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 [1]

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

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

Dated: August 2, 2017.

Anna K. Abram,

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

[FR Doc. 2017–16647 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–2017–N–1848]

Agency Information Collection Activities; Submission for 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, *PRAStaff@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 [1]

21 CFR section/activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
701.3—Ingredients in order of predominance	1,518	21	31,878	1	31,878
701.11—Statement of identity	1,518	24	36,432	1	36,432

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—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

[1] 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.

[FR Doc. 2017–16649 Filed 8–7–17; 8:45 am]

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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.* 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, *PRAStaff@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).