United States'' (September 18, 2008, 73 FR 54106).

The proposed rule does not reflect current technology and industry practice. For example, the proposed rule directed owners or consignees to affix labels to physical documents such as invoices, packing lists, bills of lading, and any other documents accompanying refused food. Many of these documents are now electronic. Therefore, since implementation of the proposed rule would not adequately address how to permanently mark electronic documentation accompanying refused food, it would not achieve the public health and efficiency benefits discussed in the notice of proposed rulemaking. As directed by section 304 of the FDA Food Safety Modernization Act (Pub. L. 111–353) that was enacted after FDA issued the proposed rule, FDA now requires, as part of its prior notice regulations, notice to FDA of the name of any country to which imported food has been refused entry. (See 21 CFR 1.281(a)(18).) This includes situations where the United States has refused entry, and it therefore provides FDA with information related to what the proposed marking rule would require.

FDA may reassess how to effectively implement the labeling of documentation accompanying refused food and consider whether to issue a revised proposed rule in the future.

The withdrawal of the proposal identified in this document does not preclude the Agency from reinstituting rulemaking concerning the issues addressed. Should we decide to undertake such a rulemaking in the future, we will re-propose the action and provide a new opportunity for comment. Furthermore, this proposed rule withdrawal is only intended to address the specific actions identified in this document, and not any other pending proposals that the Agency has issued or is considering. If you need additional information about the subject matter of the withdrawn proposed rule, you may review the Agency's website (*https://www.fda.gov*) for any current information on the matter.

Dated: September 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21145 Filed 9–27–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket Nos. FDA–2005–N–0033, FDA–2008–N–0115]

Use of Materials Derived From Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants; Reporting Information Regarding Falsification of Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA, Agency, we) is announcing the withdrawal of two proposed rules that published in the **Federal Register**. These proposed rules are not currently considered viable candidates for final action. FDA is taking this action because the regulatory requirements set forth in the proposed rules are not needed at this time to protect the public health.

DATES: As of September 28, 2018, the proposed rules published on January 12, 2007, at 72 FR 1582, and February 19, 2010, at 75 FR 7412 are withdrawn.

ADDRESSES: For access to the docket, 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: Brian Pendleton, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4250, Silver Spring, MD 20993–0002, 301–796–4614, *brian.pendleton@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1990, FDA began a process of periodically conducting comprehensive reviews of its regulation process, including reviewing the backlog of proposed rulemakings that had not been finalized. As FDA removed many proposed rules not finalized, the Agency implemented a process of reviewing existing proposed rules every 5 years.

As part of this process and the Administration's regulatory reform initiative, we continue to conduct reviews of existing proposed rules. The review determines if the proposals are outdated, unnecessary, or can be revised to reduce regulatory burden while allowing FDA to achieve our public health mission and fulfill statutory obligations.

As part of these efforts, FDA is withdrawing the following proposed rules:

Title of proposed rule	Publication date, **Federal Register** citation	Docket No.	Reason for withdrawal
1. *Use of Materials Derived from Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants.*	January 12, 2007, 72 FR 1582.	FDA–2005–N–0033	We are withdrawing the proposed rule because the risk to public health posed by the potential use of materials derived from cattle in medical products has been significantly diminished since the issuance of the proposed rule, and we believe we can address any potential concerns through application of our premarketing review authority.
2. *Reporting Information Regarding Falsification of Data.*	February 19, 2010, 75 FR 7412.	FDA–2008–N–0115	The rule is not needed to protect research subjects or to help ensure the integrity of clinical trial data submitted to FDA in support of marketing applications and petitions for product approvals. Existing regulations require study sponsors to notify FDA when they end an investigator's participation in an investigation (21 CFR 312.56(b)), and institutional review boards must notify us when they suspend or terminate their approval of research (21 CFR 56.113). Based on our review of recent data, we conclude that we are receiving adequate notice of falsification of data, and we do not believe that adopting the proposed requirements would provide us with substantial additional information.

The withdrawal of the proposed rules does not preclude the Agency from reinstituting rulemaking concerning the issues addressed in the proposed rules listed in the table. Should we decide to undertake such rulemakings in the future, we will re-propose the actions and provide new opportunities for comment. Furthermore, these proposed rules' withdrawal is only intended to address the specific actions identified in this document, and not any other pending proposals that the Agency has issued or is considering. If you need additional information about the subject

matter of the withdrawn proposed rules, you may review the Agency's website (*https://www.fda.gov*) for any current information on the matter.

Dated: September 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21133 Filed 9–27–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2018–0883]

RIN 1625–AA08

Special Local Regulation; Manasquan Inlet, Manasquan, NJ

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary special local regulation for certain waters of the Manasquan Inlet between Manasquan, NJ, and Point Pleasant Beach, NJ. This action is necessary to protect event participants, spectators, and vessels transiting the area from potential hazards during the Manasquan Inlet Intercoastal Tug marine event. During the enforcement period, unauthorized persons or vessels would be prohibited from entering into, remaining within, transiting through, or anchoring in the regulated area unless authorized by the Captain of the Port Delaware Bay or a designated representative of the Captain of the Port. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before October 5, 2018.

ADDRESSES: You may submit comments identified by docket number USCG–2018–0883 using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Petty Officer Thomas Welker, U.S. Coast Guard; Sector Delaware Bay, Waterways Management Division; telephone (215) 271–4814, email *Thomas.J.Welker@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

The Manasquan Beach and Recreation Department notified the Coast Guard that it will be conducting a tug of war event from 11 a.m. to 1:30 p.m. on October 20, 2018. The tug of war will consist of teams on opposing sides of the Manasquan Inlet with a rope extended between the sides. The event will span the entire width of the inlet. Vessel operation in the area of the event could be hazardous to both event participants and vessels. The Captain of the Port Delaware Bay (COTP) has determined that a safety concern exists for non-participant vessels within 400 feet of the tug of war rope.

The purpose of this rulemaking is to ensure the safety of participants and vessels transiting the regulated area during the event. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231.

III. Discussion of Proposed Rule

The COTP proposes to establish a temporary special local regulation to be in effect from 11 a.m. to 1:30 p.m. on October 20, 2018. The regulated area would cover all waters within 400 feet of the event located between approximate locations 40°6′9.22″ N, 74°2′7.8″ W and 40°6′9.22″ N, 74°2′8.2″ W. During the event, the inlet would be closed to all non-participant vessel traffic. There is a 30-minute break tentatively planned for midway through the event. If circumstances permit, during the break the rope will be removed from navigable waters and vessels may be allowed to transit through the area at the discretion of the COTP or COTP's designated representative. The regulation is intended to ensure the safety of event participants and vessels during the scheduled 11 a.m. to 1:30 p.m. tug of war event. No vessel or person would be permitted to enter the regulated area without obtaining permission from the COTP or a designated representative of the Captain of the Port. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This NPRM has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, and duration of the regulated area. While this regulated area would impact a designated area of the Manasquan River Inlet for 2 and ½ hours, the event sponsor has organized a 30 minute time period during the event where vessels would be able to transit through the inlet. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone during the 30 minute time period during the event.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the regulated area may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see