



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA-2000-N-0011]

Uniform Compliance Date for Food Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is establishing January 1, 2022, as the uniform compliance date for food labeling regulations that are published on or after January 1, 2019, and on or before December 31, 2020. We periodically announce uniform compliance dates for new food labeling requirements to minimize the economic impact of label changes.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Submit electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring

that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2000-N-0011 for "Uniform Compliance Date for Food Labeling Regulations." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Center for Food Safety and Applied Nutrition (HFS-24), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2112.

SUPPLEMENTARY INFORMATION: We periodically issue 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, we periodically have announced uniform compliance dates for new food labeling requirements (see, e.g., the *Federal Register* 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); December 31, 2002 (67 FR 79851); December 21, 2006 (71 FR 76599); December 8, 2008 (73 FR 74349); December 15, 2010 (75 FR 78155); November 28, 2012 (77 FR 70885); December 10, 2014 (79 FR 73201); and November 25, 2016 (81 FR 85156)). 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.

We have 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.

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the

Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct 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 13771 requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” We believe that this final rule is not a significant regulatory action under Executive Order 12866.

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, we certify 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 issuing “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 \$150 million, using the most current (2017) Implicit Price Deflator for the Gross Domestic Product. We do not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have 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, we have 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, 2019. Therefore, all final rules published by FDA in the *Federal Register* before January 1, 2019, will still go into effect on the date stated in the respective final rule. We generally encourage 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 proposed rule on April 15, 1996 (61 FR 16422), and ended with a final rule on December 24, 1996 (61 FR 67710) (together “the 1996 rulemaking”), we provided notice and an opportunity for comment on the practice of establishing uniform compliance dates by issuance of a final rule announcing the date. We received no comments objecting to this practice during the 1996 rulemaking, nor have we received comments objecting to this practice since we published a uniform compliance date on November 25, 2016 (81 FR 85156). Therefore, we find good cause to dispense with issuance of a proposed rule inviting comment on the practice of establishing the uniform compliance date because such prior notice and comment are unnecessary. Interested parties will have an opportunity to comment on

the compliance date for each individual food labeling regulation as part of the rulemaking process for that regulation. Consequently, FDA finds any further advance notice and opportunity for comment unnecessary for establishment of the uniform compliance date. Nonetheless, under 21 CFR 10.40(e)(1), we are providing an opportunity for comment on whether the uniform compliance date established by this final rule should be modified or revoked.

In addition, we find good cause for this final rule to become effective on the date of publication of this action. A delayed effective date is unnecessary in this case because the establishment of a uniform compliance date does not impose any new regulatory requirements on affected parties. Instead, this final rule provides affected parties with notice of our policy to identify January 1, 2022, as the compliance date for final food labeling regulations that require changes in the labeling of food products and that publish on or after January 1, 2019, and on or before December 31, 2020, unless special circumstances justify a different compliance date. Thus, affected parties do not need time to prepare before the rule takes effect. Therefore, we find good cause for this final rule to become effective on the date of publication of this action.

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 on or after January 1, 2019, and on or before December 31, 2020. Those regulations will specifically identify January 1, 2022, as their compliance date. All food products subject to the January 1, 2022, compliance date must comply with the appropriate regulations when initially introduced into interstate commerce on or after January 1, 2022. If any food labeling regulation involves special circumstances that justify a compliance date other than January 1, 2022, we will determine for that regulation an appropriate compliance date, which will be specified when the final regulation is published.

Dated: December 13, 2018.

Scott Gottlieb,

Commissioner of Food and Drugs.

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