

**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.*

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**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]

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**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"