VIII. Method of Application

A. Submission Instructions

Applications will be accepted during normal working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before August 3, 1998.

Applications will be considered received on time if sent or mailed on or before the receipt dates as evidenced by the legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant.

Note: Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.

B. Format of Application

Applications must be submitted on Grant Application Form PHS 398 (Rev. 5/95). All ''General Instructions'' and ''Specific Instructions'' in the application kit should be followed with the exception of the receipt dates and the mailing label addresses. Do not send applications to the Center for Scientific Review, NIH. This information collection is approved under OMB control number 00925–0001. Applications from State and local governments may be submitted on Form PHS 5161 (Rev.7/92) or PHS 398 (Rev.5/95). The face page of the application must reflect the request for applications number RFA–FDA–CDER–99–1. This information collection is approved under OMB control number 0937–0189.

C. Legend

Unless disclosure is required by the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of the Department of Health and Human Services or by a court, data contained in the portions of the application that have been specifically identified by page number, paragraph, etc., by the applicant as containing confidential commercial information or other information that is exempt from public disclosure will not be used or disclosed except for evaluation purposes.

Dated: June 9, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–16293 Filed 6–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0192]

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 ''Establishment and Product License Applications'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 8, 1998 (63 FR 17183), 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 0910–0124. The approval expires on June 30, 1998.

Dated: June 9, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–16292 Filed 6–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0529]

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 ''National Tobacco Retailer Tracking Study,'' 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 Tuesday, December 30, 1997 (62 FR 67876), 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 0910–0369. The approval expires on May 31, 2001.

Dated: June 11, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–16340 Filed 6–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0401]

Draft ''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product''; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product.'' The draft guidance document would provide guidance to applicants on the content and format of the Chemistry, Manufacturing and Controls (CMC) and Establishment Description sections of the ''Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use''

(revised Form FDA 356h) for vaccines or related products. This action is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiatives and the FDA Modernization Act of 1997, and is intended to reduce unnecessary burdens for industry without diminishing public health protection.

DATES: Written comments may be submitted at any time, however, comments should be submitted by August 18, 1998, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product'' 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 that office in processing your requests. The draft guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, 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 guidance document entitled ''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product.'' This draft guidance document, when finalized, is intended to provide guidance to applicants in completing the CMC section and the establishment description information of revised Form FDA 356h. As announced in the **Federal Register** of July 8, 1997 (62 FR 36558), this form will be used as a single harmonized application form for all drug and licensed biological products. Use of the new harmonized Form FDA 356h, when fully implemented, will allow a biologic product manufacturer to submit one biologics license application instead of two separate applications (product license application and establishment license application).

This draft guidance document represents FDA's current thinking on the content and format of the CMC and Establishment Description sections of a license application for a vaccine or related product. 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 statute, regulations, or both. As with other guidance documents, FDA does not intend this draft guidance document to be all-inclusive and cautions that not all information may be applicable to all situations. The draft guidance document is intended to provide information and does not set forth requirements.

II. Request for Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by August 18, 1998, to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance document 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 draft guidance document by using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: June 9, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–16291 Filed 6–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4349–N–24]

Submission for OMB Review: Comment Request

AGENCY: Office of the Assistant Secretary for Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments due date:* July 20, 1998.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within thirty (30) days from the date of this Notice. Comments should refer to the proposal by name and/or OMB approval number and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708–1305. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will