[Docket No. 96N–0335]

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 collections of information listed below have 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 collections of information by November 29, 1996.

ADDRESSES: Submit written comments on the collections 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: Kim A. Sanders, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1473.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), FDA has submitted the following proposed collections of information to OMB for review and clearance:

1. Temporary Marketing Permit Applications (21 CFR 130.17(c) and (i)) (OMB Control Number 0910–0133—Reinstatement)

Section 401 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 341) directs FDA to issue regulations establishing definitions and standards of identity for food ''whenever * * * such action will promote honesty and fair dealing in the interest of consumers.'' Under section 403(g) of the act (21 U.S.C. 343(g)), a food that is subject to a definition and standard of identity prescribed by regulation is misbranded if it does not conform to such definition and standard of identity. Section 130.17 (21 CFR 130.17) provides for the issuance by FDA of temporary marketing permits that enable the food industry to test consumer acceptance and measure the technological and commercial feasibility in interstate commerce of experimental packs of food that deviate from applicable definitions and standards of identity. Section 130.17(c) specifies the information that a firm must submit to FDA to obtain a temporary marketing permit. The information required in a temporary marketing permit application under § 130.17(c) enables the agency to monitor the manufacture, labeling, and distribution of experimental packs of food that deviate from applicable definitions or standards of identity. The information so obtained can be used in support of a petition to establish or amend the applicable definition or standard of identity to provide for the variations. Section 130.17(i) specifies the information that a firm must submit to FDA to obtain an extension of a temporary marketing permit.

FDA estimates the burden of the temporary marketing permit application requirements as follows:

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
130.17	15	1.33	20	11.5	230

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

The estimated number of temporary marketing permit applications and hours per response is an average based on the agency's experience with applications received from October 30, 1991, through September 30, 1994.

2. State Petitions for Exemption From Preemption (21 CFR 100.1(d)) (OMB Control Number 0910–0277—Reinstatement)

Under section 403A(b) of 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.

FDA estimates the burden resulting from the requirements of § 100.1(d) as follows:

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
100.1(d)	5	1	5	40	200

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

Since the enactment of section 403A(b) of the act as part of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), FDA has received eight petitions for exemption from preemption. Based upon these submissions, FDA estimates that no more than five petitions will be submitted annually. Because § 100.1(d) implements a statutory information collection requirement, only the additional burden attributable to the regulation has been included in the estimate.

3. State Enforcement Notification (21 CFR 100.2(d)) (OMB Control Number 0910–0275—Reinstatement)

Section 310(b) of the act (21 U.S.C. 337(b)) authorizes States to enforce certain sections of the act in their own

names, but provides that States must notify FDA before doing so. Section 100.2(d) (21 CFR 100.2(d)) sets forth the information that a State must provide to FDA in a letter of notification when it intends to take enforcement action under the act against a particular food located in the State. The information required under § 100.2(d) will enable FDA to identify the food against which the State intends to take action and advise the State whether Federal action has been taken against it. With certain narrow exceptions, Federal enforcement action precludes State action under the act.

FDA estimates the burden of complying with the enforcement notification requirement as follows:

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
100.2(d)	5	1	5	2	10

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

Based upon the small number of enforcement notifications received from the States since the enactment of section 310(b) of the act in 1990, FDA estimates that no more than five notifications will be submitted annually. Because 21 CFR 100.21(d) implements a statutory information collection requirement, only the additional burden attributable to the regulation has been included in the estimate.

4. Reference Amount Petitions (21 CFR 101.12(h)) (OMB Control Number 0910–0286—Reinstatement)

Section 403(q)(1)(A) of the act (21 U.S.C. 343(q)(1)(A)) requires that the label or labeling of food provide nutrition information that includes the serving size or, if the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food. In response to section 2(b)(1)(B) of the 1990 amendments, FDA issued regulations defining the serving size (or other unit of measure) for various types of food. Food producers are required to use the reference amount values provided in § 101.12 (21 CFR 101.12) and the rules for establishing serving sizes that are prescribed in 21 CFR 101.9(b) to determine the appropriate serving size for their products; however, a manufacturer or other interested person may submit a petition to establish or amend the reference amount value for a food or to create a new food subcategory with its own reference amount. Section 101.12(h) sets forth the information the petitioner is required to include in the petition.

FDA estimates the burden resulting from the requirements of § 101.12(h) as follows:

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating & Maintenance Costs
101.12(h)	5	1	5	80	400	$400,000

There are no capital costs associated with this collection.

Since the enactment of the 1990 amendments that revised the act by adding section 403(q), FDA has received nine petitions to amend existing reference amounts. Based upon these submissions, FDA estimates that no more than five such petitions will be submitted annually. The estimate for operating and maintenance costs is based on the average cost of conducting a consumer survey to support a reference amount petition.

Dated: October 23, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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[Docket No. 96N–0345]

Issues Related to Pharmaceutical Laboratory Practices Procedures; Notice of Public Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meetings; request for submission of topics.

SUMMARY: The Food and Drug Administration's (FDA's) Office of Regulatory Affairs (ORA) is announcing a series of meetings to be held with the pharmaceutical industry. These meetings will follow a prescribed format and will involve representatives from ORA's Division of Field Science, Field Drug laboratories, Center for Drug Evaluation and Research's (CDER's) Office of Pharmaceutical Science and other representatives from the field and headquarters. The purpose of these meetings is to continue a dialogue with trade associations, technical and professional organizations, and FDA to discuss issues of mutual concern to the agency and industry associated with pharmaceutical laboratory practices and procedures. The intent of the dialogue is to explore issues of mutual concern that affect the agency and industry laboratories.

DATES: The first meeting will be held on Wednesday, November 20, 1996, from 8:30 a.m. to 4:30 p.m. Submit topics and written comments by Friday, November 8, 1996. Interested persons may contact the information contact person (address below) for registration forms. There is no registration fee for this meeting. However, advance registration is required because space is limited.

ADDRESSES: The first meeting will be held at the Parklawn Bldg., 5600 Fishers Lane, conference room M, Rockville, MD. Submit written comments to the