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.

[FR Doc. 03–15061 Filed 6–13–03; 8:45 am]

BILLING CODE 4154–01–P

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

812.36(f) identifies the reports required to allow FDA to monitor the size and scope of the treatment IDE, to assess the sponsor's due diligence in obtaining marketing clearance of the device, and to ensure the integrity of the controlled clinical trials.

Section 812.140 lists the recordkeeping requirements for investigators and sponsors. FDA requires this information for tracking and oversight purposes. Investigators are required to maintain records, including correspondence and reports concerning the study; records of receipt, use or disposition of devices; records of each subject's case history and exposure to the device; informed consent documentation; study protocol and documentation of any deviation from the protocol. Sponsors are required to maintain records, including correspondence and reports concerning the study; records of shipment and disposition; signed investigator agreements; adverse device effects information; and, for a nonsignificant risk device study, an explanation of the nonsignificant risk determination, records on device name and intended use, study objectives, investigator information, investigational review board (IRB) information, and statement on the extent that good manufacturing practices will be followed.

The most likely respondents to this information collection will primarily be medical device manufacturers, investigators, hospitals, health maintenance organizations, and businesses.

In the **Federal Register** of March 12, 2003 (68 FR 11868), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
812.10	1	1	1	1	1
812.20, 812.25, and 812.27	600	0.5	300	80	24,000
812.35 and 812.150 (significant)	600	7	4,200	6	25,200
812.150 (nonsignificant)	600	0.017	10	6	60
812.36(c)	6	1	6	120	720
812.36(f)	6	2	12	20	240
Total					50,221

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
812.140 Original	600	0.5	300	10	3,000
Supplemental	600	7	4,200	1	4,200
Nonsignificant	600	1	600	6	3,600
Total					10,800

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

II. Reporting

Section 812.10 estimates are based on the fact that FDA has received very few, if any, waiver requests in the past, and estimates that very few will be submitted in the future. Therefore, FDA estimates a minimal burden to account for waiver requests.

Sections 812.20, 812.25, and 812.27 estimates are based on the average of IDEs submitted from fiscal years 1995 through 2002. FDA estimates the annual reporting burden for one IDE original application to be approximately 80 hours and the annual reporting burden for one IDE supplement to be approximately 6 hours.

Sections 812.35 and 812.150 estimates are based on the average of IDE supplements submitted from fiscal years 1995 through 2002 for significant risk device studies. FDA estimates the annual reporting burden for one IDE supplement to be approximately 6 hours.

The reporting burden for nonsignificant risk device studies (§ 812.150) is negligible. Nonsignificant risk device studies are not reported to FDA unless a problem is reported such as, an unanticipated adverse device reaction, failure to obtain informed consent, withdrawal of IRB approval, or a recall of a device. In the past, an

average of 10 incidences or less annually have been reported to FDA.

Section 812.36(c) and (f) estimates are based on FDA's experience with the treatment use of drugs and knowledge of the types of devices that may meet the treatment use criteria. FDA estimates that an average of six treatment use applications will be submitted each year. FDA estimates that it will take approximately 120 hours to prepare a treatment IDE and the total annual burden for preparing applications will be 720 hours. FDA also estimates that it will take approximately 20 hours to prepare a semiannual report, resulting in a total annual burden of 240 hours for annual reports.

III. Recordkeeping

Section 812.40 estimates are based on conversations with manufacturers, industry trade association groups, and businesses over the last 3 years. For significant risk device investigations, FDA has estimated that the recordkeeping burden for preparing an original IDE submission averages 10 hours for each original IDE submission. Similarly, through the same conversations previously mentioned, FDA has estimated recordkeeping for each supplement requires 1 hour. The recordkeeping burden for nonsignificant risk device investigations is difficult to estimate because nonsignificant risk device investigations are not required to be submitted to FDA. The IDE staff estimates that the number of recordkeepers for nonsignificant risk device investigations is equal to the number for active significant risk device investigations. The recordkeeping burden, however, is reduced for device nonsignificant risk studies. It is estimated that 600 recordkeepers will spend 6 hours each in maintaining these records.

Dated: June 9, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–15059 Filed 6–13–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0201]

Minimizing Medication Errors—Methods for Evaluating Proprietary Names for Their Confusion Potential; Public Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of May 30, 2003 (68 FR 32529). The document announced a public meeting to explore current methods being used to evaluate proprietary drug names to reduce medication errors due to similarity in drug names. The document published with inadvertent errors. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy and Planning (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 03–13591, appearing on page 32529 in the **Federal Register** of Friday, May 30, 2003, the following corrections are made:

1. On page 32530, in the first column, under ''**FOR FURTHER INFORMATION CONTACT**'', in the second paragraph, ''202–835–3533'' is corrected to read ''202–572–7751''.

2. On page 32530, in the third column, the first full sentence is corrected to read ''Speakers who wish to participate in the open public meeting must register by June 13, 2003.''

3. On page 32530, in the third column, under section III, the first sentence is corrected to read ''To speak at the meeting, you must preregister by June 13, 2003.''

Dated: June 9, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–15058 Filed 6–13–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Transmissible Spongiform Encephalopathies Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Transmissible Spongiform Encephalopathies Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 17, 2003, from 8 a.m. to 6 p.m., and on July 18, 2003, from 8 a.m. to 4:30 p.m.

Location: Holiday Inn Select, 8120 Wisconsin Ave., Bethesda, MD, 301–652–2000.

Contact Person: William Freas or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12392. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 17, 2003, the committee will discuss the safety of bovine bone gelatin in oral and topical drugs, food and cosmetics. The committee will then discuss bovine spongiform encephalopathy in Canada and potential implications for FDA-regulated products. In the afternoon, the committee will hear presentations on transmissible spongiform encephalopathies (TSEs) and decontamination of medical equipment and facilities. On Friday, July 18, 2003, the committee will discuss designing, interpreting, and validating studies to evaluate reprocessing methods for removing TSE contamination from medical devices. In the afternoon, the committee will discuss methods to decontaminate facilities and equipment used to prepare human cellular and tissue products, and human blood products, including plasma derivatives, to reduce the theoretical risk of transmitting TSE agents.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 10, 2003. Oral presentations from the public will be scheduled between approximately 11:35 a.m. and 11:55 a.m., and 1:55 p.m. and 2:25 p.m. on July 17, 2003; and between approximately 9:50 a.m. and 10:20 a.m., and 1:30 p.m. and 2 p.m. on July 18, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 11, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an