DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0430]

Nalco Chemical Co.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 8A4598) proposing that the food additive regulations be amended 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.

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, 202–418–3023.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 30, 1998 (63 FR 35603), FDA announced that a food additive petition (FAP 8A4598) had been filed by Nalco Chemical Co., One Nalco Center, Naperville, IL 60563. The petition proposed 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. Nalco Chemical Co. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: April 5, 2000.

Alan M. Rulis,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–313]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New Collection;

Title of Information Collection: Medicare DMEPOS Competitive Bidding Demonstration: Follow-up to Original Survey;

Form No.: HCFA–R–313;

Use: This collection is the ''follow-up'' or ''second round'' to the original Competitive Bidding Demonstration collection to compare the results of the two surveys to make inferences about the impact of the competitive bidding demonstration on issues measured by the survey (i.e., access and quality, and goods and services).

Section 4319 of the Balanced Budget Act (BBA) mandates HCFA to implement demonstration projects under which competitive acquisition areas are established for contract award purposes for the furnishing of Part B items and services, except for physician's services. The first of these demonstration projects implements competitive bidding of categories of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Under the law, suppliers can receive payments from Medicare for items and services covered by the demonstration only if their bids are competitive in terms of quality and price. Each demonstration project may be conducted in up to three metropolitan areas for a three year period. Authority for the demonstration expires on December 31, 2002. The schedule for the demonstration anticipates about a six month period required between mailing the bidding forms to potential bidders and the start of payments for DMEPOS under the demonstration. HCFA intended to operate the demonstration in two rounds, the first of two years, and the second of one year. HCFA has operated its first demonstration in Polk County, Florida, which is the Lakeland-Winter Haven Metropolitan Area. This ''second round'' evaluation is necessary to determine whether access to care, quality of care, and diversity of product selection are affected by the competitive bidding demonstration. Although secondary data will be used wherever possible in the evaluation, primary data from beneficiaries themselves is required in order to gain an understanding of changes in their level of satisfaction and in the quality and selection of the medical equipment.

The follow-up beneficiary surveys will take place July to September 2000. We will sample beneficiaries from claimant lists provided by the durable medical equipment regional carrier (DMERC). The sample will be stratified into two groups: beneficiaries who use oxygen and beneficiaries who are non-oxygen users, i.e., users of the other four product categories covered by the demonstration (hospital beds, enteral nutrition, urological supplies, and surgical dressings) but not oxygen. To draw a comparison, we will sample in both the demonstration site (Polk County, Florida) and a comparison site (Brevard County, Florida) that matches Polk County on characteristics such as number of Medicare beneficiaries and DME/POS utilization. Information collected in the beneficiary survey will be used by the University of Wisconsin-Madison (UW–M), Research Triangle Institute (RTI), and Northwestern University (NU) to evaluate the Competitive Bidding Demonstration for DME and POS. Results of the evaluation will be used by HCFA and the Congress in formulating future Medicare policy on Part B competitive bidding.

The research questions to be addressed by the surveys focus on access, quality, and product selection. Our collection process includes fielding a survey for oxygen users and a survey for non-oxygen users before the demonstration begins and again after the new demonstration prices were put into effect. The baseline beneficiary survey was conducted between March and May 1999. The same data collection process will be followed in the comparison site (Brevard County). In the analysis of the data, we will also control for socioeconomic factors. This will allow us to separate the effects of the demonstration from beneficiary or site-specific effects. In the survey, we will also ask beneficiaries about the types of equipment that they use. This will allow us to determine if certain users are affected while others are not. For example, we will be able to evaluate whether oxygen users experience a