

Dated: August 12, 1996.

Reginald F. Wells,

Deputy Commissioner Administration on Developmental Disabilities.

[FR Doc. 96-22337 Filed 8-29-96; 8:45 am]

BILLING CODE 4184-01-P

Food and Drug Administration

[Docket No. 90N-0172]

Medical Devices; Development of Design Control Inspectional Strategies; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting intended to explore and develop strategies to be utilized by FDA's investigators when inspecting a medical device facility relative to design controls, after issuing the final quality system regulation. The purpose of the meeting is to obtain information from the medical device industry and other members of the public about their perspective and practical experience in exercising design controls. This meeting is intended to provide an opportunity to work with FDA towards constructing an investigational model for design controls which will become the basis for future establishment inspections.

DATES: The public meeting will be held on September 12, 1996, from 8:30 a.m. to 4:30 p.m. There is no cost to attend, however, due to space limitations, registration is required and must be submitted by September 4, 1996.

ADDRESSES: The public meeting will be held at the Parklawn Bldg., 5600 Fishers Lane, conference room M, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Kimberly A. Trautman, Office of Compliance, Center for Devices and Radiological Health (HFZ-341), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-4648, ext. 126, FAX number 301-594-4672. Persons interested in attending this meeting should FAX a request for participation no later than the close of business on Wednesday, September 4, 1996. Please include name, firm affiliation if any, job title, address, telephone number, and FAX number to the contact person. Please do not plan to attend this meeting unless you have received a confirmation from the Center of Devices and Radiological Health (CDRH) affirming your participation. This confirmation will be sent via FAX on a first-come-first-served basis.

SUPPLEMENTARY INFORMATION: Under notice and comment rulemaking procedures initiated in 1990 to implement certain provisions of the Safe Medical Devices Act of 1990, FDA plans to issue a final rule revising the current good manufacturing practice (CGMP) requirements for medical devices and incorporating them into a quality system regulation. This action will add preproduction design controls to the CGMP regulation and achieve consistency with quality system requirements worldwide.

FDA is interested in obtaining further information regarding perspectives and practical experience in exercising design controls. Accordingly, FDA's CDRH is conducting a grassroots regulatory partnership meeting on September 12, 1996, with interested parties in the device industry and members of the public. This meeting is being conducted in accordance with President Clinton's reinventing government initiatives. The purpose of the meeting will be to address specific issues and to explore and develop strategies with regard to how design controls will be inspected for compliance with the regulation by FDA's investigators at the field District Offices. FDA headquarters and District personnel will attend and participate in the meeting.

Industry, FDA participants, and members of the public will be arranged into working teams to review and develop strategies. This is an opportunity for the regulated industry and others to work with front-line FDA's regulators towards constructing an investigational model for design controls which will become the basis for all future establishment inspections.

Upon completion of the grassroots regulatory meeting, FDA will formulate its design control inspectional strategy and make this strategy document available to the public through the publication of a notice of availability in the Federal Register.

Dated: August 27, 1996.

Joseph A. Levitt,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 96-22284 Filed 8-28-96; 9:56 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4021-N-02]

Office of Administration; Notice of Submission of Proposed Information Collection to OMB

AGENCY: Office of Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information requirement described below has been submitted to the Office of Management and Budget (OMB) for emergency review and approval, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: The due date for comments is: September 6, 1996.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within seven (7) days from the date of this Notice. Comments should refer to the proposal by name and should be sent to: Joseph F. Lackey, Jr., HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Kay F. Weaver, Reports Management Officer, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708-0050. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Weaver.

SUPPLEMENTARY INFORMATION: This Notice informs the public that if the Department of Housing and Urban Development (HUD) has submitted to OMB, for emergency processing, an information collection package with respect to a proposed "Application Kit for Economic Development and Supportive Services (EDSS) Program Grants".

This Program provides grants to public housing agencies and Indian housing authorities (collectively HAs) to (1) provide economic development opportunities and supportive services to assist residents of public and Indian housing to become economically self-sufficient and (2) to provide supportive services to assist the elderly and disabled persons to live independently or to prevent premature or unnecessary institutionalization. HUD published a Notice of Funding Availability (NOFA) which announced a total of \$ million in grant funds. The grants will be up to three years in duration.