

TABLE 1.—ESTIMATED REPORTING BURDEN¹—Continued

| 21 CFR Section/Form No. | No. of Respondents | Number of Responses Per Respondent | Total Annual Responses | Hours per Responses | Total Hours |
|---|--------------------|------------------------------------|------------------------|---------------------|-------------|
| (2) Form FDA-2656 Annual Update of Drug Establishment 21 CFR 207.21 21 CFR 207.22 21 CFR 207.25 21 CFR 207.26 21 CFR 207.40 | 8,382 | .82 | 6,859 | 2.50 hr. | 17,147.50 |
| (3) Form FDA-2657 Drug Product Listing 21 CFR 207.21 21 CFR 207.22 21 CFR 207.25 21 CFR 207.30 21 CFR 207.31 21 CFR 207.40 | 15,530 | 3 | 46,713 | 2.50 hr. | 116,782.50 |
| (4) Form FDA-2658 Registered Establishments' Report of Private Label Distributors 21 CFR 207.21 21 CFR 207.22 21 CFR 207.25 21 CFR 207.30 21 CFR 207.31 | 7,216 | 2.14 | 15,415 | 2.50 hr. | 38,537.50 |
| Total Reporting Burden | | | | | 189,217.50 |

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

In the **Federal Register** of April 8, 2004 (69 FR 18588), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Dated: July 13, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-16305 Filed 7-16-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0379]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing

that a collection of information entitled "Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 9, 2004 (69 FR 11018), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 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 0910-0518. The approval expires on June 30, 2007. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: July 13, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0063]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary Registration of Cosmetic Product Establishments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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