

Dated: August 21, 2001.

**John P. Burke III,**

*CMS Reports Clearance Officer, CMS Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards.*

[FR Doc. 01-21675 Filed 8-27-01; 8:45 am]

BILLING CODE 4120-03-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

[Document Identifier: CMS-2552-96]

#### Agency Information Collection Activities: Comment Request

**AGENCY:** Centers for Medicare and Medicaid Services, HHS.

In an effort to revise the current Hospital and Health Care Complex Cost Report, we are interested in receiving public comments to help aid in making the necessary revisions to this cost report. 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:* Revision of a currently approved collection; *Title of Information Collection:* Hospital and Health Care Complex Cost Report and Supporting Regulations in 42 CFR 413.20 and 413.24; *Form No.:* CMS-2552-96 (OMB 0938-0050); *Use:* Form CMS-2552-96 is the form used by hospitals participating in the Medicare program. This form reports the health care costs used to determine the amount of reimbursable costs for services rendered to Medicare beneficiaries; *Frequency:* Annually; *Affected Public:* Businesses or other for-profit; Not-for-profit institutions; and State, Local or Tribal Government; *Number of Respondents:* 6,038; *Total Annual Responses:* 6,038; *Total Annual Hours:* 4,274,105.

To obtain a copy of the forms and related materials for the proposed paperwork collections referenced above, access CMS's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-

mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. The revised "Hospital and Health Care Complex Cost Report" will be available after the close of this solicitation, at which time, we will publish a subsequent 60-day **Federal Register** notice announcing the revisions and canvassing public comment before submitting to OMB. Written comments and recommendations for the solicitation must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Attention: Dawn Willingham, CMS-2552-96, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: August 21, 2001.

**John P. Burke III,**

*CMS Reports Clearance Officer, CMS Office of Information Service, Security and Standards Group, Division of CMS Enterprise Standards.*

[FR Doc. 01-21676 Filed 8-27-01; 8:45 am]

BILLING CODE 4120-03-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

[Document Identifier: CMS-2088]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS), 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:* Extension of a currently approved collection; *Title of Information Collection:* Outpatient Rehabilitation Cost Report and Supporting Regulations in 42 CFR 413.20 and 413.24 *Form No.:* CMS-2088; *Use:* This form is used by Outpatient Rehabilitation Facilities to report their health care costs to determine the amount reimbursable for services furnished to Medicare beneficiaries. *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and State, Local or Tribal Government; *Number of Respondents:* 716; *Total Annual Responses:* 716; *Total Annual Hours:* 71,600.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@hcfa.gov](mailto: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 CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Attention: Dawn Willingham, CMS-2088, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: August 21, 2001.

**John P. Burke III,**

*CMS Reports Clearance Officer, CMS Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards.*

[FR Doc. 01-21677 Filed 8-27-01; 8:45 am]

BILLING CODE 4120-03-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01N-0348]

#### Index and Copies of Presiding Officer Reports and Commissioner Decisions on the Eligibility of a Clinical Investigator to Continue to Receive Investigational Products; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the presiding officer summary decisions, presiding officer reports, and the Commissioner of Food and Drugs (the Commissioner) decisions that are issued concerning a regulatory hearing on the proposed disqualification of a clinical investigator from eligibility to continue to receive investigational products for use in clinical investigations. These reports and decisions and an index are available at the FDA Internet site.

**ADDRESSES:** Copies of an index to presiding officer summary decisions, presiding officer reports, and Commissioner decisions, as well as the reports and decisions themselves, may be obtained from the Freedom of Information Office home page at <http://www.fda.gov/foi/clinicaldis>.

Copies of the index and reports and decisions are also available at the Dockets Management Branch, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Nancy E. Pirt, Office of the Ombudsman (HF-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3390.

**SUPPLEMENTARY INFORMATION:** FDA regulates scientific studies, known as clinical investigations, designed to test the safety and effectiveness of investigational human and animal drugs, biological products, and medical devices. The data from these clinical investigations may be used as the basis of applications to FDA for approval to market the investigational products. The clinical investigators who conduct clinical trials must comply with FDA's regulations that govern clinical investigations. FDA may seek to disqualify a clinical investigator if the agency has information indicating that the investigator has repeatedly or deliberately failed to comply with the requirements of the regulations for conducting clinical investigations, or repeatedly or deliberately submitted false data to the FDA or the study's sponsor. If the Commissioner makes this determination, the Commissioner will notify the investigator and the sponsor of any investigation, in which the investigator has been named as a participant, that the investigator is not entitled to receive investigational drugs.

The criteria for disqualification are set forth in FDA's regulations. For clinical investigations involving human drugs and biologic products, the applicable regulation is found at 21 CFR 312.70.

For clinical investigations involving medical devices, the applicable regulation is found at 21 CFR 812.119. For clinical investigations involving investigational animal drugs, the applicable regulation is found at 21 CFR 511.1.

The disqualification process is initiated when FDA's Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, or Center for Veterinary Medicine sends the investigator a written notice of the matter complained of, and offers the investigator an opportunity to explain in writing or, at the option of the investigator, at an informal conference. If the Center does not find the investigator's explanation to be acceptable, the agency will send the investigator a notice of opportunity for a hearing. If a regulatory hearing is held, it will be conducted under part 16 (21 CFR part 16). Under part 16, if a clinical investigator requests a hearing, a presiding officer is appointed to hear the case. A request for a hearing may be denied if the Commissioner or his or her delegate determines that there is no genuine and substantial issue of fact to justify a hearing. A written notice of this determination will be given to the parties. In addition, the presiding officer may issue a summary decision on any issue in the hearing if the presiding officer determines that there is no genuine and substantial issue of fact respecting that issue.

After a hearing is conducted, the presiding officer, under § 16.60, prepares a written report of the hearing, including a recommended decision with a statement of the reasons, on the proposed disqualification. The written report will include a recommended decision with a statement of reasons, unless the Commissioner directs otherwise. The presiding officer's report is one component of the administrative record of the hearing. Based on the administrative record, the Commissioner issues a written decision on the question of whether the investigator is entitled to receive investigational products. If the Commissioner finds that the clinical investigator repeatedly or deliberately failed to comply with agency regulations, or repeatedly or deliberately submitted false information to FDA or the sponsor, the investigator may be disqualified from receiving investigational products.

Disqualification hearings are informal, and presiding officer summary decisions, presiding officer reports, and Commissioner decisions are not

published in the **Federal Register**; they have been made publicly available to parties that request regulatory hearings on clinical investigator disqualifications. They are also publicly available under the Freedom of Information Act. The purpose of this notice is to announce that an index to, and copies of, presiding officer summary decisions, presiding officer reports, and Commissioner decisions on clinical investigator disqualification matters are now available on FDA's Internet site. These records are also available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 21, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 01-21663 Filed 8-27-01; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

**[Docket No. 93N-0195]**

**Guidance for Industry: Fish and Fishery Products Hazards and Controls Guidance, Third Edition; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the revised guidance for industry (third edition) entitled "Fish and Fishery Products Hazards and Controls Guidance" (the guidance). The guidance supports and complements FDA regulations for the safe and sanitary processing and importing of fish and fishery products using hazard analysis and critical control point (HACCP) methods. The guidance represents the agency's current views on potential hazards in seafood products and how to control them, and it is designed to assist seafood processors in the development of HACCP plans. The guidance is revised about every 2 years to address comments and to reflect our current understanding of seafood hazards and control methods.

**DATES:** General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers