. Section 701.11 requires the principal display panel of a cosmetic product to bear a statement of the identity of the product. Section 701.12 requires the label of a cosmetic product to specify the name and place of business of the manufacturer, packer, or distributor. Section 701.13 requires the label of a cosmetic product to declare the net quantity of contents of the product.

In the Federal Register of May 23, 2017 (82 FR 23576), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received which described ingredients used in the creation of cosmetics but was not PRA-related and will not be addressed here.

FDA estimates the burden of this collection of information as follows:

### Table 1—Estimated Annual Third-Party Disclosure Burden

<table>
<thead>
<tr>
<th>21 CFR section/activity</th>
<th>Number of respondents</th>
<th>Number of disclosures per respondent</th>
<th>Total annual disclosures</th>
<th>Average burden per disclosure</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>701.3—Ingredients in order of predominance</td>
<td>1,518</td>
<td>21</td>
<td>31,878</td>
<td>1</td>
<td>31,878</td>
</tr>
<tr>
<td>701.11—Statement of identity</td>
<td>1,518</td>
<td>24</td>
<td>36,432</td>
<td>1</td>
<td>36,432</td>
</tr>
</tbody>
</table>
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 that the total hour burden on members of the public for this information collection is 141,174 hours 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.


Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.
[FR Doc. 2017–16649 Filed 8–7–17; 8:45 am]
BILLING CODE 4164–01–P

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. 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.

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).