that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct
or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0131. The approval expires on November 30, 2000.

Dated: December 18, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–33798 Filed 12–29–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0048]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''Sterility Requirements for Inhalation Solution Products'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 23, 1997 (62 FR 49638), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection and has assigned OMB control number 0910–0353. The approval expires on November 30, 2000.

Dated: December 18, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–33799 Filed 12–29–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 92N–0251]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Electronic Records; Electronic Signatures'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 20, 1997 (62 FR 33660), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0303. The approval expires on August 31, 2000.

Dated: December 17, 1997

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–33801 Filed 12–29–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[Docket No. 97D–0483]

Draft Guidance for Industry on Food-Effect Bioavailability and Bioequivalence Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Food-Effect Bioavailability and Bioequivalence Studies.'' The draft guidance is intended for sponsors of new drug applications (NDA's), abbreviated new drug applications (ANDA's) and abbreviated antibiotic applications (AADA's) who intend to conduct food-effect bioavailability (BA) and bioequivalence (BE) studies for oral immediate release and modified release dosage forms. The guidance provides information and recommendations on study design, data analysis, and labeling.

DATES: Written comments may be submitted on the draft guidance by March 2, 1998. General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies ''Food-Effect Bioavailability and Bioequivalence Studies'' to the Drug Information Branch (HFD–210), 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 document to the Dockets Management Branch (HFD–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Ameeta Parekh, Center for Drug Evaluation and Research (HFD–860), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5325.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Food-Effect Bioavailability and Bioequivalence Studies.'' The draft guidance is intended to help sponsors of NDA's, ANDA's, and AADA's when conducting BA and BE studies with food for oral immediate release and modified release dosage forms.

The intake of food is known to alter gastrointestinal physiology, generally delaying gastric emptying, stimulating bile flow, altering the pH of gastric environment and the blood flow to the region. These factors can influence the BA (important in new drug and formulation situations) and BE (important in switchability of drug products) when drug products are coadministered with food. Food also may alter lumenal metabolism and can

physically or chemically interact with a drug substance. Altered BA of drug products can lead to dosage adjustments or, more commonly, to the provision of specific dosing instructions in relation to administration with meals. This draft guidance provides a general design for and recommends ways this information can be appropriately addressed in the labeling.

The draft guidance recommends that a food-effect assessment should be made early in drug development. It also recommends that subsequent studies following formulation changes may be eliminated provided that there is basis for assuming that the food-effect arises due to drug substance rather than formulation factors.

This draft guidance addresses situations when food-effect BA and BE studies should be considered and when these may not be important. It examines study considerations, such as general design, subject selection, formulation selection, test meal, treatment administration, sample collection, and data analysis. It also addresses issues related to labeling for food effects.

This draft guidance document represents the agency's current thinking on food-effect bioavailability and bioequivalence studies. 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 statute, regulations, or both.

Interested persons may submit written comments on the draft guidance document 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 draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

An electronic version of this guidance is available on the World Wide Web at http://www.fda.gov/cder/guidance/index.htm.

Dated: December 18, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–33802 Filed 12-29-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0433]

Preliminary Draft Guidance for Industry on In Vivo Bioequivalence Studies Based on Population and Individual Bioequivalence Approaches; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a preliminary draft guidance for industry entitled ''In Vivo Bioequivalence Studies Based on Population and Individual Bioequivalence Approaches.'' If this preliminary draft guidance becomes final, it will provide recommendations to sponsors of investigational new drug applications (IND's), new drug applications (NDA's), abbreviated new drug applications (ANDA's), and abbreviated antibiotic drug applications (AADA's) who intend to perform studies based on a comparison of pharmacokinetic metrics. If finalized, the guidance would replace a prior guidance entitled ''Statistical Procedures for Bioequivalence Studies Using a Standard Two-Treatment Crossover Design,'' which was published in July 1992. Because a transition to the approaches delineated in this document will require careful consideration, FDA is making it available as a preliminary draft.

DATES: Written comments may be submitted on the preliminary draft guidance document by March 2, 1998. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this preliminary draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm.'' Written requests for single copies of the preliminary draft guidance for industry should be submitted to the Drug Information Branch (HFD–210), 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 preliminary draft guidance to the Dockets Management Branch (HFD–305), Food and Drug Administration, 12420 Parklawn Dr., rm 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Mei-Ling Chen, Office of Clinical Pharmacology and Biopharmaceutics, Center for Drug Evaluation and Research (HFD–870), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5919, or

Rabindra N. Patnaik, Office of Generic Drugs, Center for Drug Evaluation and Research (HFD–651), 7500 Standish Pl., Food and Drug Administration, Rockville, MD 20855, 301–827–5847.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a preliminary draft guidance for industry entitled ''In Vivo Bioequivalence Studies Based on Population and Individual Bioequivalence Approaches.'' If it becomes final, this guidance for industry will provide recommendations to sponsors of IND's, NDA's, ANDA's, and AADA's who intend to perform in vivo bioequivalence studies based on a comparison of pharmacokinetic metrics, either prior to or following approval.

The definitions of ''bioavailability'' and ''bioequivalence;'' the requirements for submitting such data in NDA's, ANDA's, and supplements; and the types of in vivo studies that are acceptable to establish bioavailability and bioequivalence are set forth in 21 CFR part 320. These regulatory definitions and requirements reflect requirements in the Federal Food, Drug, and Cosmetic Act and other agency regulations.

Bioavailability and bioequivalence are usually measured by in vivo studies assessing metrics of a plasma or blood concentration-time curve to establish the rate and extent of absorption of an appropriate active drug/metabolite (bioavailability), or to compare the rate and extent of absorption of a test and reference formulation (bioequivalence).

In the July 1992 guidance for industry entitled ''Statistical Procedures for Bioequivalence Studies Using a Standard Two-Treatment Crossover Design,'' FDA recommended that a standard in vivo bioequivalence study design be based on administration of the test and reference products on separate occasions to healthy subjects, either in single or multiple doses, with random assignment to the two possible sequences of drug product administration.

Based on work performed during the last several years by scientists within and outside FDA, this preliminary draft guidance for industry recommends that the approach for determining average bioequivalence discussed in the 1992