

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 00N-1596]

Uniform Compliance Date for Food Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

DMR  
Display Date 12-30-02  
Publication Date 12-31-02  
Certifier G. Penley

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**SUMMARY:** The Food and Drug Administration (FDA) is establishing January 1, 2006, as the uniform compliance date for food labeling regulations that are issued between January 1, 2003, and December 31, 2004. FDA periodically announces uniform compliance dates for new food labeling requirements to minimize the economic impact of label changes. On November 20, 2000, FDA established January 1, 2004, as the uniform compliance date for food labeling regulations that issued between January 1, 2001, and December 31, 2002.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*]. Submit written or electronic comments by [*insert date 75 days after date of publication in the Federal Register*].

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Louis B. Brock, Center for Food Safety and Applied Nutrition (HFS-24), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2378.

**SUPPLEMENTARY INFORMATION:** FDA periodically issues regulations requiring changes in the labeling of food. If the effective dates of these labeling changes were not coordinated, the cumulative economic impact on the food industry of having to respond separately to each change would be substantial. Therefore, the agency periodically has announced uniform compliance dates for new food labeling requirements (see, e.g., the **Federal Registers** of October 19, 1984 (49 FR 41019), December 24, 1996 (61 FR 67710), December 27, 1996 (61 FR 68145), December 23, 1998 (63 FR 71015), and November 20, 2000 (65 FR 69666)). Use of a uniform compliance date provides for an orderly and economical industry adjustment to new labeling requirements by allowing sufficient lead time to plan for the use of existing label inventories and the development of new labeling materials. This policy serves consumers' interests as well because the cost of multiple short-term label revisions that would otherwise occur would likely be passed on to consumers in the form of higher prices.

The agency has determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 is not required.

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 effects). 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 or adversely affecting in a material way a sector of the economy, competition, or jobs. A regulation also is considered a significant regulatory action under Executive Order 12866 if it raises novel legal or policy issues. FDA finds that this final rule is not a significant regulatory action as defined by Executive Order 12866. In addition, in accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, OMB has determined that this final rule is not a major rule for purposes of congressional review. The establishment of a uniform compliance date does not impose either costs or benefits. For future labeling regulations, FDA will assess the costs and benefits of the uniform compliance date as well as the option of setting other dates.

Because FDA has issued this final rule without first publishing a general notice of proposed rulemaking, a final regulatory analysis is not required by the Regulatory Flexibility Act (5 U.S.C. 601–612). Nonetheless, the uniform compliance date does not impose any burden on small entities. The agency will assess the costs and benefits of setting alternative dates as part of the regulatory flexibility analyses of future labeling regulations.

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rulemaking if the rule would include a “Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year.” The current inflation-adjusted statutory threshold is \$112 million. FDA has

determined that this final rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

This action is not intended to change existing requirements for compliance dates contained in final rules published before January 1, 2003. Therefore, all final FDA regulations published in the **Federal Register** before January 1, 2003, will still go into effect on the date stated in the respective final rule.

The agency generally encourages industry to comply with new labeling regulations as quickly as feasible, however. Thus, when industry members voluntarily change their labels, it is appropriate that they incorporate any new requirements that have been published as final regulations up to that time.

In rulemaking that began with publication of a proposal on April 15, 1996 (61 FR 16422), and ended with a final rule on December 24, 1996, FDA provided notice and an opportunity for comment on the practice of establishing uniform compliance dates by issuance of a final rule announcing the date. Receiving no comments objecting to this practice, FDA finds any further rulemaking unnecessary for establishment of the uniform compliance date. Nonetheless, under 21 CFR 10.40(e)(1), FDA is providing an opportunity

for comment on whether this uniform compliance date should be modified or revoked.

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. After its review of any comments received to this final rule, FDA will either publish a document providing its conclusions concerning the comments or will initiate notice and comment rulemaking to modify or revoke the uniform compliance date established by this final rule.

The new uniform compliance date will apply only to final FDA food labeling regulations that require changes in the labeling of food products and that publish after January 1, 2003, and before December 31, 2004. Those regulations will specifically identify January 1, 2006, as their compliance date. All food products subject to the January 1, 2006, compliance date must comply with the appropriate regulations when initially introduced into interstate commerce on or after January 1, 2006. If any food labeling regulation involves special circumstances that justify a compliance date other than January 1, 2006, the agency will determine for that regulation an appropriate compliance date, which will be specified when the final regulation is published.

Dated: 12/24/02  
December 24, 2002.



Margaret M. Dotzel,  
Assistant Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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