meal as a color additive in salmonid fish feeds.

**FOR FURTHER INFORMATION CONTACT:** Aydin Örstan, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3076.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 721(d)(1) (21 U.S.C. 379e(d)(1))), notice is given that a color additive petition (CAP 8C0256) has been filed by Cyanotech Corp., 73–4460 Queen Kaahumanu Hwy., #102, Kailua-Kona, HI 96740. The petition proposes to amend the color additive regulations to provide for the safe use of *Haematococcus* algae meal as a color additive in salmonid fish feeds.

–The agency has determined under 21 CFR 25.32(r) that this action is of a 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: March 20, 1998.

**Laura M. Tarantino,**

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

[FR Doc. 98–10032 Filed 4–15–98; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98F–0226]**

### 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 disodium or dipotassium fluorescein for use in boilers where steam may contact food.

**DATES:** Written comments on the petitioner's environmental assessment by May 18, 1998.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Paulette M. Gaynor, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3079.

**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 7A4539) has been filed by Nalco Chemical Co., One Nalco Center, Naperville, IL 60563–1168. The petition proposes to amend the food additive regulations in 21 CFR 173.310 to provide for the safe use of disodium or dipotassium fluorescein for use in boilers where steam may contact food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated 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 May 18, 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 25.40(c).

Dated: March 26, 1998.

**Laura M. Tarantino,**

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

[FR Doc. 98–10031 Filed 4–15–98; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Research Studies on Microbiological Hazards Associated with the Food Animal Production Environment Including Animal Feeds; Availability of Cooperative Agreements; Request for Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM) is announcing the availability of research funds for fiscal year (FY) 1998 to study the microbiological hazards associated with the food animal production environment which includes animal feeds. Approximately $1 million will be available in FY 1998. FDA anticipates making 6 to 12 Cooperative Agreement awards at $100,000 to $200,000 per award per year (direct and indirect costs). Support for these agreements may be for up to 3 years. The number of agreements funded will depend on the quality of the applications received and the availability of Federal funds to support the projects.

**DATES:** Submit applications by June 1, 1998. If the closing date falls on a weekend, it will be extended to Monday; if the date falls on a holiday, it will be extended to the following workday.

**ADDRESSES:** Application forms are available from, and completed applications should be submitted to: Robert L. Robins, Grants Management Officer, Division of Contracts and Procurement Management (HFA–520), Food and Drug Administration, 5600 Fishers Lane, Park Bldg., rm. 3–40, Rockville, MD 20857, 301–443–6170. (Applications hand-carried or commercially delivered should be addressed to the Park Bldg., 12420 Parklawn Dr., rm. 3–40, Rockville, MD 20852.)

**FOR FURTHER INFORMATION CONTACT:**

Regarding the administrative and financial management aspects of this notice: Robert L. Robins (address above).

Regarding the programmatic aspects of this notice: David B. Batson, Center for Veterinary Medicine (HFV–502), Food and Drug Administration, 8401 Muirkirk Rd., Laurel, MD 20708, 301–827–8021.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of funds for FY 1998 for awarding cooperative

agreements to support research studies on microbiological hazards associated with the food animal production environment which includes animal feeds. FDA will support the research studies covered by this notice under section 301 of the Public Health Service Act (the PHS act) (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 93.103.

The Public Health Service (PHS) strongly encourages all award recipients to provide a smoke-free workplace and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

PHS urges applicants to submit workplans that address specific objectives of ''Healthy People 2000.'' Potential applicants may obtain a copy of ''Healthy People 2000'' (full report, stock no. 017–00100474–0) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, 202–512–1800.

## I. Background

FDA is mandated to assure the microbiological safety of foods, including those derived from animals. The President's Food Safety Initiative (FSI) of 1997 calls for increased allocation of resources for research by FDA to identify and investigate microbiological hazards associated with food produced by animal agriculture. Even though the American food supply is among the safest in the world, millions of Americans are stricken by illness each year caused by the food they consume and some 9,000 a year, primarily the very young and elderly, die as a result. The goal of the FSI is to further reduce the incidence of foodborne disease to the greatest extent possible. Specifically, FSI mandates research be conducted to develop the means to: (1) Identify and characterize more rapidly and accurately foodborne hazards, (2) provide the tools for regulatory enforcement, and (3) to develop interventions that can be used as appropriate to prevent hazards at each step from production to consumption of food.

The role of FDA's CVM in this research relates to microbial hazards associated with pre-harvest phases of food animal production, including aquaculture. The FSI specifically identifies a need for research addressing the microbial ecology of the food animal production environment which includes animal feeds. This research will include: (1) Development and/or evaluation of methods for the detection of human foodborne pathogens in the animal environment and feeds; (2) investigations of factors associated with the emergence, transmission, and carriage of human foodborne pathogens in or on food-producing animals and edible products derived from them; and (3) investigations of the microbiological consequences of the use of antibiotics in the animal production environment, including selection and elaboration of antibiotic resistant pathogens and possible interactions which would create conditions for increased pathogen carriage rates.

## II. Research Goals and Objectives

The specific objective of this research program will be to provide financial assistance to investigators conducting research on microbiological hazards associated with the food animal production environment, including animal feeds. It is of particular interest to FDA that this research advance scientific knowledge of human foodborne pathogens, such as salmonellae, *Escherichia coli*, and campylobacteria. Potential areas of investigation include transmission and fate in animal agriculture, antibiotic resistance development and dissemination in the animal production environment, and cultural/molecular methods evaluation/refinement for use in studying the microbiota of the animal production ecosystem.

Projects that fulfill any one or a combination of the following specific objectives will be considered for funding:

(1) Performance evaluation of the FDA Bacteriological Analytical Manual (BAM) cultural and molecular methods to identify and quanitate human foodborne pathogens in animal feeds, feed commodities, and the animal production environment, including feces, manure, and litter. Optimization of the methods found not to perform satisfactorily. Development and testing of rapid detection methods and sampling strategies for use in animal feeds and the animal production environment.

(2) Conducting surveys to establish baseline data on human foodborne pathogen content in feeds and feed commodities. Work of this type is of particular interest if it compares feed at the site of manufacture versus feed at the farm. In addition, research to investigate survival characteristics of pathogens in feeds under various manufacturing and storage conditions is of interest. Identification of species/strain differences in survival/proliferation patterns in feeds is also a topic of concern.

(3) Conducting research to investigate the fate and transmission dynamics of human foodborne pathogens, especially antibiotic resistant bacteria, after ingestion by an animal or animals or as an environmental contaminant in a herd or flock.

(4) Research associated with human foodborne pathogen identification and carriage in fish (excluding protozoans) produced in various aquaculture conditions.

(5) Research to develop background data on antibiotic resistance patterns and effects of antibiotics on human foodborne pathogen carriage rates associated with the animal production and aquaculture environments. Also investigations of the dynamic effects resulting from the introduction of specific antibiotics into animal production and aquaculture environments are of interest. Investigations of effects that antibiotic residues in the environment, including aquaculture ponds, may have on resistance development are also of interest.

## III. Reporting Requirements

A Program Progress Report and a Financial Status Report (FSR) (SF–269) are required. An original FSR and two copies shall be submitted to FDA's Grants Management Officer within 90 days of the budget expiration date of the cooperative agreement. Failure to file the FSR (SF–269) on time will be grounds for suspension or termination of the grant. Progress reports will be required quarterly within 30 days following each Federal fiscal quarter (January 31, April 30, July 30, and October 31), except for the fourth report which will serve as the annual report and will be due 90 days after the budget expiration date. CVM program staff will advise the recipient of the suggested format for the Program Progress Report at the appropriate time. A final FSR (SF–269), Program Progress Report, and Invention Statement must be submitted within 90 days after the expiration of the project period as noted on the Notice of Grant Award.

Program monitoring of recipients will be conducted on an ongoing basis and written reports will be reviewed and evaluated at least quarterly by the project officer and the project advisory group. Project monitoring may also be in the form of telephone conversations between the project officer/grants management specialist and the principal investigator and/or a site visit with appropriate officials of the recipient organization. The results of these

monitoring activities will be duly recorded in the official file and may be available to the recipient upon request.

## IV. Mechanism of Support

*A. Award Instrument*

Support for this program will be in the form of cooperative agreements. These cooperative agreements will be subject to all policies and requirements that govern the research grant programs of PHS, including the provisions of 42 CFR part 52 and 45 CFR parts 74 and 92. The regulations issued under Executive Order 12372 do not apply to this program.

*B. Eligibility*

These cooperative agreements are available to any public or private nonprofit entity (including State and local units of government) and any for-profit entity. For-profit entities must exclude fees or profit from their request for support. Organizations described in section 501(c)(4) of the Internal Revenue Code of 1968 that engage in lobbying are not eligible to receive awards.

*C. Length of Support*

This agreement is planned for up to 3 years. Funding beyond the first year will be noncompetitive and will depend on: (1) Satisfactory performance during the preceding year, and (2) the availability of Federal fiscal year appropriations.

## V. Delineation of Substantive Involvement

Inherent in the cooperative agreement award is substantive involvement by the awarding agency. Accordingly, FDA will have a substantive involvement in the programmatic activities of all the projects funded under this request for applications (RFA).

Substantive involvement includes but is not limited to the following:

(1) FDA will appoint project officers who will actively monitor the FDA supported program under each award;

(2) FDA will establish a project advisory group which will provide guidance and direction to the project officer with regard to the scientific approaches and methodology that may be used by the investigator; and

(3) FDA scientists will collaborate with the recipient and have final approval on experimental protocols. This collaboration may include protocol design, data analysis, interpretation of findings, and co-authorship of publications.

## VI. Review Procedure and Criteria

*A. Review Method*

All applications submitted in response to this RFA will first be reviewed by grants management and program staff for responsiveness. If applications are found to be nonresponsive, they will be returned to the applicants without further consideration.

Responsive applications will be reviewed and evaluated for scientific and technical merit by an ad hoc panel of experts in the subject field of the specific application. Responsive applications will also be subject to a second level of review by a National Advisory Council for concurrence with the recommendations made by the first level reviewers, and the final funding decisions will be made by the Commissioner of Food and Drugs or his designee.

*B. Review Criteria*

Applicants are strongly encouraged to contact FDA to resolve any questions regarding criteria or administrative procedure prior to the submission of their application. All questions of a technical or scientific nature must be directed to the CVM contact and all questions of an administrative or financial nature must be directed to the Grants Management Officer. (See the **"For Further Information Contact"** section at the beginning of this document.) Responsiveness will be based on the following criteria:

(1) Research should be proposed on microbiological hazards research that is within one or more of the five objectives listed in section II. of this document;

(2) Whether the proposed study is within the budget and costs have been adequately justified and fully documented;

(3) Soundness of the rationale for the proposed study and appropriateness of the study design to address the objectives of the RFA;

(4) Availability and adequacy of laboratory and associated animal facilities;

(5) Availability and adequacy of support services (e.g., biostatistical computer, etc.,); and

(6) Research experience, training, and competence of the principal investigator and support staff.

## VII. Submission Requirements

The original and five copies of the completed Grant Application Form PHS 398 (Rev. 5/95) or the original and two copies of Form PHS 5161(Rev. 7/92) for State and local governments, with copies of the appendices for each of the copies, should be hand-carried or commercially delivered to Robert L. Robins (address above). State and local governments may choose to use Form PHS 398 in lieu of Form PHS 5161. Submit applications by June 1, 1998. If the closing date falls on a weekend, it will be extended to Monday; if the date falls on a holiday, it will be extended to the following workday. No supplemental or addendum material will be accepted after the closing date.

The outside of the mailing package and item 2 of the application face page should be labeled, ''Response to RFA FDA CVM–98–1''.

## VIII. Method of Application

*A. Submission Instructions*

Applications will be accepted during normal working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established closing date.

Applications will be considered received on time if sent or mailed on or before the closing date as evidenced by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant. (Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.)

Do not send applications to the Center for Scientific Research (CSR), National Institutes of Health (NIH). Any application that is sent to NIH, not received in time for orderly processing, will be deemed unresponsive and returned to the applicant. Instructions for completing the application forms can be found on the NIH home page on the Internet (address http://www.nih.gov/grants/phs398/phs398.html; the forms can be found at http://www.nih.gov/grants/phs398/forms—toc.html). However, as noted above, applications are not to be mailed to NIH. (Applicants are advised that FDA does not adhere to the page limitations or the type size and line spacing requirements imposed by NIH on its applications). Applications must be submitted via mail delivery as stated above. FDA is unable to receive applications via the Internet.

*B. Format for Application*

Submission of the application must be on Grant Application Form PHS 398 (Rev. 5/95). All ''General Instructions''

and ''Specific Instructions'' in the application kit should be followed with the exception of the receipt dates and the mailing label address. Do not send applications to CSR, NIH. Applications from State and local Governments may be submitted on Form PHS 5161 (Rev. 7/92) or Form PHS 398 (Rev. 5/95).

The face page of the application should reflect the RFA number RFA–FDA–CVM–98–1.

Data included in the application, if restricted with the legend specified below, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on Form PHS 398 and the instructions have been submitted by PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001.

*C. Legend*

Unless disclosure is required by FOIA as amended as determined by the freedom of information officials of the Department of Health and Human Services or by a court, data contained in the portions of this application which have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information shall not be used or disclosed except for evaluation purposes.

Dated: April 10, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98–10069 Filed 4–15–98; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

**[Form #HCFA–R–224]**

### Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

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 (DHHS), has submitted to the Office of Management and Budget (OMB) the following request for Emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR, part 1320. The Agency cannot reasonably comply with the normal clearance procedures because of a statutory deadline imposed by section 1853(a)(3) of the Balanced Budget Act of 1997. Without this information, HCFA would not be able to properly implement the requirements set forth in the statute.

HCFA is requesting OMB review and approval of this collection by 5/8/98, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individual designated below, by 5/6/98.

During this 180-day period HCFA will pursue OMB clearance of this collection as stipulated by 5 CFR 1320.5.

*Type of Information Collection Request:* Extension of a currently approved collection;

*Title of Information Collection:* Collection of Managed Care Data Using the Uniform Institutional Providers Form (HCFA–1450/UB–92) and Supporting Statute Section 1853(a)(3) of the Balanced Budget Act of 1997;

*Form No.:* HCFA–R–224;

*Use:* Section 1853(a)(3) of the Balanced Budget Act (BBA) requires Medicare+Choice organizations, as well as eligible organizations with risk-sharing contracts under section 1876, to submit encounter data. Data regarding inpatient hospital services are required for periods beginning on or after July 1, 1997. These data may be collected starting January 1, 1998. Other data (as the Secretary deems necessary) may be required beginning July 1, 1998.

The BBA also requires the Secretary to implement a risk adjustment methodology that accounts for variation in per capita costs based on health status. This payment method must be implemented no later than January 1, 2000. The encounter data are necessary to implement a risk adjustment methodology.

Hospital data from the period, July 1, 1997–June 30, 1998, will serve as the basis for plan-level estimates of risk adjusted payments. These estimates will be provided to plans by March, 1999. Encounter data collected from subsequent time periods will serve as the basis for actual payments to plans for CY 2000 and beyond.

In implementing the requirements of the BBA, hospitals will submit data to the managed care plan for enrollees who have a hospital discharge using the HCFA–1450 (UB–92), Uniform Institutional Provider Claim Form. Encounter data for hospital discharges occurring on or after July 1, 1997 are required. While submission from the hospital to the plan is required, plans are provided with a start-up period during which time an alternate submission route is permitted.

The six month start up period, beginning January 1, 1998 will enable plans to accomplish the requirements of the BBA by the end of the start-up period, or June 30, 1998. Special procedures have been identified to ensure that hospital encounter data are submitted for discharges occurring on or after July 1, 1997 and before June 30, 1998. The special procedures for the start up period include the following:

1. In order to provide plans with an estimate of their Average Payment Rate (APR) by March, 1999, HCFA must receive data on hospital discharges that occurred on or after July 1, 1997 and before December 31, 1997, as well as encounter data on discharges that occur during the start up period, or January 1, 1998 through June 30, 1998. Currently, most plans do not have the capacity to submit data electronically to a fiscal intermediary (FI), and the FIs are not capable of receiving these data. Therefore, during this period only, unless an alternative approach is approved by HCFA, hospitals must submit completed UB–92s for the Plan's enrollees. These pseudo-claims must be submitted to the hospital's regular fiscal intermediary. This is a current requirement for hospitals, and they are expected to comply with this requirement throughout this period. Plans must provide hospitals with the Medicare identification number of all enrollees admitted who have Medicare coverage.

If hospitals are unable to submit these data on behalf of the plan during the start-up period, an alternate method of submitting the data may be developed by HCFA. If such a method is developed, it would require the plans to submit a subset of data elements that are found on the UB–92. Possible data elements include the following: Plan Contract Number; HIC (or Medicare Identification Number); enrollee's name; enrollee's state and county of residence; enrollee's birthdate and gender; Medicare Provider Number for the Hospital; claim from and thru date; admission date; and principal and secondary diagnoses codes. HCFA will specify the data elements, submission route, and format for these data.

2. During the start up period, the plan is expected to establish an electronic data linkage to a FI to be determined by HCFA. By June 30, 1998, the Plan is expected to have completed this