FDA estimates the burden incurred by interested regulatory agencies and retail industry to provide FDA with a letter of interest to be a one time burden. FDA estimates the burden of collecting and maintaining food safety information based upon HACCP principles during the pilot program will vary considerably across the wide spectrum of retail activities and establishments and the type and number of products involved, and the nature of the equipment or instruments required by the retail establishment for monitoring. The estimated burden by the retail industry for maintaining their food safety system would involve the development, if not already implemented, and maintenance of the food safety plan based upon HACCP principles, the implementation and records generated by that plan, and the verification of the plan's implementation activities and records.

These estimates are based on FDA's experience with other government pilot programs and with comments received through the conference of food protection, public meetings, and retail industry advice. This information was utilized to design the pilot program with the least amount of burden to the retail industry.

Dated: July 22, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–20309 Filed 7–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0194]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by August 31, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Registration of Cosmetic Product Establishment—21 CFR Part 710 (OMB Control Number 0910–0027—Extension)

Under the Federal Food, Drug, and Cosmetic Act (the act), cosmetic products that are adulterated under section 601 of the act (21 U.S.C. 361) or misbranded under section 602 of the act (21 U.S.C. 362) may not be distributed in interstate commerce. To assist FDA in carrying out its responsibility to regulate cosmetics, FDA requests that establishments that manufacture or package cosmetic products register with the agency on Form FDA 2511 entitled ''Registration of Cosmetic Product Establishment.'' Regulations providing procedures for the voluntary registration of cosmetic product establishments are found in 21 CFR part 710.

Since mandatory registration of cosmetic establishments is not authorized by statute, voluntary registration provides FDA with the best information available about the location, business trading names used, and the type of activity (manufacturing or packaging) of cosmetic product establishments that participate in this program. In addition, the registration information is an essential part of planning onsite inspections to determine the scope and extent of noncompliance with applicable provisions of the act. The registration information is used to estimate the size of the cosmetic industry regulated. Registration is permanent, although FDA requests that firms submit an amended registration on Form FDA 2511 if any of the information originally submitted changes.

FDA uses registration information as input for a computer data base of cosmetic product establishments. This data base is used for mailing lists to distribute regulatory information or to invite firms to participate in workshops on topics in which they may be interested. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Part	Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
710	FDA 2511	50	1	50	0.4	20

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimates are based on past experience and on discussions with registrants during routine communications. FDA receives an average of 50 registration submissions annually. There has been no change over the past 13 years in the number of submissions of Form FDA 2511 or in the time it takes to complete this form.

Dated: July 23, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–20302 Filed 7–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 98D–0264, 98D–0265, et al.]

Food and Drug Administration Modernization Act of 1997; Establishment of Public Dockets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is establishing a series of public dockets containing information on the implementation of the Food and Drug Administration Modernization Act of 1997 (Modernization Act). This action is intended to ensure that information submitted to FDA on the implementation of the Modernization Act is available to all interested persons in a timely fashion.

ADDRESSES: The public dockets are located in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The public dockets may be accessed directly under the docket numbers provided in the list below, and they are also posted on the agency's Internet World Wide Web (WWW) site at ''http://www.fda.gov/ohrms/dockets''.

FOR FURTHER INFORMATION CONTACT:

Nancy E. Derr, Center for Drug Evaluation and Research (HFD–5), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400;

Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6210;

Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2974; or

George A. Mitchell, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5587.

SUPPLEMENTARY INFORMATION: On November 21, 1997, the President signed the Modernization Act into law (Pub. L. 105–115). The Modernization Act provides for the reauthorization of the Prescription Drug User Fee Act of 1992, codifies many FDA initiatives undertaken in recent years under the Administration's Reinventing Government Program, and implements certain other reforms of FDA processes.

FDA has received numerous recommendations on how the agency should implement various Modernization Act provisions for which dockets have not yet been established. To provide timely public access to these recommendations, FDA is establishing a series of public dockets through which interested persons can have access to these recommendations and other information submitted to FDA. Each docket contains information pertaining to a specific section of the Modernization Act and may be accessed directly under the docket numbers provided in the list below. FDA expects to place submissions containing recommendations on how the agency should implement the Modernization Act in one of these public dockets, or in a new docket created for the specific provision addressed in the recommendations. These dockets are in addition to those already established in connection with implementation of other provisions of the Modernization Act, i.e., dockets assigned to the Modernization Act-related notices, guidances, or rules.

The following is a list of dockets that FDA is establishing at this time to provide access to information submitted relating to the implementation of specific provisions of the Modernization Act. The list includes the section number of the Modernization Act, the title of the docket, and the docket number.

Section No.	Docket Title	Docket No.
111	Pediatric Studies of Drugs	98D–0265
112	Fast Track Products	98D–0267
113	NIH Data Bank—Clinical Trials for Serious Diseases	98D–0293
114	Health Care Economic Information	98D–0468
118	Data Requirements for Drugs and Biologics	98D–0264
121	Positron Emission Tomography (PET)	98D–0266
122	Radiopharmaceuticals	98D–0372
127	Pharmacy Compounding	98D–0272
216	Six-Year Use of Data	98D–0466
406	Agency Plan for Statutory Compliance	98N–0339

From time to time, FDA may establish dockets on other Modernization Act provisions but does not intend to separately announce the creation of such dockets. Instead, a list of the Modernization Act dockets will be maintained on the agency's Internet WWW site at ''http//www.fda.gov/ohrms/dockets''. The dockets created in connection with specific notices, guidances, or rules published in the **Federal Register** are also listed at this site.

The public dockets are available for public review in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 22, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–20307 Filed 7–29–98; 8:45 am]

BILLING CODE 4160–01–F