for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Jeffrey B. Governale, Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–632–6851.

SUPPLEMENTARY INFORMATION:

I. Background

In 1992 and 1994, the Association for the Advancement of Medical Instrumentation (AAMI) issued two revised standards that were approved by the American National Standards Institute (ANSI) namely, ''ANSI/AAMI SP9–1994 American National Standard Non-Automated Sphygmomanometers'' and ''ANSI/AAMI SP10–1992 American National Standard for Electronic or Automated Sphygmomanometers.''

As amended by the FDA Modernization Act of 1997 (FDAMA), section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)) allows FDA to recognize consensus standards, established by international and national standard development organizations, for use in satisfying portions of device premarket review submissions or other requirements. FDA now recognizes the complete standards ANSI/AAMI SP9–1994 and ANSI/AAMI SP10–1992 for the purpose of premarket clearance (63 FR 55617, October 16, 1998; 67 FR 1774, January 14, 2002). To be consistent with current industry practice, FDA intends to use the accuracy and exhaust rate criteria identified in these recognized consensus standards as guidance for testing, surveillance, and compliance purposes, as well as for premarket clearance. Therefore, this draft revised guidance reflects the accuracy and exhaust rate criteria in the currently recognized revisions of these two voluntary standards.

II. Significance of Guidance

This draft guidance represents the agency's current thinking on this topic. 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.

In accordance with FDA's good guidance practices regulation (21 CFR 10.115), this draft document is considered a level 1 guidance. This draft guidance is being issued for public comment only and is not in effect at this time. Only after a notice of availability is published in the **Federal Register** for the final document will the agency implement the guidance.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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 agency will review all comments, but in issuing final guidance, need not specifically address each comment. If appropriate, the agency will make changes to the guidance in response to comments. 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.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/ora/compliance_ref/revisions.htm*.

Dated: February 10, 2005.

John Marzilli,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 05–3116 Filed 2–17–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0047]

Draft Guidance for Industry: Considerations for Plasmid Deoxyribonucleic Acid Vaccines for Infectious Disease Indications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Considerations for Plasmid DNA Vaccines for Infectious Disease Indications'' dated February 2005. The draft guidance document is intended to assist manufacturers and/or sponsors in the development and testing of deoxyribonucleic acid (DNA) vaccines to prevent infectious diseases. The draft guidance, when finalized, will update and replace the guidance document entitled ''Points to Consider on Plasmid DNA Vaccines for Preventive Infectious Disease Indications'' dated December 1996.

DATES: Submit written or electronic comments on the draft guidance by May 19, 2005, to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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*.

FOR FURTHER INFORMATION CONTACT: Joseph L. Okrasinski, Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Considerations for Plasmid DNA Vaccines for Infectious Disease Indications'' dated February 2005. The draft guidance is intended to assist manufacturers and/or sponsors in the development and testing of DNA vaccines to prevent infectious diseases. The document describes the manufacturing information that should be submitted to CBER for a new DNA vaccine product for clinical study under an investigational new drug application (IND). Plasmid DNA products intended for non-infectious therapeutic indications are not addressed in the draft guidance. The draft guidance, when finalized, will update and replace the guidance document entitled ''Points to Consider on Plasmid DNA Vaccines for Preventive Infectious Disease Indications'' dated December 1996.

The 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 this topic. 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 requirement of the applicable statutes and regulations.

II. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final 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 the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. The Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection(s) of information mentioned in the guidance regarding the submission of manufacturer's information in an IND was approved under OMB control number 0910–0014.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: February 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–3106 Filed 2–17–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0049]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Commitment Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is required, under the Food and Drug Administration Modernization Act of 1997 (Modernization Act), to report annually in the **Federal Register** on the status of postmarketing study commitments made by sponsors of approved drug and biological products. This is the agency's report on the status of the studies sponsors have agreed to or are required to conduct.

FOR FURTHER INFORMATION CONTACT: Beth Duvall-Miller, Center for Drug Evaluation and Research (HFD–20), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301–594–3937; or Robert Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1400 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

Section 130(a) of the Modernization Act (Public Law 105–115) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding a new provision requiring reports of certain postmarketing studies (section 506B of the act (21 U.S.C. 356b)) for human drug and biological products. Section 506B of the act provides FDA with additional authority to monitor the progress of a postmarketing study commitment that an applicant has been required or has agreed to conduct by requiring the applicant to submit a report annually providing information on the status of the postmarketing study commitment. This report must also include reasons, if any, for failure to complete the commitment.

In the **Federal Register** of December 1, 1999 (64 FR 67207), FDA published a proposed rule providing a framework for the content and format of the annual progress report. The proposed rule also clarified the scope of the reporting requirement and the timing for submission of the annual progress reports. The final rule, published in the **Federal Register** of October 30, 2000 (65 FR 64607), modified annual report requirements for new drug applications (NDAs) and abbreviated new drug applications (ANDAs) by revising § 314.81(b)(2)(vii) (21 CFR 314.81(b)(2)(vii)). The rule also created a new annual reporting requirement for biologics license applications (BLAs) by establishing § 601.70 (21 CFR 601.70). These regulations became effective on April 30, 2001. The regulations apply only to human drug and biological products. They do not apply to animal drug or to biological products that also meet the definition of a medical device.

Sections 314.81(b)(2)(vii) and 601.70 apply to postmarketing commitments made on or before enactment of the Modernization Act (November 21, 1997) as well as those made after that date. Sections 314.81(b)(2)(vii) and 601.70 require applicants of approved drug and biological products to submit annually a report on the status of each clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology study that is required by FDA (e.g., accelerated approval clinical benefit studies) or that they have committed to conduct either at the time of approval or after approval of their NDA, ANDA, or BLA. The status of other types of postmarketing commitments (e.g., those concerning chemistry, manufacturing, production controls, and studies conducted on an applicant's own initiative) are not required to be reported under §§ 314.81(b)(2)(vii) and 601.70, and are not addressed in this report. It should be noted, however, that applicants are required to report to FDA on these commitments made for NDAs and ANDAs under § 314.81(b)(2)(viii).

According to the regulations, once a postmarketing study commitment has been made, an applicant must report on the progress of the commitment on the anniversary of the product's approval until the postmarketing study commitment is completed or terminated, and FDA determines that the postmarketing study commitment has been fulfilled or that the postmarketing study commitment is either no longer feasible or would no longer provide useful information. The annual progress report must include a description of the postmarketing study commitment, a schedule for completing the study commitment, and a characterization of the current status of the study commitment. The report must also provide an explanation of the postmarketing study commitment's status by describing briefly the postmarketing study commitment's progress. A postmarketing study commitment schedule is expected to