

to short/long-term budget projections, trend analysis, and target areas for improved technical assistance. The data

will provide information about foster care placements, adoptive parents, length of time in care, delays in

termination of parental rights and placements for adoption.

*Respondents:* State governments.

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Reporting system .....	51	2	3,251	331,602

*Estimated Total Annual Burden Hours:* 331,602.

*Additional Information:* Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Ms. Wendy Taylor.

Dated: August 26, 1996.

Bob Sargis,

*Acting Reports Clearance Officer, Office of Information Management Services.*

[FR Doc. 96-22050 Filed 8-28-96; 8:45 am]

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## Food and Drug Administration

[Docket No. 96N-0185]

### Agency Information Collection Activities: Proposed Collection; Comment Request; Reinstatement

**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, Federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed reinstatement 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 Cosmetic Product Voluntary Reporting Program.

**DATES:** Submit written comments on the collection of information by October 28, 1996.

**ADDRESSES:** Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Charity B. Smith, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B-19, Rockville, MD 20857, 301-827-1686.

**SUPPLEMENTARY INFORMATION:** Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (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 reinstatement of an existing collection of information. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c). To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (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 Product Voluntary Reporting Program (21 CFR 720.4, 720.6, 720.8(b)) (OMB Control Number 0910-0030—Reinstatement)

Under the Federal Food, Drug, and Cosmetic Act (the act) cosmetic products that are adulterated under section 601 of the act (21 U.S.C. 361) or misbranded under section 602 of the act (21 U.S.C. 362) cannot legally be distributed in interstate commerce. To assist FDA in carrying out its responsibility to regulate cosmetics FDA requests, under part 720 (21 CFR part 720), but does not require, that firms that manufacture, pack, or distribute cosmetics file an ingredient statement for each of their products with the agency (§ 720.4). Ingredient statements for new submissions (§ 720.1) are reported on Form FDA 2512, "Cosmetic Product Ingredient Statement" and Form FDA 2512a, a continuation form. Changes in product formulation (§ 720.6) are also reported on Forms FDA 2512 and FDA 2512a. When a firm discontinues the commercial distribution of a cosmetic, FDA requests that the firm file Form FDA 2514, "Discontinuance of Commercial Distribution of Cosmetic Product Formulation" (§ 720.6). If any of the information submitted on or with these forms is confidential, the firm may submit a request for confidentiality under § 720.8.

FDA uses the information received on these forms as input for a computer-based information storage and retrieval system. These voluntary formula filings provide FDA with the best information available about cosmetic product formulations, ingredients and their frequency of use, businesses engaged in the manufacture and distribution of cosmetics, and approximate rates of product discontinuance and formula modifications. FDA's database also lists cosmetic products containing ingredients suspected to be carcinogenic or otherwise deleterious to humans and the public health generally. The information provided under the Cosmetic Product Voluntary Reporting Program assists FDA scientists in evaluating reports of alleged injuries and adverse reactions to the use of cosmetics. The information also is

utilized in defining and planning analytical and toxicological studies pertaining to cosmetics.

FDA shares nonconfidential information from its files on cosmetics with consumers, medical professionals, and industry. For example, by submitting a Freedom of Information Act request, consumers can obtain

information about which products do or do not contain a specified ingredient and about the levels at which certain ingredients are typically used. Dermatologists use FDA files to cross-reference allergens found in patch test kits with cosmetic ingredients. The Cosmetic, Toiletry, and Fragrance

Association, which is conducting a review of ingredients used in cosmetics, has relied on data provided by FDA in selecting ingredients to be reviewed based on frequency of use.

FDA estimates the burden of the Cosmetic Product Voluntary Reporting Program as follows:

#### ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Burden Hours
720.1 & 720.4 (new submissions)	FDA 2512/2512a	550	4.2	2,310	0.50	1,155
720.4 & 720.6 (amendments)	FDA 2512/2512a	550	1.4	770	0.33	254
720.6 (notice of discontinuance)	FDA 2514	550	4.5	2,500	0.1	250
720.8 (request for confidentiality)		2	1.0	2	1.5	3
Total						1,662

There are no capital costs or operating and maintenance costs associated with this collection.

This estimate is based on the number and frequency of submissions received in the past and on discussions between FDA staff and respondents during routine communications. The actual time required for each submission will vary in relation to the size of the company and the breadth of its marketing activities.

Dated: August 21, 1996.

William K. Hubbard,  
Associate Commissioner for Policy  
Coordination.

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[Docket No. 96N-0261]

#### Agency Information Collection Activities: Proposed Collection; Comment Request; Reinstatement

**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, Federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements relating to the submission

of reclassification petitions for medical devices.

**DATES:** Submit written comments on the collection of information by October 28, 1996.

**ADDRESSES:** Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Charity B. Smith, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B-19, Rockville, MD 20857, 301-827-1686.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (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 reinstatement 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 listed below.

With respect to the following collection of information, FDA invites comments on: (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.

#### Reclassification Petitions for Medical Devices—21 CFR Part 860 (OMB Control Number 0910-0138)

*Type of OMB Approval Requested:*  
Reinstatement Without Change of a  
Previously Approved Collection for  
Which Approval has Expired

FDA has the responsibility under sections 513(e), 513(f), 514(b), 515(b), and 520(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(e) and (f), 360d(b), 360e(b), and 360j(l)) and 21 CFR part 860, subpart C, to collect data and information contained in reclassification petitions. The reclassification provisions of the act allow any person to petition for reclassification of a medical device from