

The MAI *Plan* Narrative that accompanies the *Plan* Web forms provides (1) an explanation of the data submitted in the *Plan* Web forms; (2) a summary of the *Plan*, including the plan and timeline for disbursing funds, monitoring service delivery, and implementing any service-related capacity development or technical assistance activities; and (3) the plan and timeline for documenting client-level outcome measures. In addition, if the EMA/TGA revised any planned services, allocation amounts or target communities after their grant application was submitted, the changes must be highlighted and explained. The accompanying MAI *Annual Report*

Narrative describes (1) progress towards achieving specific goals and objectives identified in the Grantee's approved MAI *Plan* for that fiscal year and in linking MAI services/activities to Part A and other Ryan White HIV/AIDS Program services; (2) achievements in relation to client-level health outcomes; (3) summary of challenges or barriers at the provider or grantee levels, the strategies and/or action steps implemented to address them, and lessons learned; and, (4) discussion of MAI technical assistance needs identified by the EMA/TGA.

*This information is needed to monitor and assess:* (1) Changes in the type and amount of HIV/AIDS health care and

related services being provided to each disproportionately impacted community of color; (2) the aggregate number of persons receiving HIV/AIDS services within each racial and ethnic community; and (3) the impact of Part A MAI-funded services in terms of client-level and service-level health outcomes. The information also is used to plan new technical assistance and capacity development activities, and inform the HRSA policy and program management functions. The data provided to HRSA does not contain individual or personally identifiable information.

The annual estimated response burden for grantees is as follows:

Form	Estimated number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Part A MAI Report .....	56	2	112	5	560

**Note:** Data collection system enhancements have resulted in a shortened response burden (from 6 to 5 total hours per response) for respondents since the previous OMB approval request.

E-mail comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Written comments should be received within 30 days of this notice.

Dated: March 5, 2010.

**Sahira Rafiullah,**  
Director, Division of Policy and Information Coordination.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0120]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Cosmetic Labeling Regulations**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of

information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection provisions in FDA's cosmetic labeling regulations.

**DATES:** Submit written or electronic comments on the collection of information by May 17, 2010.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies

to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Cosmetic Labeling Regulations—21 CFR Part 701 (OMB Control Number 0910-0599)—Extension**

The Federal Food, Drug, and Cosmetic Act (the 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, 502, 601, 602, 603, 701, and 704 of the 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 act or misbranded under section 602 of the 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.

FDA's cosmetic labeling regulations remain unchanged by this document. FDA is publishing this document in compliance with the PRA. This document does not represent any new regulatory initiative.

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

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

21 CFR Section	No. of Respondents	Annual Frequency of Disclosure	Total Annual Disclosures	Hours per Disclosure	Total Hours
701.3	1,518	21	31,878	1	31,878
701.11	1,518	24	36,432	1	36,432
701.12	1,518	24	36,432	1	36,432
701.13	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.

According to the 2001 census, there are 1,518 cosmetic product establishments in the United States (U.S. Census Bureau, <http://www.census.gov/epcd/susb/2001/us/US32562.HTM>). FDA calculates label design costs based on stockkeeping units (SKUs) because each SKU has a unique product label. Based on data available to the agency and on communications with industry, FDA estimates that cosmetic establishments will offer 94,800 SKUs for retail sale in 2010. This corresponds to an average of 62 SKUs per establishment.

One of the four provisions that FDA discusses 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. FDA estimates 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, FDA estimates that cosmetic establishments may redesign up to one-third of SKUs per year. Therefore, FDA estimates that the annual frequency of response will be 21 (31,878 SKUs) for § 701.3 and 24 each (36,432 SKUs) for §§ 701.11, 701.12, and 701.13.

FDA estimates that each of the required label elements may add approximately 1 hour to the label design process. FDA bases 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, FDA estimates that the total hour burden on members of the public for this information collection is 141,174 hours per year.

Dated: March 11, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0119]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the agency's regulations that require registration for domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States.