Nancy Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–16–99]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

1. National Surveillance of Dialysis-Associated Diseases (0920–0009)—Reinstatement—National Center for Infectious Diseases (NCID). The Hospital Infectious Program, NCID is proposing renewal of a yearly mail survey of dialysis practices and dialysis-associated diseases at U.S. outpatient hemodialysis centers. The rehabilitation of individuals in the United States who suffer from chronic renal failure has been identified as an important national priority; and since 1973, chronic hemodialysis patients have been provided financial support by the Federal Government. The Hospital Infections Program and the Hepatitis Branch, Division of Viral and Rickettsial Diseases, Centers for Disease Control and Prevention, have responsibility for formulating strategies for the control of hepatitis, bacteremia, pyrogenic reactions, and other hemodialysis-associated disease.

In order to devise such control measures, it is necessary to determine the extent to which the incidence of these dialysis-associated diseases changes over time. This request is to continue surveillance activities among chronic hemodialysis centers nationwide. In addition, once control measures are recommended it is essential that such measures be monitored to determine their effectiveness. The survey is conducted once a year by mailing it to all chronic hemodialysis centers licensed by the Health Care Financing Administration (HCFA). Dialysis practices surveyed include the use of hepatitis B vaccine in patients and staff members, whether isolation rooms are used to treat hepatitis B surface antigen-positive patients, the types of vascular access and dialyzers used, whether certain dialysis items are disinfected for reuse, and whether the dialysis center has any policy for insuring judicious use of antimicrobial agents. Among dialysis-associated diseases, the survey includes hepatitis B virus infection, antibody to hepatitis C virus, antibody to human immunodeficiency virus, pyrogenic reactions, and vancomycin-resistant enterococci. The total annual burden hours are 3200.

Respondents	Number of respondents	Number of responses/respondent	Avg. Burden/response (in hrs.)
Chronic Hemodialysis Centers	3,200	1	1

Dated: August 3, 1999.

Nancy Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–20380 Filed 8–6–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0185]

Agency Information Collection Activities: Proposed Collection; Comment Request; Cosmetic Product Voluntary Reporting Program

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 Cosmetic Product Voluntary Reporting Program.

DATES: Submit written comments on the collection of information by October 8, 1999.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (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: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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 a 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 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, and 720.8(b) (OMB Control Number 0910–0030—Extension)

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 with the agency an ingredient statement for each of their products (§ 720.4). Ingredient statements for new submissions (§ 720.1) are reported on Form FDA 2512 entitled ''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 entitled ''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 data base also lists cosmetic products containing ingredients suspected to be carcinogenic or otherwise harmful to the general public health. 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.

The Cosmetic Product Voluntary Reporting Program was suspended during fiscal year (FY) 1998 because of a lack of funding and was reinstated at the beginning of FY 1999. Participation returned to the previous level. Thus, FDA estimates that the burden of this collection of information will remain the same as the estimate presently on file with OMB.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
720.4 (New submissions)	FDA 2512/FDA 2512a	550	4.2	2,310	0.5	1,155
720.6 (Amendments)	FDA 2512/2512a	550	1.4	770	0.33	254
720.6 (Notices of discontinuance)	FDA 2514	550	4.5	2,500	0.1	250
720.8 (Requests for confidentiality		2	1.0	2	1.5	3
Total						1,662

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

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 2, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–20359 Filed 8–6–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. [99F–2552]]

Asahi Denka Kogyo K.K.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Asahi Denka Kogyo K.K. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of phosphorous acid, cyclic neopentanetetrayl bis(2,6-di-tert-butyl-4-methylphenyl) ester as an antioxidant and/or stabilizer in polyolefins intended to contact food.

FOR FURTHER INFORMATION CONTACT: Vivian Gilliam, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3094.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9B4679) has been filed by Asahi Denka Kogyo K.K., c/o Japan Technical Information Center, Inc., 775