billion pounds in 2016.[9] Therefore, the projected Namibian beef imports in the first year would only be about 0.008 percent of total United States production, and 0.07 percent of total United States imports. If Namibia achieves the projected export goal in five years, and assuming that United States beef production and import volume stay about the same, the projected beef imports from Namibia would still only be about 0.05 percent of total United States production, and 0.44 percent of total United States imports.

Although Namibia indicates that, for now, it is seeking to export boneless beef products only, this final rule would not preclude their exporting other meat products in the future, if the products meet all other applicable requirements of the United States, including those of USDA's APHIS, and any additional requirements that FSIS might have in place with regard to the products. Therefore, the long-term economic impact could be larger than what FSIS can assess right now.

Regulatory Flexibility Act Assessment

The FSIS Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601–602), this final rule will not have a significant impact on a substantial number of small entities in the United States. As mentioned above, the expected trade volume is very small. Therefore, the action should have no significant impact on small entities that produce beef products domestically.

Executive Order 12988, Civil Justice Reform

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

No new paperwork requirements are associated with this rule. Foreign countries wanting to export meat and meat products to the United States are required to provide information to FSIS certifying that their inspection systems provide standards equivalent to those of the United States, and that the legal authority for the system and their implementing regulations are equivalent to those of the United States. This information collection was approved under OMB number 0583–0153. The rule contains no other paperwork requirements.

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Additional Public Notification

FSIS will officially notify the World Trade Organization's Committee on Sanitary and Phytosanitary Measures (WTO/SPS Committee) in Geneva, Switzerland, of this rule and will announce it online through the FSIS Web page located at: *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/interim-and-final-rules.*

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: *http://www.fsis.usda.gov/federal-register.*

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *http://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

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How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at *http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf,* or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250–9410.

Fax: (202) 690–7442.

Email: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

List of Subjects in 9 CFR Part 327

Food labeling, Food packaging, Imports, Meat inspection.

For the reasons set out in the preamble, FSIS amends 9 CFR part 327 as follows:

PART 327—IMPORTED PRODUCTS

■ 1. The authority citation for part 327 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

§ 327.2 [Amended]

■ 2. Amend § 327.2(b) by adding ''Namibia'' in alphabetical order to the list of countries.

Done at Washington, DC, on July 1, 2016.

Alfred V. Almanza,

Acting Administrator.

[FR Doc. 2016–16546 Filed 7–12–16; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2016–N–1813]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Metallic Biliary Stent System for Benign Strictures

AGENCY: Food and Drug Administration, HHS.

[9] Ibid.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the metallic biliary stent system for benign strictures into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the metallic biliary stent system for benign strictures' classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective July 13, 2016. The classification was applicable on June 3, 2016.

FOR FURTHER INFORMATION CONTACT: April Marrone, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G218, Silver Spring, MD 20993–0002, 240–402–6510, *april.marrone@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i), to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1) of the FD&C Act. Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1), the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

On August 27, 2015, Boston Scientific Corporation submitted a request for classification of the WallFlex Biliary RX Fully Covered Stent System RMV under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on June 3, 2016, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 876.5011.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a metallic biliary stent system for benign strictures will need to comply with the special controls named in this final order. The device is assigned the generic name metallic biliary stent system for benign strictures, and it is identified as a prescription device intended for the treatment of benign biliary strictures. The biliary stents are intended to be left indwelling for a limited amount of time and subsequently removed. The device consists of a metallic stent and a delivery system intended to place the stent in the bile duct. This device type is not intended for use in the vasculature.

FDA has identified the following risks to health associated with this type of device, and the measures required to mitigate these risks, in table 1.

TABLE 1—METALLIC BILIARY STENT SYSTEM FOR BENIGN STRICTURES RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measure
Adverse tissue reaction	Biocompatibility Evaluation. Labeling.
Infection	Sterilization Validation. Shelf Life Validation. Labeling.
Bile duct obstruction	Clinical Performance Testing.
Stent migration	Non-clinical Performance Testing.
Stent does not resolve obstruction	Shelf Life Validation.
Stent cannot be placed	Labeling.
Expansion/compression forces.	
Foreshortening.	
Trauma to bile ducts	Clinical Performance Testing.

TABLE 1—METALLIC BILIARY STENT SYSTEM FOR BENIGN STRICTURES RISKS AND MITIGATION MEASURES—Continued

Identified risk	Mitigation measure
During stent deployment During removal Due to stent migration During stent indwell. Inability to safely remove stent. Expansion/compression forces.	Non-clinical Performance Testing. Shelf Life Validation. Labeling.

FDA believes that the special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness.

A metallic biliary stent system for benign strictures is not safe for use except under the supervision of a practitioner licensed by law to direct the use of the device. As such, the device is a prescription device and must satisfy prescription labeling requirements (see 21 CFR 801.109, *Prescription devices*).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the metallic biliary stent system for benign strictures they intend to market.

II. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) 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.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. 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 part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov.*

1. DEN150040: De Novo request from Boston Scientific Corporation, dated August 27, 2015.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 876.5011 to subpart F to read as follows:

§ 876.5011 Metallic biliary stent system for benign strictures.

(a) *Identification.* A metallic biliary stent system for benign strictures is a prescription device intended for the treatment of benign biliary strictures. The biliary stents are intended to be left indwelling for a limited amount of time and subsequently removed. The device consists of a metallic stent and a delivery system intended to place the biliary stent in the bile duct. This device type is not intended for use in the vasculature.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must demonstrate or provide the following:

(i) The ability to safely place and subsequently remove the stent after the maximum labeled indwell period.

(ii) All adverse event data including bile duct obstruction and trauma to the bile duct.

(iii) The stent resolves strictures during the maximum labeled indwell period.

(iv) Stricture resolution is maintained post-stent removal.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be demonstrated:

(i) Corrosion testing to demonstrate that the stent maintains its integrity during indwell and does not release potentially toxic levels of leachables.

(ii) Stent dimensional testing supports the intended use.

(iii) Compression and expansion forces must be characterized.

(iv) The delivery catheter must deliver the stent to the intended location and the stent must not be adversely impacted by the delivery catheter during deployment and catheter withdrawal.

(v) The delivery system must withstand clinically anticipated forces.

(vi) Compatibility in a magnetic resonance environment.

(3) All patient contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of the device components intended to be provided sterile.

(5) Shelf life testing must demonstrate that the device maintains its performance characteristics and that packaging maintains sterility for the duration of the labeled shelf life.

(6) Labeling for the device must include:

(i) A detailed summary of the clinical testing including device effectiveness, and device- and procedure-related adverse events.

(ii) Appropriate warning(s) to accurately ensure usage of the device for the intended patient population.

(iii) Shelf life.

(iv) Compatibility information for use in the magnetic resonance environment.

(v) Stent foreshortening information supported by dimensional testing.

Dated: July 6, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–16530 Filed 7–12–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0643]

Drawbridge Operation Regulation; Willamette River at Portland, OR

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 four Multnomah County bridges: The Broadway Bridge, mile 11.7; Burnside Bridge, mile 12.4; Morrison Bridge, mile 12.8; and Hawthorne Bridge, mile 13.1; all crossing the Willamette River at Portland, OR. This deviation is necessary to accommodate the annual Portland Providence Bridge Pedal event. The deviation allows the bridges to remain in the closed-to-navigation position to allow safe roadway movement of event participants.

DATES: This deviation is effective from 6 a.m. to 12:30 p.m. on August 14, 2016.

ADDRESSES: The docket for this deviation, [USCG–2016–00643] is available 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 deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206–220–7282, email *d13-pf-d13bridges@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Multnomah County has requested a temporary deviation from the operating schedule for the Broadway Bridge, mile 11.7; Burnside Bridge, mile 12.4; Morrison Bridge, mile 12.8; and Hawthorne Bridge, mile 13.1; all crossing the Willamette River at Portland, OR. The requested deviation is to accommodate the annual Portland Providence Bridge Pedal event. To facilitate this event, the draws of theses bridges will be maintained as follows: The Broadway Bridge provides a vertical clearance of 90 feet in the closed-to-navigation position; Burnside Bridge provides a vertical clearance of 64 feet in the closed-to-navigation position; Morrison Bridge provides a vertical clearance of 69 feet in the closed-to-navigation position; and Hawthorne Bridge provides a vertical clearance of 49 feet in the closed-to-navigation position; all clearances are referenced to the vertical clearance above Columbia River Datum 0.0. The normal operating schedule for all four bridges is in 33 CFR 117.897. This deviation allows the Broadway Bridge, Burnside Bridge, Morrison Bridge, and Hawthorne Bridge to remain in the closed-to-navigation position and need not open for maritime traffic from 6 a.m. to 12:30 p.m. on August 14, 2016. Waterway usage on this part of the Willamette River includes vessels ranging from commercial tug and barge to small pleasure craft.

Vessels able to pass through the bridge in the closed-to-navigation positions may do so at any time. The bridges will be able to open for emergencies, and there is no immediate alternate route for vessels to pass. The Coast Guard will inform the users of the waterway, through our Local and Broadcast Notices to Mariners, of the change in operating schedule for the bridges so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridges must return to their regular operating schedules immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: July 6, 2016.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2016–16471 Filed 7–12–16; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 60 and 63

[EPA–HQ–OAR–2010–0682; FRL–9948–92–OAR]

RIN 2016–AS83

National Emission Standards for Hazardous Air Pollutant Emissions: Petroleum Refinery Sector Amendments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action amends the National Emissions Standards for Hazardous Air Pollutants (NESHAP) for Petroleum Refineries in three respects. First, this action adjusts the compliance date for regulatory requirements that apply at maintenance vents during periods of startup, shutdown, maintenance or inspection for sources constructed or reconstructed on or before June 30, 2014. Second, this action amends the compliance dates for the regulatory requirements that apply during startup, shutdown, or hot standby for fluid catalytic cracking units (FCCU) and startup and shutdown for sulfur recovery units (SRU) constructed or reconstructed on or before June 30, 2014. Finally, this action finalizes technical corrections and clarifications to the NESHAP and the New Source Performance Standards (NSPS) for Petroleum Refineries. These amendments are being finalized in response to new information submitted after these regulatory requirements were promulgated as part of the residual risk and technology review (RTR) rulemaking, which was published on December 1, 2015. This action will have an insignificant effect on emissions reductions and costs.

DATES: This final rule is effective on July 13, 2016.

ADDRESSES: The Environmental Protection Agency (EPA) has established a docket for this action under Docket ID No. EPA–HQ–OAR–2010–0682. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are