as late and will not be considered in the competition.

2. Deadline. Mailed applications shall be considered as meeting an announced deadline if they are either received on or before the deadline date or sent on or before the deadline date and received by ACF in time for the independent review to: U.S. Department of Health and Human Services, Administration for Children and Families, Division of Discretionary Grants, Attention: Lois Hodge/Tribal Child Support, 370 L'Enfant Promenade, S.W., Mail Stop 6C–462, Washington, D.C. 20447.

Applicants must ensure that a legibly dated U.S. Postal Service postmark or a legibly dated, machine-produced postmark of a commercial mail service is affixed to the envelope/package containing the application(s). To be acceptable as proof of timely mailing, a postmark from a commercial mail service must include the logo/emblem of the commercial mail service company and must reflect the date the package was received by the commercial mail service company from the applicant. Private Metered postmarks shall not be acceptable as proof of timely mailing. (Applicants are cautioned that express/overnight mail services do not always deliver as agreed.)

Applications handcarried by applicants, applicant couriers, or by other representatives of the applicant will be considered as meeting an announced deadline if they are received on or before the deadline date, between the hours of 8:00 a.m. and 4:30 p.m., EST, at the U.S. Department of Health and Human Services, Administration for Children and Families, Division of Discretionary Grants, ACF Mailroom, 2nd Floor (near loading dock), Aerospace Building, 901 D Street, S.W., Washington, D.C. 20024, between Monday and Friday (excluding Federal holidays). The address must appear on the envelope/package containing the application with the note ''Attention: Lois Hodge/Tribal Child Support.'' ACF cannot accommodate transmission of applications by fax or through other electronic media. Therefore, applications transmitted to ACF electronically will not be accepted regardless of date or time of submission and time of receipt.

3. Late applications. Applications which do not meet the criteria above are considered late applications. ACF shall notify each late applicant that its application will not be considered in the current competition.

4. Extension of deadlines. ACF may extend an application deadline for applicants affected by acts of God such as floods and hurricanes, or when there is widespread disruption of the mails. A determination to waive or extend deadline requirements rests with the Chief Grants Management Officer.

Dated: June 19, 1998.

David Gray Ross,

Commissioner, Office of Child Support Enforcement.

[FR Doc. 98–17265 Filed 6–29–98; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0022]

Agency Information Collection Activities: Proposed Collection; Comment Request

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 a notice in the **Federal Register** concerning each 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 reporting and recordkeeping requirements relating to the manufacture and distribution of hearing aid devices.

DATES: Submit written comments on the collection of information requirements by August 31, 1998.

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: Margaret R. 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 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 collections of information set forth below.

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

Hearing Aid Devices: Professional and Patient Package Labeling and Conditions for Sale—21 CFR 801.420 and 801.421 (OMB Control Number 0910–0171—Extension)

Under section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(e)), the Secretary of the Department of Health and Human Services may, under certain conditions, require by regulation that a device be restricted to sale, distribution, or use only upon authorization of a licensed practitioner or upon other prescribed conditions. Sections 801.420 and 801.421 (21 CFR 801.420 and 801.421) implement this authority for hearing aids, which are restricted devices. The regulations require that the manufacturer or distributor provide to the user data useful in selecting, fitting, and checking the performance of a hearing aid through distribution of a User Instructional Brochure. The User Instructional Brochure must also contain technical data about the device, instructions for its use, maintenance, and care, a warning statement, a notice about the medical evaluation

requirement, and a statement if the aid is rebuilt or used.

Hearing aid dispensers are required to provide the prospective user, before the sale of a hearing aid, with a copy of the User Instructional Brochure for the hearing aid model that has been, or may be, selected for the prospective user and to review the contents of the brochure with the buyer. In addition, upon request by an individual who is considering the purchase of a hearing aid, the dispenser is required to provide a copy of the User Instructional Brochure for that model hearing aid or the name and address or telephone number of the manufacturer or distributor from whom a User Instructional Brochure for the hearing aid may be obtained. Under conditions of sale of hearing aid devices, manufacturers or distributors shall provide sufficient copies of the User Instructional Brochure to sellers for distribution to users and prospective users and provide a copy of the User Instructional Brochure to any health care professional, user, or prospective users who requests a copy in writing. The regulations also require that the patient provide a written statement that he or she has undergone a medical evaluation within the previous 6 months before the hearing aid is dispensed, although informed adults may waive the medical evaluation requirement by signing a written statement. Finally, the regulation requires that the dispenser retain for 3 years copies of all physician statements or any waivers of medical evaluations.

The information obtained through this collection of information is used by FDA to ensure that hearing aids are sold and used in a way consistent with the public health.

The information contained in the User Instructional Brochure is intended not only for the hearing aid user but also for the physician, audiologist, and dispenser. The data is used by these health care professionals to evaluate the suitability of a hearing aid, to permit proper fitting of it, and to facilitate repairs. The data also permits the comparison of the performance characteristics of various hearing aids. Noncompliance could result in a substantial risk to the hearing impaired because the physician, audiologist, or dispenser would not have sufficient data to match the aid to the needs of the user.

The respondents to this collection of information are hearing aid manufacturers, distributors, dispensers, health professionals, or other for profit organizations.

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

TABLE 1.—Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
801.420(c)	40	5	200	40	8,000
801.421(a)(1)	9,900	52	514,800	0.10	51,480
801,421(a)(2)	9,900	97	960,300	0.30	288,090
801.421(b)	9,900	162	1,600,000	0.30	480,000
801.421(c)	9,900	5	49,700	0.17	8,449
Totals					836,019

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

TABLE 2.—Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
801.421(d)	9,900	162	1,600,000	0.25	400,000

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

Section 801.420(c) estimate assumes that 40 hearing aid manufacturers/distributors each distribute 5 different models of hearing aids. Thus, the 40 hearing aid manufacturers/distributors will provide 5 different User Instructional Brochures to sellers for distribution to prospective users and users. The completion of each User Instructional Brochure is estimated to require 40 staff hours.

Sections 801.421(a)(1) and 801.421(a)(2) estimates are based on information obtained in the FDA review mentioned previously which revealed that medical evaluations were obtained in 32 percent of the sales and signed waivers were obtained in 60 percent of the sales. For § 801.421(a)(1) estimate, the figure was derived by multiplying the current number of annual hearing aid sales (1.6 million) by .32 and then dividing by the number of hearing aid dispensers (9,900). FDA estimates that it will take hearing aid dispensers .10 hours to request and obtain the required medical evaluation documentation. For § 801.421(a)(2) estimate, the figure was derived by multiplying the current number of hearing aid sales (1.6 million) by .60 and then dividing by the number of hearing dispensers (9,900). FDA estimates that it will take hearing aid dispensers .30 hours to articulate the required disclosure and prepare and make available a waiver form for adults 18 years of age or older to sign. For § 801.421(b) estimate, FDA assumes that 9,900 hearing aid dispensers will have 162 sales annually. For all such sales, the dispenser must provide the prospective user a copy of the User Instructional Brochure and the opportunity to read and review the contents with him/her orally, or in the predominant method used during the sale. FDA estimates that this exchange will involve .30 staff hours.

Section 801.421(c) estimate assumes that 40 hearing aid manufacturers/distributors, and 9,900 dispensers will provide copies of the User Instructional Brochure to any health care professional, user, or prospective user who request a copy in writing. It is estimated that 5 written requests for copies of the brochures will be received by each hearing aid manufacturer/distributor and dispenser annually. It is estimated that each request for a brochure will take .17 staff hours to complete. This effort consists of the hearing aid manufacturer/distributor or

hearing aid dispenser locating the appropriate User Instructional Brochure for the specific model and mailing the brochure to the requester.

Section 801.421(d) recordkeeping estimate assumes that 9,900 hearing aid dispensers will each retain 162 records. Each record documents the dispensing of a hearing aid to a hearing aid user. Each recordkeeping entry is estimated to require 0.25 staff hours.

Dated: June 19, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–17289 Filed 6–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0430]

Nalco Chemical Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Nalco Chemical Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of sodium acrylate/styrene sulfonate copolymer for use as an antiscalant boiler treatment where steam from treated boilers may contact food.

DATES: Written comments on the petitioner's environmental assessment by July 30, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Parvin M. Yasaei, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3189.

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 8A4598) has been filed by Nalco Chemical Co., One Nalco Center, Naperville, IL 60563. The petition proposes to amend the food additive regulations in § 173.310 *Boiler water additives* (21 CFR 173.310) to provide for the safe use of sodium acrylate/sulfonated styrene copolymer for use as an antiscalant boiler treatment where steam from treated boilers may contact food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before July 30, 1998, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.51(b)(1).

Dated: June 8, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–17292 Filed 6–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0433]

Servo Delden BV; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Servo Delden BV has filed a petition proposing that the food additive regulations be amended to provide for the safe use of polyethylene glycol mono-isotridecyl ether sulfate, sodium salt as a surfactant in adhesives intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

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 8B4600) has been filed by Servo Delden BV, c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations to provide for the safe use of polyethylene glycol mono-isotridecyl ether sulfate, sodium salt as a surfactant in adhesives intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: June 4, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–17321 Filed 6–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Center for Veterinary Medicine; Change of Internet Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a change in the Internet address for the Center for Veterinary Medicine (CVM) to ensure that users can continue to have uninterrupted access to CVM's Internet site. The CVM Internet site is one of the agency's methods of communicating with the public regarding the ongoing mission of CVM, which is the organization within the agency that regulates the manufacture and distribution of animal drugs, feeds, and related products.

FOR FURTHER INFORMATION CONTACT: Jerome J. McDonald, Center for Veterinary Medicine (HFV–16), Food and Drug Administration, 7500 Standish