including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or, (2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a federal, state, or local health, law enforcement, or other appropriate agency;

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e) and (f). The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant (use attachments, if needed):

Place of Performance (Street Address, City, County, State, Zip Code)

_____

Check ____ if there are workplaces on file that are not identified here. Sections 76.630(c) and (d)(2) and 76.635(a)(1) and (b) provide that a Federal agency may designate a central receipt point for state-wide and state agency-wide certifications, and for notification of criminal drug convictions. For the Department of Health and Human Services, the central receipt point is: Grants Management Division; 330 Independence Avenue, SW, Room 4256–Cohen; Washington, D.C. 20201

Signature _____

Date _____

Title _____

Organization _____

DGMO Form #2 Revised May 1990

Certification Regarding Debarment, Suspension, and Other Responsibility Matters—Primary Covered Transactions

By signing and submitting this proposal, the applicant, defined as the primary participant in accordance with 45 CFR Part 76, certifies to the best of its knowledge and belief that its principals involved:

(a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any federal department or agency;

(b) Have not within a 3-year period preceding this proposal been convicted of or had a civil judgement rendered against the principal for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (federal, state, or local) transaction or contract under a public transaction; violation of federal or state antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

(c) Are not presently indicted or otherwise criminally or civilly charged by a government entity (federal, state or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and

(d) Have not within a 3-year period preceding this application/proposal had one or more public transactions (federal, state, or local) terminated for cause or default.

The inability of a person to provide the certification required above will not necessarily result in denial of participation for this covered transaction. If necessary, the prospective participant shall submit an explanation of why it cannot provide the certification. The certification or explanation will be considered in connection with the Department of Health and Human Services (HHS) determination whether to enter into this transaction. However, failure of the prospective primary participant to furnish a certification or an explanation shall disqualify such person from participation in this transaction.

The prospective primary participant agrees that by submitting this proposal, it will include the clause entitled ''Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion—Lower Tier Covered Transactions'', provided below, without modification in all lower tier covered transactions and in all solicitations for lower tier covered actions.

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusions—Lower Tier Covered Transactions (To be supplied to Lower Tier Participants)

By signing and submitting this lower tier proposal, the prospective lower tier participant, as defined in 45 CFR Part 76, certifies to the best of its knowledge and belief that it and its principals:

(a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.

(b) Where the prospective lower tier participant is unable to certify to any of the above, such prospective participant shall attach an explanation of this proposal.

The prospective lower tier participant further agrees by submitting this proposal that it will include this clause entitled ''Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusions—Lower Tier Covered Transactions'' without modification in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

Signature _____

Date _____

Title _____

Organization _____

Certification Regarding Lobbying

Certification for Contracts, Grants, Loans, And Cooperative Agreements

The undersigned certifies, to the best of his or her knowledge and belief, that:

(1) No federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a member of congress, an officer or employee of congress, or an employee of a member of congress in connection with the awarding of any federal contract, the making of any federal grant, the making of any federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a member of congress, an officer of employee of congress, or an employee of a member of congress in connection with this federal contract, grant, loan or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, ''Disclosure Form to Report Lobbying,'' in accordance with its instructions.

(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less that $10,000 and not more than $100,000 for each such failure.

_____

Organization

_____

Authorized Signature Title Date

Note: If Disclosure Forms are required, please contact: Margaret A. Tolson, Director; Grants Management Division, 330 Independence Avenue, SW, Room 4256-Cohen; Washington, DC 20201–0001.

[FR Doc. 98–29088 Filed 10–29–98; 8:45 am]

BILLING CODE 4130–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Peer Review Meeting of the Draft Research Protocol of the Full Ensemble Fire Testing of Fire Fighters' Protective Clothing and Equipment

The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Peer Review meeting on the NIOSH-funded study by the National Institute of Standards and Technology (NIST) entitled: ''Full Ensemble Fire Testing of Fire Fighters' Protective Clothing and Equipment.''

Time and Date: 8 a.m.—5 p.m., December 2, 1998.

Location: National Institute of Standards and Technology, Lecture Room D, Administration Building 101,

Building and Fire Research Laboratory, Gaithersburg, MD 20899–0001.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: To provide peer review of the draft research protocol of a study of burn hazards associated with full ensemble fire fighters' protective clothing and equipment. Also, to exchange information among government, Page 2 stakeholders, and interested parties on the scientific, procedural, and related aspects of the study.

Participants will provide NIOSH with their individual advice and comments regarding the technical and scientific aspects of the study protocol, ''Full Ensemble Fire Testing of Fire Fighters' Protective Clothing and Equipment.''

Matters to be Discussed: The agenda will include a review of the NIST research plan; request for field experience and other information and scientific input on the planned research topics; and scientific discussion on the types and usage of thermal sensors of relevance to exposure estimation. Viewpoints and suggestions from industry, labor, academia, other government agencies, and the public are invited. Written comments will also be considered.

Contact Person for Additional Information: Thomas K. Hodous, M.D., Project Officer, Division of Safety Research, NIOSH, CDC, M/S P–1172, 1095 Willowdale Road, Morgantown, West Virginia 26505–2888. Telephone 304/285–5943, E-mail thh1@cdc.gov. Copies of the draft protocol may be obtained by contacting Dr. Hodous.

Dated: October 23, 1998.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–29098 Filed 10–29–98; 8:45 am]

BILLING CODE 4160–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0331]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Devices; FDAMA Third-Party Review

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Submit written comments on the collection of information by November 30, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices; FDAMA Third-Party Review (OMB Control Number 0910–0375—Extension)

Section 210 of FDAMA establishes a new section 523 of the Federal Food, Drug, and Cosmetic Act (the act), directing FDA to accredit persons in the private sector to review certain premarket applications and notifications. As with the Third-Party Review Pilot Program previously conducted by FDA, participation in this Third-Party Review Pilot Program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation. Accredited third-party reviewers will have the ability to review a manufacturer's 510(k) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation, to FDA. Third-party reviewers should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time. This information collection will allow FDA to implement the Accredited Person Review Program established by FDAMA and improve the efficiency of 510(k) review for low- to moderate-risk devices.

Description of Respondents: Businesses or other for profit organizations.

In the **Federal Register** of August 4, 1998 (63 FR 41575), the agency requested comments on the proposed collections of information. No significant comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Item	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Respondent	Total Hours
Requests for accreditation	40	1	40	24	960
510(k) reviews conducted by accredited third parties	35	4	140	40	5,600
Total hours					6,560

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.