TABLE 2.—ANNUAL REPORTING BURDEN: SURVEY[1]

Year	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1998	1,000	1	1,000	.32	320
1999	0	0	0	0	0
2000	1,000	1	1,000	.32	320
Annual average	667		667		213

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

This estimate of 434 total annual burden hours is based on the 1996 survey administration, in which 11,044 potential respondents were contacted to obtain 1,000 interviews.

Dated: March 16, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–7475 Filed 3–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0486]

Agency Information Collection Activities; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution; 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 April 22, 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: 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 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 Producers of Drugs and Listing of Drugs in Commercial Distribution (21 CFR Part 207)—(OMB Control Number 0910–0045)

Under section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360), FDA is authorized to establish a system for registration of producers of drugs and for listing of drugs in commercial distribution. To implement section 510 of the act, FDA issued part 207 (21 CFR part 207). The regulations require an initial listing of products and a twice-yearly update. In addition, all registered drug firms are required to re-register annually between January and July. The penalties for failure to register or drug list are potential seizure and injunctions, as well as criminal enforcement actions.

The following are the specific reporting requirements under part 207: (1) Section 207.20 requires that owners and operators of all drug establishments that engage in the manufacture, preparation, propagation, or processing of drugs must register and use Form FDA 2656 (Registration of Drug Establishment) and Form FDA 2658 (Registered Establishments' Report of Private Label Distributors) to submit drug listing information or to request a Labeler Code, or both. (2) Section 207.21 requires that owners and operators must register an establishment within 5 days of beginning operations and shall complete Form FDA 2656e (Annual Registration of Drug Establishment) each year between January and July. Annual registration forms are mailed by FDA in each calendar year according to a schedule based on the establishment parent company's name and must be completed within 30 days of the receipt. (3) Section 207.22(a) requires that Form FDA 2656 must be submitted when an establishment registers the first time. An establishment whose drug registration is validated under § 207.35(a) is required to make subsequent annual registrations as described in § 207.21(a). (4) Section 207.22(b) requires that Form FDA 2657 must be submitted for the first listing of drugs and subsequent June and December updates. (5) Section 207.25 specifies the information required in the establishment registration and drug listing. (6) Section 207.25(c) specifies the information about the drug that is required to be submitted (name, active ingredients, dosage strength, NDC number, manufacturer or distributor, size, shape, color, code imprint). (7) Section 207.26 specifies the information required in the amendments to the establishment registration. (8) Section 207.30 specifies the information required for updating the drug listing. (9) Section 207.31 specifies additional drug listing information that may be needed beyond that required in §§ 207.25 and 207.30.

The information obtained from the establishment registration forms FDA 2656 and FDA 2656(e) is used by FDA and other government agencies to keep an accurate and current list of all human and animal drug manufacturers, repackers, relabelers, and other drug processors located in this country. This list is used by FDA for inspectional

purposes as required by the act. In addition, the data is used by the public and private sector as a listing of the names and locations of drug firms. The information obtained from the listing forms FDA–2657 and FDA–2658 is used, through assignment of the National Drug Code numbers, for third party reimbursement payment in Medicare and Medicaid as well as other health care insurance firms.

Respondents to this collection of information are all owners and operators that engage in the manufacture, preparation, propagation, compounding, or processing of drugs and that are not exempt under section 510(g) of the act or subpart D of 21 CFR part 207.

In the **Federal Register** of December 11, 1997 (62 FR 65274), the agency requested comments on the proposed collections of information. No significant comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form	21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Form FDA–2656 Registration of Drug Establishment	207.20 207.22 207.25 207.26	2,500	1	2,500	.5	1,250
Form FDA–2656(e) Annual Re-registration of Drug Establishments	207.21 207.25 207.26	9,000	1	9,000	.5	4,500
Form FDA–2657 Drug Product Listing Form	207.22 207.30 207.31	45,000	1	45,000	.5	22,500
Form FDA–2658 Registered Establishment's Report of Private Label Distribution	207.20 207.21 207.25 207.26	6,200	1	6,200	.5	3,100
Total	207.25(c)	1,500	12.04	18,066	.5	9,033 40,383

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

These estimates are based on FDA's Center for Drug Evaluation and Research, Product Information Management Branch, and its data and information on drug listing and establishment registration of manufacturers, repackers, relabelers, and other drug processors.

Dated: March 16, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–7476 Filed 3–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0433]

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 ''Food Additives: Threshold of Regulation for Substances Used in Food-Contact Articles'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

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 the **Federal Register** of January 5, 1998 (63 FR 233), 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 0910–0298. The approval expires on March 31, 2001.

Dated: March 16, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–7471 Filed 3–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0512]

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 ''Use of Impact-Resistant Lenses in