

in their products, provided it is done in a manner that is not misleading, but the panel itself is to be in compliance with this final rule.

(Comment 30) FDA received only one comment in response to the November 1999 proposal to deny the petitioner's request to require that "partially hydrogenated" fat be listed on food labels as "partially saturated" fat (64 FR 62746 at 62762). The comment concurred with the agency's tentative conclusion to deny the request stating that "partially hydrogenated" fat is the most appropriate terminology for use on food label ingredient statements.

The agency concurs with the comment and, accordingly, is denying this request.

(Comment 31) Although a great many comments supported CSPI's petition in general, these comments did not specifically address the petitioner's request to limit "vegetable oil" claims to foods that are low in saturated and *trans* fats combined.

In the November 1999 proposal, the agency referred to § 101.65(c)(3), which states, in part, that a claim "that a food is made only with vegetable oil is a claim that the food is low in saturated fat," and tentatively concluded that the petitioner's request was being addressed by the action taken in the proposed rule to limit the amount of *trans* fat in foods bearing "low in saturated fat" claims (64 FR 62746 at 62762). However, in this final regulation those sections of the proposed rule pertaining to limiting the amount of *trans* fat in foods making a "low in saturated fat" claim are being withdrawn. Therefore, the agency is not restricting "vegetable oil" claims as proposed or as petitioned at this time.

As discussed in section VI of this document, FDA plans to proceed with a new rulemaking pertaining to limits on the amount of *trans* fat in claims relating to saturated fat when the science on *trans* fat has evolved to a point where the agency believes it can proceed with scientifically-based definitions and levels for these claims.

VIII. Effective Date

In the November 1999 proposal, the agency proposed that any final rule that may issue based upon the proposal become effective in accordance with the uniform effective date for compliance with food labeling requirements that is announced by notice in the **Federal Register** and that it not be sooner than 1 year following publication of any final rule based on the proposal. Also, the agency said it will not object to voluntary compliance immediately upon publication of the final rule.

(Comment 32) FDA received several comments about the effective date for a final rule. One comment stated that the proposed effective date was appropriate while a few other comments recommended that it be sooner than proposed. Several comments suggested that the effective date be 24 months after publication of the final rule or January 1, 2004, whichever comes later. Some comments, however, requested that the effective date be extended several years (e.g., 4 to 7 years) for small businesses. These comments stated that it was important for small businesses to be able to phase in the cost associated with the new label requirements so that they have extra time to absorb the costs of these changes. Many small manufacturers reported that they have significant inventories of labels. Also, smaller manufacturers indicated that they would incur costs including loss and disposal of obsolete packaging inventories, product in obsolete packages, and new printing plates. These small businesses believe that a longer compliance period would allow these companies to more easily manage their inventories and phase in the *trans* fat labeling requirements along with other scheduled labeling revisions. This will help minimize unnecessary labeling costs and costs passed on to consumers. At least one comment requested that the effective date be one year after establishment of an official AOAC method for measuring *trans* fatty acids in complex food matrices.

To minimize the need for multiple labeling changes and to provide additional time for compliance by small businesses to allow them to use current label inventories and phase in label changes, the agency is setting the effective date at January 1, 2006, the next uniform effective date following publication of this rule. This allows firms more than 2 years to implement this final rule providing some regulatory relief and economic savings for small businesses. Extending the effective date for products containing *trans* fat would delay the benefits of this rule to the public health.

The agency notes that there are several methods for measuring the amounts of *trans* fat in food products including but not limited to AOAC Method 996.06, as modified (17th edition of the "Official Methods of Analysis of the AOAC International") (Refs. 105 and 106). Consequently, the agency does not believe that there is any need to extend the effective date because of the lack of appropriate methodology.

Although the effective date of the final rule is some time away, FDA

encourages manufacturers to have new labels printed that are in compliance with these final rules so they may be used as soon as current inventories are exhausted to ensure a smooth and timely changeover. The agency will not object to voluntary compliance immediately upon publication of the final rule.

IX. Final Regulatory Impact Analysis

FDA has examined the economic implications of this final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of \$100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this final rule is a significant regulatory action as defined by Executive Order 12866.

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of \$100 million; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, Office of Management and Budget (OMB) has determined that this final rule is a major rule for the purpose of congressional review.

A. The Current Situation and the Need for This Regulation

Current nutrition labeling regulations do not allow manufacturers to disclose information about *trans* fat content of their products in the Nutrition Facts panel of product labels. The regulation, in § 101.9(c) reads, in part, "No nutrients or food components other than those listed in this paragraph as either mandatory or voluntary may be