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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-1393]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; State Petitions for Exemption from Preemption

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.

DATES: Submit written comments on the collection of information by (*insert date 30 days after date of publication in the Federal Register*).

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: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy 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 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

State Petitions for Exemption From Preemption (21 CFR 100.1(d)) (OMB Control Number 0910-0277—Extension)

Under section 403A(b) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 343-1(b)), States may petition FDA for exemption from Federal preemption of State food labeling and standard of identity requirements. Section 100.1(d) (21 CFR 100.1(d)) sets forth the information a State is required to submit in such a petition. The information required under § 100.1(d) enables FDA to determine whether the State food labeling or standard of identity requirement comports with the statutory criteria for exemption from Federal preemption.

In the **Federal Register** of June 4, 1999 (64 FR 30037), the agency requested comments on the proposed collections of information. One comment was received that was supportive of the proposal and encouraged FDA to continue this information collection request.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
100.1(d)	1	1	1	40	40

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

The reporting burden for § 100.1(d) is insignificant because petitions for exemption from preemption are seldom submitted by States requesting the agency grant an exemption from preemption by labeling requirements based upon certain sections of the act. Over the last 3 years, FDA has not received any preemption petitions. Since the enactment of section 403A(b) of the act as part of the Nutrition Labeling and Education Act of 1990, FDA has received only eight petitions for seeking exemption from preemption. Although FDA believes that the burden will

be insignificant, it believes these information collection provisions should be extended to provide for the potential future need of a State or local government to petition for an exemption from preemption under the provisions of section 403A(b) of the act.

Dated: August 16, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



William K. Hubbard
Senior Associate Commissioner
for Policy, Planning and Legislation



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