

this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: May 4, 2001.

Alan M. Rulis,

*Director, Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.*
[FR Doc. 01-13068 Filed 5-22-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products 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 June 11, 2001, 11:30 a.m. to 2:30 p.m.

Location: Food and Drug Administration, 8800 Wisconsin Ave., Bldg. 29-B, conference room 1NN06, Bethesda, MD. This meeting will be held via telephone conference call. A speaker phone will be provided in the conference room to allow public participation in the meeting.

Contact: Nancy T. Cherry or Denise H. Royster, 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 12391. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the intramural scientific research program of the Laboratory of Pediatric and Respiratory Viral Diseases.

Procedure: On June 11, 2001, from 11:30 a.m. to 1:30 p.m., the meeting is open to the public. 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 May 31, 2001. Oral presentations from the public will be scheduled between approximately 12:20 p.m. and 1:25 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 31, 2001, 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 indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On June 11, 2001, from 1:30 p.m. to 2:30 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The meeting will be closed to discuss personal information concerning individuals associated with the research program.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 17, 2001.

Linda A. Suydam,

Senior Associate Commissioner.
[FR Doc. 01-13070 Filed 5-22-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-1195]

Guidance for Industry on Bioanalytical Method Validation; 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 "Bioanalytical Method Validation." This guidance provides assistance to sponsors of investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), and their supplements in developing validation information on bioanalytical methods for pharmacokinetic (PK) evaluation of human clinical pharmacology, bioavailability (BA), and bioequivalence (BE) studies. The guidance also applies to bioanalytical methods used for nonhuman pharmacology/toxicology

studies and preclinical studies. For studies related to the veterinary drug approval process, this guidance applies only to blood and urine BA, BE, and PK studies.

DATES: Submit written 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Vinod P. Shah, Center for Drug Evaluation and Research (HFD-350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5635.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Bioanalytical Method Validation." This guidance provides recommendations to sponsors of INDs, NDAs, ANDAs, and their supplements in developing validation information for bioanalytical methods for PK evaluations of human clinical pharmacology, BA studies, and BE studies. The information in this guidance generally applies to bioanalytical procedures such as gas chromatography (GC), high-pressure liquid chromatography (LC), combined GC and LC mass spectrometric (MS) procedures such as LC-MS, LC-MS-MS, GC-MS, GC-MS-MS, and immunological and microbiological procedures performed for quantitative determination of drugs and or metabolites in biological matrices such as serum, plasma, or urine. The guidance also applies to other bioanalytical matrices such as tissue and skin samples.

In the **Federal Register** of January 5, 1999 (64 FR 517), FDA announced the availability of a draft guidance entitled "Bioanalytical Methods Validation for Human Studies." This January 1999 document gave interested persons an opportunity to comment through March 8, 1999. The agency received a total of 36 comments. All comments received

during the comment period have been carefully reviewed and incorporated in this revised guidance where appropriate. In addition, a workshop entitled "Bioanalytical Method Validation—A Revisit with a Decade of Progress" was held January 12 to 14, 2000. This guidance also incorporates the recommendations from the January 2000 workshop.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The guidance represents the agency's current thinking on the validation of methods for the assay of drugs and/or metabolites in human biological matrices. 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 (address above). 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 <http://www.fda.gov/cder/guidance/index.htm>.

Dated: May 11, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01-12908 Filed 5-22-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1497]

The Mammography Quality Standards Act Final Regulations Document #4; Final Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the

availability of the guidance entitled "The Mammography Quality Standards Act Final Regulations Document #4; Final Guidance for Industry and FDA." The final regulations implementing the Mammography Quality Standards Act of 1992 (the MQSA) became effective April 28, 1999. The final guidance document is intended to assist facilities and their personnel to meet the MQSA final regulations.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "The Mammography Quality Standards Act Final Regulations Document #4; Final Guidance for Industry and FDA" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT:

Charles A. Finder, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332.

SUPPLEMENTARY INFORMATION:

I. Background

The draft guidance document was issued for public comment in the **Federal Register** of September 13, 2000 (65 FR 55265). The comment period ended on December 13, 2000. The draft guidance was discussed with the National Mammography Quality Assurance Advisory Committee at the September 28, 2000, meeting. The final guidance document has been modified from the original draft guidance to address the seven public comments received. There were several clarifying changes made to the document, particularly dealing with the issues of what constitutes a "major repair" and when the physicist must perform onsite evaluations. Several decision tree flow diagrams were added to the document to help clarify these issues. Overall,

there were no major substantive changes made to the document.

II. Significance of the Guidance

This guidance document represents the agency's current thinking on the MQSA final regulations guidance. 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 applicable statutes and regulations.

The agency has adopted the good guidance practices (GGPs) regulation, which sets forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document is issued as a level 1 guidance consistent with GGPs.

III. Electronic Access

In order to receive "The Mammography Quality Standards Act Final Regulations Document #4; Final Guidance for Industry and FDA" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1159) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. "The Mammography Quality Standards Act Final Regulations Document #4; Final Guidance for Industry and FDA" will also be available on CDRH's mammography Web site at <http://www.fda.gov/cdrh/mammography>. Guidance documents are also available on the Dockets Management Branch Web site at <http://www.fda.gov/ohrms/dockets/default.htm>.