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