Persons who are not registered in advance will not be permitted into the Federal Building and thus not be able to attend the meeting. Persons attending the meeting will be required to show a photographic identification, preferably a valid drivers' license before entering the building. Please note that if the meeting is cancelled we will post that information on our website.

Attendees will be provided with meeting materials at the time of the meeting. Written meeting materials will be posted on the CMS website before the January 16, 2002 meeting at: *http://www.hcfa.gov* and *http://www.cms.hhs.gov.* We will accept written questions about meeting logistics or requests for meeting materials either before the meeting or up to 14 days after the meeting. Written submissions must be sent to:

Aspen Systems Corporation, ATTN: Kim Slaughter, 2275 Research Boulevard, Mail Stop 5W, Rockville, Maryland 20850.

You may also contact Encounter Data Representative: Kim Slaughter, Telephone Number: (301) 519–5388, Fax Number: (301) 519–6360, E-mail: *encounterdata@aspensys.com.*

Written public comments will be accepted until February 1, 2002. Written public comments should be sent to Bobbie Knickman at bknickman@cms.hhs.gov or fax to (410) 786–1048.

(Authority: Sections 1851 through 1859 of the Social Security Act (42 U.S.C. 1395w–21 through 1395w–28))

(Catalog of Federal Domestic Assistance Program No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 11, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 01–30991 Filed 12–13–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0393]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Prescription Drug Product Labeling; Medication Guide Requirements

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 (the PRA).

DATES: Submit written comments on the collection of information by January 14, 2002.

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: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Prescription Drug Product Labeling; Medication Guide Requirements (OMB Control No. 0910–0393)—Extension

FDA regulations require the distribution of patient labeling, called Medication Guides, for certain prescription human drug and biological products used primarily on an outpatient basis that pose a serious and significant public health concern requiring distribution of FDA-approved patient medication information. These Medication Guides inform patients about the most important information they should know about these products in order to use them safely and effectively. Included are information such as the drug's approved uses, contraindications, adverse drug reactions, and cautions for specific populations, with a focus on why the particular product requires a Medication Guide. These regulations are intended to improve the public health by providing information necessary for patients to use certain medication safely and effectively.

The regulations contain the following reporting requirements that are subject to the PRA. The estimates for the burden hours imposed by the following regulations are listed in table 1 of this document:

21 CFR 208.20—Applicants must submit draft Medication Guides for FDA approval according to the prescribed content and format.

21 CFR 314.70(b)(3)(ii) and 601.12(f)—Application holders must submit changes to Medication Guides to FDA for prior approval as supplements to their applications.

21 CFR 208.24(e)—Each authorized dispenser of a prescription drug product for which a Medication Guide is required, when dispensing the product to a patient or to a patient's agent, must provide a Medication Guide directly to each patient unless an exemption applies under § 208.26 (21 CFR 208.26).

Section 208.26(a)—Requests may be submitted for exemption or deferral from particular Medication Guide content or format requirements.

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
208.20	8	1	8	242	1,936
314.70(b)(3)(ii) and 601.12(f)	3	1	3	24	72
208.24(e)	55,000	8.3	460,000	.0014	644
208.26(a)	1	1	1	4	4
Total					2,656

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

In the **Federal Register** of September 25, 2001 (66 FR 49024), the agency requested comments on the proposed collections of information. FDA received one comment on the September 25, 2001, notice. The

comment stated that clarification is needed as to whether Medication Guides would be needed for medical devices that have a prescription drug either as a coating or incorporated into the material of the device, or as a component in a kit. The comment said that some of these types of products might be considered combination products.

FDA requested comments on the information collection burden estimates described in the notice. Because the comment does not pertain to the burden estimates, FDA has forwarded the comment to Docket Number 93N–0371, ''Prescription Drug Product Labeling; Medication Guide Requirements.'' FDA appreciates the comment and will consider it as part of its Medication Guide program.

Dated: December 7, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–30852 Filed 12–13–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis, Panel.

Date: January 6–8, 2002.

Time: 7 p.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Wales, 1295 Madison Avenue, New York, NY 10128.

Contact Person: Francisco O. Calvo, PhD, Chief, Review Branch, DEA, NIDDK, Room 752, 6707 Democracy Boulevard, National Institutes of Health, Bethesda, MD 20892–6600, (301) 594–8897.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: December 5, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–30874 Filed 12–13–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communications Disorders; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Deafness and Other Communications Disorders Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Deafness and Other Communication Disorders Advisory Council.

Date: January 18, 2002.

Open: 8:30 a.m. to 11:15 a.m.

Agenda: Staff reports on divisional, programmatic, and special activities.

Place: 31 Center Drive, Bldg. 31, Conf. Rm. 6, Bethesda, MD 20892.

Closed: 11:15 a.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: 31 Center Drive, Bldg. 31, Conf. Rm. 6, Bethesda, MD 20892.

Contact Person: Craig A. Jordan, PhD, Chief, Scientific Review Branch, NIH/NIDCD/DER, Executive Plaza South, Room 400C, Bethesda, MD 20892–7180, 301–496–8683.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

Information is also available on the Institute's/Center's home page: *www.nidcd.nih.gov/about/councils/ndcdac/ndcdac.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: December 5, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–30875 Filed 12–13–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel, Mental Retardation and Developmental Disabilities.

Date: December 10, 2001.

Time: 11 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: 6100 Executive Blvd., Room 5E01, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Norman Chang, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, National Institute of Health, 6100 Executive Blvd., Room 5E03, Bethesda, MD 20892, (301) 496–1485.

This notice is being published less than 15 days prior to the meeting due to the timing