DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: October 23, 2002.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 02–27759 Filed 10–31–02; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Women's Health Initiative Subcommittee of the Advisory Committee for Reproductive Health Drugs; Notice of Postponement of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is postponing the meeting of the Women's Health Initiative Subcommittee of the Advisory Committee for Reproductive Health Drugs scheduled for November 12 and 13, 2002. The meeting was announced in the **Federal Register** of October 21, 2002 (67 FR 64651). FDA's Center for Drug Evaluation and Research is going to evaluate additional data relevant to the topic. Future meeting dates will be announced in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Jayne E. Peterson, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, FAX 301–827–6776, or e-mail: *PETERSONJ@CDER.FDA.GOV*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12537. Please call the Information Line for up-to-date information on this meeting.

Dated: October 24, 2002.

LaJuana D. Caldwell,

Acting Senior Associate Commissioner for External Relations.

[FR Doc. 02–27884 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–0427]

Guidance for Industry on Antiretroviral Drugs Using Plasma Human Immunodeficiency Virus Ribonucleic Acid Measurements—Clinical Considerations for Accelerated and Traditional Approval; 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 ''Antiretroviral Drugs Using Plasma HIV RNA Measurements—Clinical Considerations for Accelerated and Traditional Approval.'' This guidance is intended to assist sponsors in the clinical development of drugs for the treatment of human immunodeficiency virus (HIV) infection. Specifically, this guidance addresses the agency's current thinking regarding designs of clinical trials that use HIV ribonucleic acid (RNA) measurements to support accelerated and traditional approvals of antiretroviral drug products.

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: Jeffrey S. Murray, Center for Drug Evaluation and Research (HFD–530), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2330.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Antiretroviral Drugs Using Plasma HIV RNA Measurements—Clinical Considerations for Accelerated and Traditional Approval.'' This guidance is intended to assist sponsors in the clinical development of drugs for the treatment of HIV infection. Specifically, this guidance addresses the agency's current thinking regarding designs of clinical trials that use HIV RNA measurements to support accelerated and traditional approvals of antiretroviral drug products. It is also intended to serve as a focus for continued discussions among the Division of Antiviral Drug Products (DAVDP), pharmaceutical sponsors, the academic community, and the public.

The draft version of this document, first issued in August 1999, was based on a DAVDP advisory committee meeting, convened in July 1997, to discuss the use of HIV RNA endpoints for traditional approval of antiretroviral drugs. This document has been updated to address public comments to the draft version and to include pertinent information from a DAVDP advisory committee meeting held in January 2001 that addressed issues relating to trial design in HIV-infected patients who have already been heavily treated for the disease. The guidance summarizes the rationale for using HIV RNA as a primary endpoint in clinical trials to support both accelerated and traditional approval. It describes the amount and type of safety and efficacy data recommended for new drug applications. The guidance also reviews pertinent clinical trial design issues including choice of control arms, study procedures, and statistical considerations. An appendix addresses the use of experimental HIV RNA assays in phase 3 studies.

This guidance does not address specific phase-1 and -2 development issues, development of alternate dosing regimens, or the use of HIV–1 resistance testing. These issues will be addressed in separate future guidance documents.

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 clinical considerations for accelerated and

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, 2022'' 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