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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, 2016, as the uniform compliance date for food labeling regulations that are issued between January 1, 2013, and December 31, 2014. We periodically announce uniform compliance dates for new food labeling requirements to minimize the economic impact of label changes. On December 15, 2010, we established January 1, 2014, as the uniform compliance date for food labeling regulations issued between January 1, 2011, and December 31, 2012.

DATES: This rule is effective November 28, 2012. Submit electronic or written comments by January 28, 2013.

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

Electronic Submissions

Submit electronic comments in the following way:

- *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 or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2000–N–0011 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'' heading 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: Paul L. Ferrari, Center for Food Safety and Applied Nutrition (HFS–24), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1722.

SUPPLEMENTARY INFORMATION:

I. Background

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, 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); and December 15, 2010 (75 FR 78155). 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.

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, 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). 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, FDA 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 $139 million, using the most current (2011) 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, 2013. Therefore, all final rules published by FDA in the **Federal Register** before January 1, 2013, 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, 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. Receiving no comments objecting to this practice, we find any further rulemaking 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 this uniform compliance date should be modified or revoked.

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, 2013, and before December 31, 2014. Those regulations will specifically identify January 1, 2016, as their compliance date. All food products subject to the January 1, 2016, compliance date must comply with the appropriate regulations when initially introduced into interstate commerce on or after January 1, 2016. If any food labeling regulation involves special circumstances that justify a compliance date other than January 1, 2016, we will determine for that regulation an appropriate compliance date, which will be specified when the final regulation is published.

II. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov.*

Dated: November 20, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–28817 Filed 11–27–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 127

[Docket No. USCG–2011–0227]

RIN 1625–AB67

Reconsideration of Letters of Recommendation for Waterfront Facilities Handling LNG and LHG

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: This final rule clarifies the role and purpose of the Letter of Recommendation (LOR) issued by the Coast Guard Captain of the Port regarding the suitability of a waterway for liquefied natural gas (LNG) or liquefied hazardous gas (LHG) marine traffic. It also establishes a separate process for reconsideration of LORs by the Coast Guard. The process applies only to LORs issued after the effective date of the rule.

DATES: This final rule is effective December 28, 2012.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2011–0227 and are available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet by going to *http://www.regulations.gov* and inserting ''USCG–2011–0227'' in the ''Search'' box.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Ken Smith (CG–OES–2), U.S. Coast Guard; telephone (202) 372–1413, email *Ken.A.Smith@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Contents for Preamble

I. Abbreviations

APA Administrative Procedure Act
CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FERC Federal Energy Regulatory Commission
FR **Federal Register**
LHG Liquefied hazardous gas
LNG Liquefied natural gas
LOI Letter of Intent
LOR Letter of Recommendation
NEPA National Environmental Policy Act of 1969
NPRM Notice of proposed rulemaking
Pub. L. Public Law
PWSA Ports and Waterways Safety Act of 1972, as amended
U.S.C. United States Code

II. Regulatory History

On December 16, 2011, we published a notice of proposed rulemaking (NPRM) entitled ''Reconsideration of Letters of Recommendation for Waterfront Facilities Handling LNG and LHG'' in the **Federal Register** (76 FR