

has submitted the following proposed collection of information to OMB for review and clearance.

With the 2003 National Surveys of Older Americans Act Participants, the Administration on Aging continues its initiative, started with the Performance Outcomes Measures Project (POMP), to develop and test performance outcome measures for Older Americans Act programs. Surveys to be conducted in 2003 will test consumer assessment instruments at the national and state level for nutrition, transportation, homemaker, information and assistance and caregiver services.

AoA estimates the burden of this collection of information as follows: Area Agency on Aging—Number of Respondents: 120; Number of Responses per Respondent: one; Average Burden per Response: 2 hours; Area Agency on Aging Burden: 240 hours—National Survey—Number of Respondents: 5040; Number of Responses per Respondent: one; Average Burden per Response: .5 hours; National Survey Burden: 2,520 hours—State Surveys—Number of Respondents: 5600; Number of Responses per Respondent: one; Average Burden per Response: .5 hours; State Survey Burden: 2,800 hours—Total Burden—5,560 hours.

Dated: June 3, 2003.

Josefina G. Carbonell,

Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N-0050]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Investigational Device Exemptions Reports and Records

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.

DATES: Submit written or electronic comments on the collection of information by July 16, 2003.

ADDRESSES: The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, 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 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Investigational Device Exemptions Reports and Records—21 CFR Part 812 (OMB Control Number 0910-0078)—Extension

Section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) establishes the statutory authority to collect information regarding investigational devices and establishes rules under which new medical devices may be tested using human subjects in a clinical setting. The Food and Drug Administration Modernization Act of 1997 added section 520(g)(6) to the act and permitted changes to be made either to the investigational device or to the clinical protocol without FDA approval of an investigational device exemption (IDE) supplement.

An IDE allows a device, which would otherwise be subject to provisions of the act, such as premarket notification or premarket approval, to be used in investigations involving human subjects. The safety and effectiveness of the device involving human subjects is being studied. The purpose of part 812 (21 CFR part 812) is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use. The IDE regulation is designed to encourage the development of useful medical devices and allow investigators the maximum freedom possible, without jeopardizing the health and safety of the public or violating ethical standards.

To do this, the regulation provides for different levels of regulatory control depending on the level of potential risk the investigational device presents to

human subjects. Investigations of significant risk devices, ones that present a potential for serious harm to the rights, safety, or welfare of human subjects, are subject to the full requirements of the IDE regulation. Nonsignificant risk device investigations, ones that do not present a potential for serious harm, are subject to the reduced burden of the abbreviated requirements.

The regulation also includes provisions for treatment IDEs. The purpose of these provisions is to facilitate the availability, as early in the device development process as possible, of promising new devices to patients with life-threatening or serious conditions for which no comparable or satisfactory alternative therapy is available.

Section 812.10 allows the sponsor of the IDE to request a waiver to all of the requirements of part 812. This information is needed for FDA to determine if waiver of the requirements of part 812 will impact the public's health and safety.

Sections 812.20, 812.25, and 812.27 consist of the information necessary to file an IDE application with FDA. The submission of an IDE application to FDA is required only for significant risk device investigations. Section 812.20 lists the data requirements for the original IDE application; § 812.25 lists the contents of the investigational plan; and § 812.27 lists the data relating to previous investigations or testing. The information in this original IDE application is evaluated by the Center for Devices and Radiological Health to determine whether the proposed investigation will reasonably protect the public health and safety and for FDA to make a determination to approve the IDE.

Once FDA approves an IDE application, a sponsor must submit certain requests and reports. Under § 812.35, a sponsor who wishes to make a change in the investigation, which affects the scientific soundness of the study or the rights, safety, or welfare of the subjects, is required to submit a request for the change to FDA. Under § 812.150, a sponsor is required to submit reports to FDA. These requests and reports are submitted to FDA as supplemental applications. This information is needed for FDA to assure protection of human subjects and to allow review of the study's progress.

Section 812.36(c) identifies the information necessary to file a treatment IDE application. FDA uses this information to determine if wider distribution of the device is in the interests of the public health. Section