The Secretary of Health and Human Services has the discretion to allow Form FDA 1815, a duly certified statement signed by an accredited official of a foreign government, to be submitted in lieu of Forms FDA 1994 and 1995. To date, Form FDA 1815 has been submitted in lieu of these forms.

Dated: May 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–10703 Filed 5–27–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0174]

Draft Guidance on Expiration Dating of Unit-Dose Repackaged Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Expiration Dating of Unit-Dose Repackaged Drugs.'' The draft guidance is a proposed revision of section 480.200 of FDA's Compliance Policy Guide (CPG) (CPG 7132b.11). We are proposing to revise CPG 7132b.11 so that FDA enforcement policy regarding expiration dating of nonsterile unit-dose repackaged drugs under the agency's current good manufacturing practice (CGMP) regulations is substantially comparable to the expiration dating standards for such drugs set forth in the U.S. Pharmacopeia (USP).

DATES: Submit written or electronic comments on the draft guidance by August 29, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Barry Rothman, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–9026.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance on ''Expiration Dating of Unit-Dose Repackaged Drugs.'' The document provides guidance on FDA's enforcement policy regarding expiration dating of repackaged nonsterile solid and liquid unit-dose drugs under § 211.137 (21 CFR 211.137). Specifically, the draft guidance states certain circumstances under which we intend to exercise enforcement discretion and do not intend to take action against repackagers for failure to conduct stability studies to support expiration dates for drug products in accordance with FDA regulations.

The draft guidance is a proposed revision of section 480.200 of the CPG (CPG 7132b.11), which we issued in February 1984 and revised in March 1995. We originally issued CPG 7132b.11 because unit-dose packaging systems had become widespread in health care, and questions had arisen as to whether drugs that were repackaged into unit-dose containers needed expiration dates based on stability data on the drugs in the unit-dose containers.

The CGMP regulations require that each drug product bear an expiration date derived from tests conducted on samples stored in the immediate container closure system in which the drug is marketed (see § 211.137(a), § 211.166(a)(4) (21 CFR 211.166(a)(4))). This expiration dating ensures the drugs' safety and efficacy over their intended shelf life. CPG 7132b.11 notes that the USP contains standards on beyond-use dating of nonsterile solid and liquid unit-dose drug products.

Since its adoption in 1984, the CPG has stated that, in light of the USP standards and under certain conditions, the agency does not deem it necessary that stability studies be conducted on drugs that are repackaged into unit-dose containers. Therefore, the CPG has stated that we do not intend to initiate enforcement action against any unit-dose repackaging firm for failure to have stability studies supporting expiration dates, provided certain conditions are met, including that the expiration date does not exceed 6 months. At the time the CPG was adopted, this recommendation was substantially comparable to the USP standards on expiration dating of nonsterile unit-dose repackaged drug products.

In 2000, the USP revised its standards on the beyond-use dating of nonsterile solid and liquid dosage forms that are packaged in single-unit and unit-dose containers. The USP now states that, for such products, the beyond-use date must be 1 year from the date the drug is packaged into the single-unit or unit-dose container or the expiration date on the manufacturer's container, whichever is earlier, unless stability data or the manufacturer's labeling indicates otherwise (USP 27, General Notices and Requirements, at 11).

We have considered the USP revision to its beyond-use standard and believe that similar conditions are appropriate for CPG 7132b.11 for expiration dating. We believe that under certain specified conditions, it may be appropriate to assign up to a one-year expiration dating period to solid and liquid oral dosage form drug products repackaged into unit-dose containers, without conducting new stability studies on the repackaged drug products. Therefore, we are proposing to revise CPG 7132b.11 to clarify the agency's exercise of enforcement discretion concerning expiration dating of nonsterile solid and liquid oral dosage form drug products that are repackaged into unit-dose containers.

Under draft revised CPG 7132b.11, the expiration date for a nonsterile repackaged unit-dose drug would not exceed the following: (1) One year from the date of repackaging, or (2) the expiration date on the container of the original manufacturer's product, whichever is earlier, unless stability data or the original manufacturer's product labeling indicated otherwise, and provided certain other recommendations specified in CPG 7132b.11 were met. These other conditions include, but are not limited to, standards for containers, repackaging operations, and the repackaging environment.

Additionally, because CPG 7132b.11 serves as Attachment B to section 430.100 of the CPG (CPG 7132b.10, ''Unit Dose Labeling for Solid and Liquid Oral Dosage Forms''), the proposed revision of CPG 7132b.11 will serve as Attachment B to CPG 7132b.10 when CPG 7132b.11 is finalized.

We invite comments on the draft guidance. Additionally, we intend to conduct further study of the appropriateness of the proposed revision of CPG 7132b.11 regarding expiration dating on the unit-dose containers of nonsterile repackaged solid and liquid oral dosage form drug

products. We do not intend to make a final decision on the proposed revision of CPG 7132b.11 until we complete further study of the expiration dating issue to determine the most scientifically sound approach. We invite interested persons to submit data establishing appropriate expiration dating for such drug products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on expiration dating on nonsterile unit-dose repackaged drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the current requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cder/guidance/index.htm* or *http://ohrms/dockets/default.htm*.

Dated: May 19, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–10702 Filed 5–27–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 Cancer Institute Initial Review Group, Subcommittee A—Cancer Center.

Date: August 4–5, 2005.

Time: 7 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Bethesda North Hotel, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: David E. Maslow, PhD, Scientific Review Administrator, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Blvd., Room 8117, Bethesda, MD 20892–7405, (301) 496–2330, *dm65y@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 19, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–10755 Filed 5–27–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; 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 Center for Complementary and Alternative Medicine Special Emphasis Panel Meeting Conflict.

Date: June 24, 2005.

Time: 12 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: NIH/NCCAM, Democracy II, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892.

Contact Person: Jeanette M. Hosseini, Scientific Review Administrator, National Center for Complementary and Alternative Medicine, 6707 Democracy Blvd, Suite 401, Bethesda, MD 20892, (301) 594–9096.

Dated: May 19, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–10753 Filed 5–27–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center on Minority Health and Health Disparities; 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 Advisory Council on Minority Health and Health Disparities.

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 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 Advisory Council on Minority Health and Health Disparities.

Date: June 21, 2005.

Open: 8:30 a.m. to 4 p.m.

Agenda: The agenda will include Opening Remarks, Administrative Matters, Director's Report, NCMHD, National Academy of Sciences Report on Assessment of NIH Minority Research an Training Programs, NIH IC Health Disparities Research Report, NCMHD Program Highlights, other business of the Council.