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