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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2000–N–0011] (formerly Docket No. 2000N–1596)

Uniform Compliance Date for Food Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is establishing January 2, 2012, as the uniform compliance date for food labeling regulations that are issued between January 1, 2009, and December 31, 2010. (January 1, 2012, falls on a Sunday; therefore, the uniform compliance date will be January 2, 2012). FDA periodically announces uniform compliance dates for new food labeling requirements to minimize the economic impact of label changes. On December 21, 2006, FDA established January 1, 2010, as the uniform compliance date for food labeling regulations issued between January 1, 2007, and December 31, 2008.

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: You may submit comments, identified by Docket No. FDA–2000–N–0011, formerly Docket No. 2000N–1596, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

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• Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

• FAX: 301–827–6870.

• Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the "Comments" paragraphs of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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), November 20, 2000 (65 FR 69666), and December 31, 2002 (67 FR 79851), and December 21, 2006 (71 FR 76599)). 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 under the Paperwork Reduction Act of 1995 is not required.

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). 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). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The establishment of a uniform compliance date does not in itself lead to costs or benefits. We will assess the costs and benefits of the uniform compliance date in the regulatory impact analyses of the labeling rules that take effect at that date.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. Because the final rule does not impose compliance costs on small entities, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any 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 one year." The current threshold after adjustment for inflation is $130 million, using the most current (2007) Implicit

Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

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, 2009. Therefore, all final FDA regulations published in the **Federal Register** before January 1, 2009, 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 Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

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, 2009, and before December 31, 2010. Those regulations will specifically identify January 1, 2012, as their compliance date. All food products subject to the January 1, 2012, compliance date must comply with the appropriate regulations when initially introduced into interstate commerce on or after January 1, 2012. If any food labeling regulation involves special circumstances that justify a compliance date other than January 1, 2012, the agency will determine for that regulation an appropriate compliance date, which will be specified when the final regulation is published.

Dated: 12/1/08

December 1, 2008.

Jeffrey Shuren

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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[FR Doc. 08–????? Filed ??–??–08; 8:45 am]

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