

traditional approval of antiretroviral drugs using plasma HIV RNA measurements. 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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written or electronic comments on the guidance to the Dockets Management Branch (see **ADDRESSES**). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

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

Dated: October 28, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-27885 Filed 10-31-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0407]

Diagnostic X-Ray Field Size; Revocation of Compliance Policy Guide 7133.17; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice that appeared in the **Federal Register** of October 10, 2002 (67 FR 63108). The document revoked the compliance policy guide entitled "Sec. 398.475 Minimum X-Ray Field Size for Spot-Film Operation of Fluoroscopic Systems with Fixed SID and Without Stepless Adjustment of the Field Size (CPG 7133.17)." The document was published with an inadvertent error. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy (HF-27),

Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 02-25881, appearing on page 63108 in the **Federal Register** of Thursday, October 10, 2002, the following correction is made:

1. On page 63108, in the third column, at the end of the document, the phrase "Dated: October 1, 2002" is corrected to read "Dated: October 1, 2002".

Dated: October 25, 2002.

John M. Taylor,

Senior Associate Commissioner for Regulatory Affairs.

[FR Doc. 02-27886 Filed 10-31-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0177]

Guidance for Industry on Immunotoxicology Evaluation of Investigational New Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Immunotoxicology Evaluation of Investigational New Drugs." This guidance provides recommendations for sponsors of investigational new drugs (INDs) on what parameters to routinely assess in toxicology studies to determine effects on immune function, when to conduct additional immunotoxicity studies, and when additional mechanistic information could better characterize a given effect on the immune system.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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 guidance to the Dockets Management Branch (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 guidance document.

FOR FURTHER INFORMATION CONTACT: Kenneth L. Hastings, Center for Drug Evaluation and Research (HFD-590), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2489.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Immunotoxicology Evaluation of Investigational New Drugs." The human immune system is a complex set of cells and organs that can be adversely affected by drugs. Impairment of the immune system can result in increased susceptibility to infections and tumors, allergic responses to drugs, autoimmune reactions, or other forms of immune system disease. Immunotoxicology studies can be conducted in animals to determine the potential of an investigational drug to adversely affect the immune system. This guidance provides advice on: (1) When to conduct immunotoxicology studies, (2) what types of effects can be observed in standard nonclinical toxicology studies that would indicate that a drug has immunotoxic potential, and (3) what types of studies could be useful in determining the nature of the immunotoxicity. It is expected that this guidance will provide sponsors with useful information for proper assessment of the immunotoxic potential of drugs.

In the **Federal Register** of May 11, 2001 (66 FR 24145), FDA published a draft guidance entitled "Immunotoxicology Evaluation of Investigational New Drugs." The notice gave interested persons an opportunity to submit comments. Based on the comments, FDA has revised the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on immunotoxicology evaluation of INDs. 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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management

Branch (see **ADDRESSES**). Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

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

Dated: October 28, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-27883 Filed 10-31-02; 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 Special Emphasis Panel; Special Emphasis Panel to Review Two R25, Two K12 and One K23 Grant Applications.

Date: November 19, 2002.

Time: 3 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: 6116 Executive Blvd, Room 8137, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Raymond A. Petryshyn, PhD, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Blvd., 8th Fl., Room 8109, Bethesda, MD 20892, 301/594-1216, petryshr@mail.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: October 24, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-27754 Filed 10-31-02; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye 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 Eye Institute Special Emphasis Panel; NEI Clinical Applications (U10 clinical trials, R03, R01, R21, K08, K23).

Date: December 10, 2002.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Anne E. Schaffner, PhD, Scientific Review Administrator, Division of Extramural Research, National Eye Institute, 6120 Executive Blvd., Suite 350, Bethesda, MD 20892, 301-451-2020.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: October 24, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-27753 Filed 10-31-02; 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; Fragile X Research Center.

Date: November 18-29, 2002.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Madison Hotel, 15th and M Street, NW., Washington, DC 20005.

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

(Catalogue of Federal Domestic Assistance Program Nos. 93.209, Contraception and Infertility Loan Repayment Program; 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research, National Institutes of Health, HHS)

Dated: October 24, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-27748 Filed 10-31-02; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meetings

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