derivatives markets to hedge risk—and who, we should always remember, did not cause the financial crisis. Trade options are a type of commodity option primarily used in the agricultural, energy and manufacturing sectors. Today, the Commission has finalized some amendments to its rules that recognize trade options are different from the swaps that are the focus of the Dodd-Frank reforms. These changes will reduce the burdens on these commercial businesses and allow them to better address commercial risk.

The action we have taken today will eliminate any potential obligation of commercial participants, who are not swap dealers (SD) or major swap participants (MSP), to report trade options to a swap data repository. We also have eliminated the requirement that these entities must report their trade option activities on ''Form TO,'' and we have eliminated Form TO altogether. Further, we have ended the swap-related recordkeeping requirements for these end-users in connection with their trade option activities, although when transacting in trade options with SDs or MSPs, they will need to obtain a legal entity identifier. These changes will reduce burdens and costs for trade option counterparties that are not SDs or MSPs and, in particular, for smaller end-users.

We also have decided not to impose a requirement in the proposed rule that a commercial participant would need to provide notice to the Commission of its trade options activities if such activities have a value of more than $1 billion in any calendar year. This followed careful consideration of the benefits of such information to the Commission, as compared with the difficulties commercial end-users would face in valuating, tracking, and classifying their trade options.

I'm pleased that today we have addressed some reasonable concerns of commercial end-users who are the critical users of the derivatives markets. This is just one of the many actions we have taken in this regard. We will continue to evaluate our rules with an eye towards the concerns of these businesses. I thank my fellow Commissioners for supporting today's action.

Appendix 3—Concurring Statement of Commissioner Sharon Y. Bowen

Our ruling today provides additional clarity for trade options, but I encourage market participants to look at it closely.

Trade options have been caught in a difficult legal bind. Congress sought to ensure that people could not evade our swaps regulations. It did so by both having a very broad definition of a swap, while also limiting this Commission's authority to exempt swaps by regulation.

Fortunately, however, Congress preserved the Commission's authority to exempt trade options, which is the authority we are once again using today. Importantly, this exemption provides additional legal certainty that our interpretations cannot. But we cannot overrule the Commodity Exchange Act with regulations and interpretations; we will always be bound by that statute. Therefore, I want to caution anyone tempted to rely on an interpretation to avoid CFTC jurisdiction when it comes to options.

I fully recognize the difficulty in distinguishing between different types of physical contracts. If a particular contract or an element of a contract serves an economic purpose similar to an option, I believe the best course of action is to exercise caution and not assume your contract is outside of our jurisdiction based on an interpretation. While it may seem fine for a person using these contracts to hope that the interpretation is not called into question, I believe it would be wise, as a backstop, to make sure it also falls within the trade option exemption.

[FR Doc. 2016–06260 Filed 3–18–16; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. FDA–2016–N–0001]

Patient Engagement Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the standing advisory committees' regulations to add the Patient Engagement Advisory Committee.

DATES: This rule is effective March 21, 2016.

FOR FURTHER INFORMATION CONTACT: Letise Williams, Office of Center Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, email: *Letise.Williams@fda.hhs.gov,* 301–796–8398.

SUPPLEMENTARY INFORMATION: The Patient Engagement Advisory Committee (the Committee) was established on October 6, 2015 (80 FR 57007, September 21, 2015).

The Committee will provide advice to the Commissioner of Food and Drugs (the Commissioner), or designee, on complex issues relating to medical devices, regulation of devices, and their use by patients.

The Committee will be composed of a core of nine voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities who are knowledgeable in areas such as clinical research, primary care patient experience, and healthcare needs of patient groups in the United States, or who are experienced in the work of patient and health professional organizations, methodologies for eliciting patient preferences, and strategies for communicating benefits, risks, and clinical outcomes to patients and research subjects. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons.

The function of the Committee is to provide advice to the Commissioner on complex issues relating to medical devices, the regulation of devices, and their use by patients. Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes, and device-related quality of life or health status issues are among the topics that may be considered by the Committee. The Committee provides relevant skills and perspectives in order to improve communication of benefits, risks, and clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. It performs its duties by identifying new approaches, promoting innovation, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy.

The Committee name and function were established with the Committee charter on October 6, 2015. Therefore, the Agency is amending 21 CFR 14.100 to add the Committee name and function to its current list as set forth in the regulatory text of this document.

Under 5 U.S.C. 553(b)(3)(B) and (d) and 21 CFR 10.40(d) and (e), the Agency finds good cause to dispense with notice and public comment procedures and to proceed to an immediate effective date on this rule. Notice and public comment and a delayed effective date are unnecessary and are not in the public interest as this final rule is merely codifying the addition of the name and function of the Patient Engagement Advisory Committee to reflect the committee charter.

Therefore, the Agency is amending 21 CFR 14.100 to add paragraph (d)(5) as set forth in the regulatory text of this document.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

■ 1. The authority citation for 21 CFR part 14 continues to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264; Pub. L. 107–109; Pub. L. 108–155; Pub. L. 113–54.

■ 2. In § 14.100, add paragraph (d)(5) to read as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(d) * * *

(5) *Patient Engagement Advisory Committee.*

(i) Date Established: October 6, 2015.

(ii) Function: Provides advice to the Commissioner on complex issues relating to medical devices, the regulation of devices, and their use by patients. Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes, and device-related quality of life or health status issues are among the topics that may be considered by the Committee. The Committee provides relevant skills and perspectives in order to improve communication of benefits, risks, and clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. It performs its duties by identifying new approaches, promoting innovation, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy.

* * * * *

Dated: March 15, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–06240 Filed 3–18–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 169

[156A2100DD/AAKC001030/A0A501010.999900 253G]

RIN 1076–AF20

Rights-of-Way on Indian Land

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final rule; extension of effective date and compliance date.

SUMMARY: The Bureau of Indian Affairs (BIA) is announcing the extension of the effective date of the final rule published November 19, 2015 governing rights-of-way on Indian land, which was scheduled to take effect on December 21, 2015, and later extended to March 21, 2016. The final rule will now take effect on April 21, 2016. The BIA is also announcing an extension of the compliance date by which documentation of past assignments must be submitted from the extended date of July 17, 2016, to August 16, 2016. The final rule comprehensively updates and streamlines the process for obtaining Bureau of Indian Affairs (BIA) grants of rights-of-way on Indian land and BIA land, while supporting tribal self-determination and self-governance.

DATES: The effective date of the final rule published on November 19, 2015 (80 FR 72492) is extended until April 21, 2016. The compliance date for submission of documentation of past assignments is extended until August 16, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Elizabeth Appel, Director, Office of Regulatory Affairs & Collaborative Action, (202) 273–4680; *elizabeth.appel@bia.gov.*

SUPPLEMENTARY INFORMATION: On November 19, 2015, BIA published a final rule addressing rights-of-way on Indian land and BIA land. *See* 80 FR 72492. In a document published December 21, 2015, BIA extended the effective date of the rule to March 21, 2016, in response to requests from tribes and industry in order to provide additional time to prepare for implementation to ensure compliance. *See* 80 FR 79258. BIA is again extending the effective date of the final rule. This document extends the effective date of the final rule to April 21, 2016, and likewise extends the deadline for providing BIA with documentation of past assignments to August 16, 2016. The substance of the rule remains unchanged and this will be the final extension of the effective date.

The BIA has determined that the extension of the effective date and compliance date without prior public notice and comment is in the public interest because it would allow more time for the public to comply with the rule. This is a rule of agency procedure or practice that is exempt from notice and comment rulemaking under 5 U.S.C. 553(b)(A).

Correction

In FR Rule Doc. No. 2015–28548, published November 19, 2015, at 80 FR 72492, make the following corrections:

■ 1. On page 72537, in the center and right columns, in revised § 169.7, remove the date ''December 21, 2015'' wherever it appears and add in its place ''April 21, 2016''.

■ 2. On page 72537, in the right column, in paragraph (d) of revised § 169.7, remove the date ''April 18, 2016'' and add in its place ''August 16, 2016''.

Dated: March 15, 2016.

Lawrence S. Roberts,

Acting Assistant Secretary—Indian Affairs.

[FR Doc. 2016–06269 Filed 3–18–16; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0183]

Drawbridge Operation Regulation; Trent River, New Bern, NC

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the US 70 (Alfred C. Cunningham) Bridge across the Trent River, mile 0.0, at New Bern, NC. The deviation is necessary to ensure the safety of attendees to the annual Mumfest celebration. This deviation allows the bridge draw span to remain in the closed to navigation position at two hour increments to accommodate the free movement of pedestrians and vehicles during the annual Mumfest celebration.

DATES: This deviation is effective from 9 a.m. on October 8, 2016 to 7 p.m. on October 9, 2016.

ADDRESSES: The docket for this deviation, [USCG–2016–0183] is