Other Requirements

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations, 45 CFR Part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and forms provided in the application kit.

Paperwork Reduction Act

Projects that involve the collection of information from 10 or more individuals and funded by this grant program will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Women and Minority Inclusion Policy

It is the policy of the CDC to ensure that women and racial and ethnic groups will be included in CDC supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application.

In conducting the review of applications for scientific merit, review groups will evaluate proposed plans for inclusion of minorities and both sexes as part of the scientific assessment and assigned score. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, Friday, September 15, 1995, pages 47947–47951.

Application Submission and Deadlines

A. Preapplication Letter of Intent

Although not a prerequisite of application, a non-binding letter of intent-to-apply is requested from potential applicants. The letter should be submitted to the Grants Management Specialist (whose address is reflected in section B, ''Applications''). It should be postmarked no later than March 20, 1997. The letter should identify the announcement number, name the principal investigator, and specify the priority area of study the proposal addresses as outlined under the section Programmatic Priorities. The letter of intent does not influence review or funding decisions, but it will enable CDC to plan the review more efficiently, and will ensure that each applicant receives timely and relevant information prior to application submission.

B. Applications

Applicants should use Form PHS–398 (OMB No. 0925–0001 Revised 5/95) and adhere to the ERRATA Instruction Sheet for Form PHS–398 contained in the Grant Application Kit. Please submit an original and five copies, on or before April 22, 1997, to: Lisa G. Tamaroff, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 321, Atlanta, Georgia 30305, telephone (404) 842–6796.

C. Deadlines

1. Applications shall be considered as meeting a deadline if they are either:

A. Received at the above address on or before the deadline date, or

B. Sent on or before the deadline date to the above address, and received in time for the review process. Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailings.

2. Applications which do not meet the criteria above are considered late applications and will be returned to the applicant.

Where to Obtain Additional Information

To receive additional written information call (404) 332–4561. You will be asked to leave your name, address, and telephone number and will need to refer to Announcement 723. You will receive a complete program description, information on application procedures, and application forms. Business management technical information may be obtained from Lisa Tamaroff, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E–13, Atlanta, GA 30305, telephone (404) 842–6796 or internet: <lgt1.cdc.gov≤.

Programmatic technical assistance may be obtained from Ted Jones, Project Officer, Extramural Research Grants Branch, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), Mailstop K–58, 4770 Buford Highway, NE., Atlanta, Georgia 30341–3724, telephone (770) 488–4824, internet: <tmj1.cdc.gov≤.

This and other CDC announcements are also available through the CDC homepage on the Internet. The address for the CDC homepage is <http://www.cdc.gov≤.

CDC will not send application kits by facsimile or express mail.

Please refer to Announcement Number 723 when requesting information and submitting an application.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402–9325, telephone (202) 512–1800.

Copies of Injury Control in the 1990s: A National Plan for Action. Atlanta: Centers for Disease Control and Prevention, 1993 and A Framework for Assessing the Effectiveness of Disease and Injury Prevention, (CDC, Morbidity and Mortality Weekly Report, March 27, 1992, Volume 41, Number RR–3, pages 5–11) may be obtained by calling (770) 488–4265.

Information for obtaining the suggested readings, Understanding Violence Against Women, Violence and the Public's Health, Understanding and Preventing Violence, and Violence in America: A Public Health Approach, is included on a separate sheet with the application kit.

Dated: February 11, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–4010 Filed 2–18–97; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 93F–0195]

Fish and Fishery Products Hazards and Controls Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the

availability of the first edition of the ''Fish and Fishery Products Hazards and Controls Guide'' (the guide). FDA has prepared the guide as, among other things, an adjunct to the regulations it issued on the safe and sanitary processing and importing of fish and fishery products using Hazard Analysis and Critical Control Point (HACCP) methodology.

DATES: Submit written comments on the guide by May 20, 1997. Comments received after that date will be considered for subsequent editions.

ADDRESSES: Submit written requests for single copies of the guide to the Office of Seafood (HFS–400), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3133. The guide may also be obtained from FDA district offices (contact Donald Kraemer (address below) for FDA district office addresses). Send two self-addressed adhesive labels to assist those offices in processing your requests. Copies of the guide on diskette (in WordPerfect 6.0) may be ordered for $30.00 each, plus handling, from the National Technical Information Service (NTIS), U.S. Department of Commerce, by calling 703–487–4650 and requesting PB96–503180. Paper copies may be ordered for $30.00 each, plus handling, by requesting PB 96–207337. The diskette and paper copies may be ordered as a set for $50.00, plus handling, by requesting PB96–207329. Payment may be made by charge card (American Express, VISA, or Mastercard), check, money order, or other billing arrangements made with NTIS. Rush orders may be placed by calling 800–553–NTIS. Persons with access to the Internet may obtain the guide via the World Wide Web at FDA's web site (http://www.fda.gov) by selecting ''Foods'' and then selecting ''HACCP.'' Alternately, it may be accessed directly at http://www.cfsan.fda.gov/~lrd/haccpsub.html.

The guide is also being issued as a companion document to the ''HACCP: Hazard Analysis Critical Control Point Training Curriculum'' (the training document), which was developed by the Seafood HACCP Alliance for Training and Education (the Alliance). The Alliance is an organization of Federal and State regulators, including FDA, academia, and food industry trade associations. FDA encourages processors of fish and fishery products to use the two documents together in the development of their HACCP systems. Copies of the training document and the guide may be obtained from North Carolina Sea Grant, North Carolina State University, P.O. Box 8605, Raleigh, NC 27695, 919–515–2454. The cost for both of these documents is $35.00, payable by check or money order to ''N.C. Sea Grant.'' Submit written comments on the guide to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. The guide and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Donald W. Kraemer, Center for Food Safety and Applied Nutrition (HFS–400), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3160.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 18, 1995 (60 FR 65096), FDA published a final rule entitled ''Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products,'' which requires that HACCP principles be applied in the commercial processing of fish and fishery products for distribution in interstate commerce. HACCP involves: (1) The identification of food safety hazards that are reasonably likely to occur in a particular product; (2) the selection of the appropriate control measures to reduce the risk of occurrence of these hazards; and (3) the preparation of a HACCP plan that sets out how these measures will be applied.

To aid processors in responding to the new requirements and in developing their HACCP plans, FDA has developed the guide. The controls and practices provided in the guide are, for the most part, recommendations and guidance to the fish and fishery products industry. The guide provides information that will likely result in a HACCP plan that is acceptable to FDA under ordinary circumstances. However, the guide is in no way a binding set of requirements. Processors may choose to use other control measures, provided that they provide an equivalent degree of assurance that the product will be safe. Nor is the guide a substitute for the performance of a hazard analysis by a processor of fish or fishery products, as required by FDA's regulations. A hazard analysis is an assessment of what, if any, food safety hazards are reasonably likely to occur in a product being produced by a specific processor, and whether those hazards can be controlled by that processor. While the guide contains FDA's best advice for most ordinary circumstances, it does not cover every situation. For example, hazards not covered by the guide may be relevant to certain products in certain circumstances. In particular, processors should be alert to new or emerging problems (e.g., the occurrence of natural toxins in fish not previously associated with that toxin).

In the Federal Register of March 18, 1994 (59 FR 12949), FDA published a notice of availability of a draft version of the guide (the draft guide) and requested comments on it. The agency has carefully reviewed the comments it received. Based on these comments, FDA has made significant changes in the format and content of the guide. Given the magnitude of the changes, FDA believes that additional comment by the public would be useful.

A number of comments stated that, while the draft guide provided useful information on fish and fishery products hazards and controls, it did not adequately explain how to develop a HACCP plan on the basis of this information.

In response to these comments, the agency has revised the guide to provide a step-by-step procedure for the preparation of a HACCP plan. The agency has tried to provide information that will help the processor answer questions that are likely to arise during this process.

To further facilitate HACCP plan development, the guide provides samples of key portions of HACCP plans for each of the categories of hazards that are discussed. The guide also contains a fill-in-the-blank HACCP plan and a blank hazard analysis worksheet that may be used by processors.

Many comments stressed that the draft guide unnecessarily restricted their flexibility in developing hazard control strategies that were uniquely tailored to their operations. It did so, they contended, by limiting its advice to only one or a few control strategies per hazard even though other strategies may also exist, depending upon the circumstances.

It was never the intent of the guide to limit a processor's flexibility to only the control strategies provided in the guide. The agency could not realistically provide advice on every valid control strategy that might be available under every circumstance. Nonetheless, the guide is intended to be as inclusive as is reasonably possible about known control strategies. Therefore, FDA has revised the guide to provide more control strategy examples than were provided in the draft guide. For example, the guide includes

recommended maximum exposure times for temperature-sensitive fishery products for a variety of exposure temperatures and target pathogens, rather than one ''rule-of-thumb'' maximum exposure time, as was the case in the draft guide.

The agency recognizes, however, that the inclusion of more control strategies greatly lengthens the guide and could make it more difficult for the smaller, less sophisticated processor to use. FDA specifically invites comment on whether this will in fact be the case and on whether the agency should attempt to develop an abbreviated version of the guide for those who might benefit from it.

The guide includes tables of potential food safety hazards that may be associated with the hundreds of species of fish (vertebrate and invertebrate), as well as the numerous product forms (e.g., breaded, cooked, raw), that are commercially marketed in the United States. These tables are designed to aid the processor in the performance of the hazard analysis.

A separate chapter is devoted to each category of hazard (e.g., parasites, natural toxins, pathogen growth, metal fragments). Each chapter includes the steps necessary to complete the hazard analysis and, ultimately, the HACCP plan for that hazard. These steps include: (1) Understanding the potential hazard; (2) determining whether the potential hazard is significant and must therefore be controlled; (3) identifying the critical control points, where the hazard can best be controlled; (4) setting the critical limits, to which the operation must be held at the critical control points; (5) establishing the monitoring procedures, to ensure that the critical limits are consistently being met; (6) establishing corrective action procedures for when the critical limit is not met; (7) establishing a recordkeeping system to document the performance of the monitoring, corrective action, and verification procedures; and (8) establishing verification procedures.

There are two areas that were addressed in the draft guide but are not included in the first edition because they are the subject of policy reevaluation by FDA. The agency will update the guide in these areas when the policy reevaluation is complete.

The first of these areas involves the chemical methyl mercury. A number of comments objected to the testing regimen that the draft guide recommended for the control of the methyl mercury hazard in certain species of fish. The agency's recommendation was based on the 1.0 part per million action level for methyl mercury. While FDA has not changed this action level, the agency is reevaluating its policy in light of significant new data on the health effects of methyl mercury from consumption of fish that have become available since the action level was developed.

One other area in which the guidance contained in the guide is incomplete is the hazard of pathogens in raw fish and fishery products that are intended to be cooked by the consumer or end user. FDA policy identifies pathogens in such products as adulterants under the Federal Food, Drug, and Cosmetic Act. FDA is still evaluating what would constitute an appropriate hazard analysis, and what would constitute the appropriate HACCP controls for these products. The agency welcomes comment on this subject.

FDA expects that its reevaluation of the methyl mercury action level and its pathogen policy will be completed before the effective date of the regulations. When the reevaluation is completed, FDA will, among other things, update the guide by including advice on how to assess the significance of these potential hazards, and what controls, if any, are necessary to ensure the safety of fish.

The guide, which provides advice on how to prepare a HACCP plan when a plan is required by 21 CFR part 123, should be used until superseded by a subsequent edition. Although this guidance does not create or confer any rights, for or on any person, and does not operate to bind FDA, it does represent the agency's best thinking on how to prepare a HACCP plan for the processing of fish and fishery products.

Interested persons may, on or before May 20, 1997, submit to the Dockets Management Branch (address above) written comments on the guide for consideration in the preparation of the second edition of the guide. Comments received after that date will be considered for subsequent editions. 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. The guide and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 11, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–4022 Filed 2–18–97; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[Document Identifier: HCFA–1514]

Agency Information Collection Activities: Proposed Collection; 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, is publishing the following summary of proposed collections for public comment. 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 currently approved collection; *Title of Information Collection:* Hospital Request for Certification in the Medicare/Medicaid Program; *Form No.:* HCFA–1514; *Use:* Section 1861 of the Social Security Act and 42 CFR part 482 requires hospitals to be certified to participate in the Medicare/Medicaid program. As part of the certification process, providers must complete form HCFA–1514. This certification form is a facility identification and screening form used to initiate the certification process and to determine if the provider has sufficient personnel to participate in the Medicare/Medicaid program. *Frequency:* Annually; *Affected Public:* State, Local or Tribal Gov't.; *Number of Respondents:* 2,500; *Total Annual Responses:* 2,500; *Total Annual Hours:* 625.

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 to obtain the supporting statement and any related forms, 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 60 days of this notice directly to the HCFA Paperwork Clearance Officer