Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jennifer Shepherd, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *MIDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committee will discuss the potential risk of gadolinium retention in the brain and other body organs in patients receiving gadolinium-based contrast agents for magnetic resonance clinical imaging procedures.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the docket (see the **ADDRESSES** section) on or before August 24, 2017, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 16, 2017. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 17, 2017.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require special accommodations due to a disability, please contact Jennifer Shepherd at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 7, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–16891 Filed 8–9–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–2834]

Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule.'' This guidance is intended to assist persons who manufacture, package, sell, offer to sell, distribute, or import for sale and distribution within the United States newly regulated tobacco products, roll-your-own (RYO) tobacco, and cigarette tobacco in complying with the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), and FDA regulations.

DATES: Submit either electronic or written comments on Agency guidances at any time.

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–2017–D–2834 for ''Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule.'' Received comments 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.'' The Agency will review this copy, including the claimed confidential information, in its 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.

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Gerie Voss, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule.'' This guidance is intended to assist persons who manufacture, package, sell, offer to sell, distribute, or import for sale and distribution within the United States newly regulated tobacco products, RYO tobacco, and cigarette tobacco in complying with the FD&C Act, as amended by the Tobacco Control Act, and FDA regulations. We are issuing this guidance consistent with our good guidance practices (GGP) regulation (section 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment, because we have determined that prior public participation is not feasible or appropriate (section 10.115(g)(2)). We made this determination because FDA needs to communicate the extensions in a timely manner given the upcoming compliance deadlines and the amount of time needed for firms to prepare for them. Although this guidance document is immediately effective, it remains subject to comment in accordance with FDA's GGP regulation.

The Tobacco Control Act (Pub. L. 111–31) granted FDA the authority to immediately regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, RYO, and smokeless tobacco products to protect the public health and to reduce tobacco use by minors.

The Tobacco Control Act also gave FDA the authority to issue a regulation deeming all other products that meet the statutory definition of a tobacco product to be subject to Chapter IX of the FD&C Act (section 901(b) (21 U.S.C. 387a(b)) of the FD&C Act). On May 10, 2016, FDA issued that rule, extending FDA's tobacco product authority to all products that meet the definition of tobacco product in the law (except for accessories of newly regulated tobacco products), including electronic nicotine delivery systems, cigars, hookah, pipe tobacco, nicotine gels, dissolvables that were not already subject to the FD&C Act, and other tobacco products that may be developed in the future (81 FR 28974 at 28976) (''the final deeming rule'')). Chapter IX of the FD&C Act now applies to newly regulated tobacco products, including sections 904(a)(1) and (4) (21 U.S.C.387d(a)(1) and (4)) (ingredient listing, health document submissions), 903(a)(4) and (a)(8) (21 U.S.C. 387c(a)(4) and (a)(8)) (labeling requirements), 904(c)(1), 905(b), (c), (d), (h) (registration), (21 U.S.C. 387e(b), (c), (d), (h)) 905(i)(1) (product listing), 907(a)(1)(B) (21 U.S.C. 387g(a)(1)(B)) (additional special rule), 911 (21 U.S.C. 387k) (modified risk claims), 904(a)(3) and 915 (21 U.S.C. 387o) (harmful and potentially harmful constituent reporting), and 920 (21 U.S.C. 387t) (labeling, recordkeeping, records inspection). The final rule also included several requirements that apply to a subgroup of products referred to as ''covered tobacco products.''

In May 2017, FDA published the first edition of this guidance document, under which it provided a 3-month extension of all future compliance deadlines for requirements under the final deeming rule. This guidance is the second edition, and it revises and updates the first edition by further extending certain of the future compliance dates.

The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in section 910(c)(1)(A)(i) of the FD&C Act and 21 CFR part 1143 have been approved under OMB control number 0910–0768; the collections of information in section 905(j) of the FD&C Act have been approved under OMB control number 0910–0673; the collections of information in section 904(a)(4) of the FD&C Act have been approved under OMB control number 0910–0654; the collections of information in 21 CFR part 1107 have been approved under OMB control number 0910–0684; the collections of information in section 904(c)(1), 905(b),(c),(d), (h),and 905(i)(1) of the FD&C Act have been approved under OMB control number 0910–0650.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the guidance at either *https://www.regulations.gov* or *https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm.*

Dated: August 4, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–16839 Filed 8–9–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2017–0648]

Certificate of Alternative Compliance for Viking Yacht Company's 92C Enclosed Bridge Yacht, HIN: VKY92111I617

AGENCY: Coast Guard, DHS.

ACTION: Notice.

SUMMARY: The Coast Guard announces that the District Five Prevention Division (Dp) has issued a Certificate of Alternate Compliance (COAC) from the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), for Viking Yacht Company's 92C Enclosed Bridge yacht, HIN: VKY92111I617, as required by statue. Due to the construction and placement of the pilothouse aft of amidships, the vessel cannot fully comply with the masthead light provisions of the 72 COLREGS without interfering with the vessel's design and construction, as there are no structures forward of amidships on which a masthead light could be affixed. This notice promotes the Coast Guard's maritime safety and stewardship missions.

ADDRESSES: Documents mentioned in the preamble are part of docket USCG–2017–0648. To view documents mentioned in this preamble as being available in the docket, go to the Federal eRulemaking Portal at *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box, and click ''SEARCH.'' Click on ''Open Docket Folder'' on the line associated with this notice.

FOR FURTHER INFORMATION CONTACT: For further information or questions about this notice, call or email: CDR Scott W. Muller, District Five, Chief, Inspections and Investigations, U.S. Coast Guard; telephone: 757–398–6389, email: *Scott.W.Muller@uscg.mil.*

SUPPLEMENTARY INFORMATION: The United States is signatory to the International Maritime Organization's International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), as amended. The special construction or purpose of some vessels makes them unable to comply with the light, shape, and sound signal provisions of the 72 COLREGS. Under statutory law [1] and Coast Guard regulation, [2] a vessel may instead meet alternative requirements and the vessel's owner, builder, operator, or agent may apply for a COAC. For vessels of special construction, the cognizant Coast Guard District Office determines whether the vessel for which the COAC is sought complies as closely as possible with the 72 COLREGS and decides whether to issue the COAC. Once issued, a COAC remains valid until information supplied in the COAC application or the COAC terms become inapplicable to the vessel. Under the governing statute [3] and regulation,[4] the Coast Guard must publish notice of this action.

The Commandant, U.S. Coast Guard, hereby finds and certifies that Viking Yacht Company's 92C Enclosed Bridge yacht, HIN: VKY92111I617, is a vessel of special construction or purpose and that, with respect to the position of the masthead light, it is not possible to comply fully with the requirements of the provisions enumerated in the 72 COLREGS without interfering with the design and construction of the vessel. The Prevention Division, Fifth Coast Guard District, further finds and certifies that the proposed placement of the masthead light is in the closest possible compliance with the applicable provisions of the 72 COLREGS and that full compliance with the 72 COLREGS would not significantly enhance the safety of the vessel's operation.

This notice is issued under authority of 33 U.S.C. 1605(c) and 33 CFR 81.

Dated: July 31, 2017.

Jerry R. Barnes,

Captain, Chief, Prevention Division, U. S. Coast Guard.

[FR Doc. 2017–16844 Filed 8–9–17; 8:45 am]

BILLING CODE 9110–04–P

[1] 33 U.S.C. 1605(c).

[2] 33 CFR 81.3.

[3] 33 U.S.C. 1605(c).

[4] 33 CFR 81.18.

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2017–0219]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0078

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting a Reinstatement, without change, of a previously approved collection for which approval has expired: 1625–0078, Credentialing and Manning Requirements for Officers on Towing Vessels; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before October 10, 2017.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2017–0219] to the Coast Guard using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: COMMANDANT (CG–612), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR AVE SE., STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION: Contact Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a