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.


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., 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.

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

[FR Doc. 00–10931 Filed 5–2–00; 8:45 am]

BILLING CODE 4160–01–F

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, 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...
greater increase or decrease in access
and quality than beneficiaries who
receive enteral nutrition.

The information that this survey will
provide about access, quality, and
product selection will be very important
to the future of competitive bidding
within the Medicare program.

Frequency: Other: One time.

Affected Public: Individuals or
households;
Number of Respondents: 2,128;
Total Annual Responses: 2,128;
Total Annual Hours: 637.

To obtain copies of the supporting
statement and any related forms for the
proposed paperwork collections
referenced above, access HCFA’s web
site address at http://www.hcfa.gov/
regs/prdact95.htm, or E-mail your
request, including your address, phone
counter, OMB number, and HCFA
document identifier, to
Paperwork@hcfa.gov, or call the Reports
Clearance Office on (410) 786–1326.

Written comments and
recommendations for the proposed
information collections must be mailed
within 60 days of this notice directly to
the HCFA Paperwork Clearance Officer
designated at the following address:
HCFA, Office of Information Services,
Security and Standards Group, Division of
HCFA Enterprise Standards,
Attention: Dawn Willingham, Room N2–
14–26, 7500 Security Boulevard,
Baltimore, Maryland 21244–1850.


John P. Burke III,
HCFA Reports Clearance Officer, HCFA Office
of Information Services, Security and
Standards Group, Division of HCFA
Enterprise Standards.

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Health Care Financing Administration

Agency Information Collection
Activities: Submission for OMB
Review; Comment Request

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, has submitted to the
Office of Management and Budget
(OMB) the following proposal for the
collection of information. Interested
persons are invited to send comments
regarding the 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: Extension of a currently
approved collection:

Title of Information Collection:
Medicare, Managed Care Disenrollment
Form;
Form No.: HCFA–566 (OMB #0938–
0507);
Use: This form is used to disenroll
from managed care plans. This is to be
to be used in Social Security Field Offices to
allow Medicare beneficiaries to
disenroll from a managed care plan;
Frequency: On occasion;
Affected Public: Individuals or
households, business or other for-profit,
Not-for-profit institutions, and Federal
Government;
Number of Respondents: 85,000;
Total Annual Responses: 85,000;
Total Annual Hours: 2,805.

To obtain copies of the supporting
statement for the proposed paperwork
collections referenced above, access
HCFA’s web site address at http://
www.hcfa.gov/regs/prdact95.htm, or E-
mail your request, including your
address and phone number, to
Paperwork@hcfa.gov, or call the Reports
Clearance Office on (410) 786–1326.

Written comments and
recommendations for the proposed
information collections must be mailed
within 30 days of this notice directly to
the OMB Desk Officer designated at the
following address: OMB Human
Resources and Housing Branch,
Attention: Allison Eydl, New Executive
Office Building, Room 10235,
Washington, D.C. 20503.


John P. Burke III,
HCFA Reports Clearance Officer, HCFA
Office of Information Services, Security and
Standards Group, Division of HCFA
Enterprise Standards.

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DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Health Care Financing Administration

Agency Information Collection
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(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: Health
Care Services for Deaf and Hard of
Hearing Adults—Case Story Forms;
Form No.: HCFA–R–310 (OMB
#0938–NEW);
Use: The Agency seeks to obtain
beneficiary information that helps
providers (1) better understand
situations in which problems may be
avoided when encountering a hearing-
impaired or deaf individual, (2) explore
how such encounters may affect the
delivery of quality care of adversely
impact health care outcomes, and (3)
provide an opportunity for hearing-
impaired individuals to develop more
appropriate health-seeking behavior,
where indicated. This form is to be
used by deaf and hard of hearing individuals
accessing the Delmarva web site who
may wish to identify experiences
receiving health care in the United
States. The experiences may be either
good or bad. Respondents are asked to
complete a form for each case or
experience;
Frequency: On occasion;
Affected Public: Individuals or
Households;
Number of Respondents: 100;
Total Annual Responses: 100;
Total Annual Hours: 17.