

TABLE 17.—ESTIMATED REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Responses per Respondent	Total No. of Responses	Hours per Response	Total Hours	Operating Costs (in thousands)
101.9(c)(2)(ii)	10,490	27	278,100	2	556,200	\$155,200
101.36(b)(2)	910	32	29,500	2	59,000	\$16,500
Totals					615,200	\$171,700

<sup>1</sup> There are no capital costs and or maintenance costs associated with this collection of information.

The impact of these requirements concerning *trans* fatty acids would be largely a one-time burden created by the need for firms to revise food and dietary supplement labels. FDA used data from the 1999 County Business Patterns to estimate the number of respondents. The total number of responses is equal to the total number of SKUs being changed (table 3 of this document). Based upon its knowledge of food and dietary supplement labeling, FDA estimates that firms would require less than 2 hours per SKU (hours per response) to comply with the nutrition labeling requirements in this final rule. This 2 hour per SKU estimate is based on assumptions about the amount of time required per SKU to test a product for *trans* fat, to redesign the label as needed, and to order the change for the label. FDA received no comments objecting to this estimate.

Multiplying the total number of responses by the hours per response gives the total hours. FDA has estimated operating costs by combining the medium testing and relabeling costs from table 7 of this document (\$44.9 million + \$126.8 million for relabeling) to get the total operating cost. This total was then apportioned between §§ 101.9 and 101.36 according to the proportion of responses for each section. Based on the labeling cost model, FDA expects that, with a compliance period of over 2 years, 75 percent of firms will coordinate labeling revisions required by this final rule with other planned labeling changes for their products.

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective date of this final rule, FDA will publish a document in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. 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.

#### XIV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule has a preemptive effect on State law. Section 4(a) of the Executive order requires agencies to “construe \* \* \* a Federal Statute to preempt State law only where the statute contains an express preemption provision, or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” Section 403A of the act (21 U.S.C. 343–1) is an express preemption provision. That section provides that “no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce” certain food labeling requirements, unless an exemption is provided by the Secretary (and, by delegation, FDA). Relevant to this final rule, one such requirement that States and political subdivisions may not adopt is “any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) \* \* \* ” (act section 403A(a)(4), 21 U.S.C. 343–1(a)(4)). Prior to the effective date of this rule, this provision operated to preempt States from imposing nutrition labeling requirements concerning *trans* fat because no such requirements had been imposed by FDA under section 403(q) of the act. Once this rule becomes effective, States will be preempted from imposing any nutritional labeling requirements for *trans* fat that are not identical to those required by this rule.

Section 403A(a)(4) of the act (21 U.S.C. 343–1(a)(4)) displaces both state legislative requirements and state common-law duties. *Medtronic v. Lohr*, 518 U.S. 470, 503 (1996) (Breyer, J., concurring in part and concurring in the judgment); *id.* at 510 (O'Connor, J., joined by Rehnquist, C. J., Scalia, J., and Thomas, J., concurring in part and dissenting in part); *Cippollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992)

(plurality opinion); *id.* at 548–49 (Scalia, J., joined by Thomas, J., concurring in part in the judgment and dissenting in part). Although this rule has preemptive effect in that it would preclude States from adopting statutes, issuing regulations, or adopting or enforcing any requirements that are not identical to the *trans* fat labeling required by this final rule, including State tort-law imposed requirements, this preemptive effect is consistent with what Congress set forth in section 403(A) of the act.

Section 4(c) of the Executive order further requires that any “regulatory preemption of State law shall be restricted to the minimum level necessary” to achieve the regulatory objective. The agency is exercising its discretion under section 403(q)(2)(A) of the act, in a manner that is consistent with such section, to require that the amount of *trans* fat be listed in the label or labeling of food. This action is the minimum level necessary to achieve the agency regulatory objective. Further, section 4(e) of the Executive order provides that “when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.” FDA sought input from all stakeholders through publication of the proposed rule in the **Federal Register**. Eight comments from State and local governmental entities were received; all supported the proposal. In addition, one supportive comment was received from a municipal health agency in response to the reopening of the comment period relating to the proposed footnote.

In conclusion, FDA has determined that the preemptive effects of the final rule are consistent with Executive Order 13132.

#### XV. References

The following references have been placed in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9