4. Letter dated May 3, 2016, from Society of Plastics Industry, Inc., and other organizations to Michael Taylor and Stephen Ostroff of FDA.
5. FDA, ''Part 117. FSMA Final Rulemaking for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food: Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, Final Unfunded Mandates Reform Act Analysis, and Final Paperwork Reduction Act Analysis,'' 2015. (*http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM472884.pdf).*
6. FDA, ''Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis for the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,'' 2015. (*http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM472330.pdf*).

Dated: August 18, 2016.

Jeremy Sharp,

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

[FR Doc. 2016–20176 Filed 8–23–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2016–N–1896]

New Animal Drugs for Use in Animal Feed; Category Definitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, we) is amending the animal drug regulations by revising the definitions of the two categories of new animal drugs used in medicated feeds to base category assignment only on approved uses in major animal species. This revision will preserve the availability of medicated feeds intended for therapeutic use in minor animal species and prevent a significant disincentive for future development of additional minor species therapies.

DATES: This rule is effective December 1, 2016. Submit either electronic or written comments by November 7, 2016. See Section IV for further discussion of the effective date.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2016–N–1896 for ''Category Definitions For Minor Species.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper 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: David Edwards, Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6205, *david.edwards@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Direct Final Rule

FDA is issuing this direct final rule to revise the definitions of the two categories of new animal drugs used in

medicated feeds to base category assignment only on approved uses in major animal species. This action is being taken to address a potential consequence of animal drug sponsor cooperation in implementing a strategy initiated by the FDA Center for Veterinary Medicine (CVM) to address antimicrobial resistance by taking measures to ensure the judicious use of antimicrobial drugs in animal agriculture. Under this program, sponsors of antimicrobial new animal drugs that also have importance in human medicine were requested to voluntarily withdraw approval of production (*e.g.,* growth production, feed efficiency) indications for their drug products that are intended for use in the feed or water of food-producing animals. Based on the existing drug category definitions, the voluntary withdrawal of production indications by these drug sponsors would, in some cases, result in a change to a medicated feed drug's category, potentially leading to additional consequences not foreseen at the time the program was initiated.

The category in which a new animal drug used in medicated feeds is placed is based on their likelihood of producing unsafe residues in the edible products of treated animals. Category I consists of those drugs that require no withdrawal period at the lowest use level in each species for which they are approved. Category II consists of those drugs that require a withdrawal period at the lowest use level for at least one species for which they are approved, or that are regulated on a ''no-residue'' basis or with a zero tolerance because of a carcinogenic concern, regardless of whether a withdrawal period is required.

New animal drugs approved for use in medicated feeds are approved as Type A medicated articles, the most concentrated form of the drug product for use by feed mills. Category I Type A medicated articles can be handled by both licensed and unlicensed feed mills, whereas Category II Type A medicated articles can be handled only by licensed feed mills.

Certain Category I Type A medicated articles would be recategorized to Category II when a production indication is voluntarily withdrawn by a sponsor as part of the judicious use initiative that is currently underway, based on the next lowest use level that remains once the production use is withdrawn having a withdrawal period such that the drug would then meet the definition for Category II. For Category I Type A medicated articles that include indications for minor species, FDA is concerned that if such a Type A medicated article is recategorized to Category II based on a withdrawal period for an approved therapeutic use in a minor species, sponsors may opt to request withdrawal of approval of these minor species indications in order to ensure the Type A medicated article can remain in Category I. Sponsors may also decline to pursue development of additional therapies for minor species if these uses would require a withdrawal period that would trigger a recategorization to Category II.

This direct final rule revises the category definitions such that they will be based only on whether a withdrawal period is required for a major species.[1] Under this new definition, a Category I Type A medicated article will not be recategorized to Category II based on the existence of a withdrawal period for an approved indication in a minor species, even if that minor species indication is the next lowest approved use level that remains after the production indication has been withdrawn. However, if the next lowest use level (apart from the minor species indication) is an indication approved for use in a major species that has a withdrawal period, under the new definition the drug will move to Category II.

The purpose of this revision is to preserve the present availability of medicated feeds intended for therapeutic uses in minor species and to prevent a significant disincentive for future development of additional therapies for minor species. We believe this revision will not compromise public health due to the comparatively lower exposure by humans to potential drug residues in edible tissues of food-producing minor species inherent in their less frequent consumption.

B. Summary of the Major Provisions of the Direct Final Rule

FDA is amending 21 CFR 558.3 *Definitions and general considerations applicable to this part* (§ 558.3) to base the definition for each of the two categories (Category I and Category II) of new animal drugs used in medicated feeds only on approved uses in major species. Definitions for ''major species'' and ''minor species'' are also being added to this section.

C. Legal Authority

FDA is issuing these regulations based on its authority under the new animal drug provisions in sections 512 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b) and under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), which gives the Agency general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act.

D. Costs and Benefits

The revisions made by this direct final rule are intended to preserve the availability of medicated feeds intended for therapeutic use in minor animal species. In addition, these revisions will prevent a significant disincentive for future development of additional therapies for minor species. No additional costs or benefits will accrue from this rulemaking.

II. Background

FDA is issuing this direct final rule to revise the definitions of the two categories of new animal drugs used in medicated feeds to base category assignment only on approved uses in major animal species. To strengthen the Agency's medicated feed program, FDA issued a final rule in the **Federal Register** of March 3, 1986 (51 FR 7382), which, among other things, established two categories of new animal drugs used in medicated feeds. As discussed in the final rule, the Agency placed these drugs into categories based on their likelihood of producing unsafe residues in the edible products of treated animals (51 FR 7382). Category I consists of those drugs that require no withdrawal period at the lowest use level in each species for which they are approved. Category II consists of those drugs that require a withdrawal period at the lowest use level for at least one species for which they are approved, or that are regulated on a ''no-residue'' basis or with a zero tolerance because of a carcinogenic concern, regardless of whether a withdrawal period is required.

New animal drugs approved for use in medicated feeds are approved as Type A medicated articles, the most concentrated form of the drug product for use by feed mills. Category I Type A medicated articles can be handled by both licensed and unlicensed feed mills, whereas Category II Type A medicated articles can be handled only by licensed feed mills.

This action is being taken to address a potential consequence of animal drug

[1] As a practical matter, categorization under the revised definitions in this direct final rule will be driven by approved indications for major food-producing species (cattle, poultry, swine, and turkeys). While the definition for major species includes horses, dogs, and cats, they are not regulated as food-producing major species and thus drugs approved for use in these species do not require an assessment of human food safety that may result in assignment of a withdrawal period. Minor species are defined as animals, other than humans, that are not major species. Minor species include animals such as sheep, goats, ducks, geese, and aquaculture species such as catfish, salmon, and trout.

sponsor cooperation in implementing a strategy initiated by CVM to address antimicrobial resistance by taking measures to ensure the judicious use of antimicrobials of importance to human medicine (*i.e.,* medically important antimicrobials) in animal agriculture. Specifically, CVM's initiative to ensure the judicious use of medically important antimicrobial drugs in animal agriculture advocates two specific changes to the approved conditions of use of medically important antimicrobials that are administered through the medicated feed or water of food-producing animals.

These changes, which are described in Guidance for Industry (GFI) #213, ''New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209,'' published December 2013 (*http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf*), are intended to reduce the development of antimicrobial resistance and thereby preserve the effectiveness of these important drugs for use in treating infections in humans. Following publication of GFI #213, all sponsors of these medically important antimicrobial new animal drug products approved for use in the feed or water of food-producing animals notified FDA in writing of their intent to voluntarily make changes to their affected products as outlined in the guidance.

Under GFI #213, sponsors of medically important antimicrobial new animal drugs approved for over-the-counter use in the feed or water of food-producing animals were asked to change the marketing status of their products to veterinary prescription (Rx) marketing status in the case of new animal drugs administered in water, or to veterinary feed directive (VFD) marketing status for drugs administered in or on animal feed. New animal drugs with Rx or VFD marketing status can legally only be used with a veterinarian's oversight. Prescription animal drugs require a veterinarian's prescription, while use of VFD drugs requires a VFD; both types of orders must be issued by a licensed veterinarian in the course of the veterinarian's professional practice.

In addition, under GFI #213 sponsors of medically important new animal drugs used in animal feed or water that have production indications were requested to voluntarily withdraw these indications; approved therapeutic indications for use of these drugs would remain.

In some instances, once a sponsor withdraws the production indication from a drug approved for use in animal feed (which is generally the lowest use level of the drug), the remaining lowest therapeutic use level will require a withdrawal period. Based on the existing definitions of the feed drug categories, this results in a Category I new animal drug being recategorized as a Category II drug, the more restrictive of the two possible categories of drugs used in medicated feed. Category II drugs require that the manufacture of Type B and Type C medicated feeds from Type A medicated articles be done in facilities possessing a medicated feed mill license, which number roughly 900 in the United States. In contrast, there are tens of thousands of unlicensed feed mills in this country. Such a recategorization to Category II, thereby limiting the use of the Type A medicated article to a much smaller subset of feed mills, may disrupt the existing movement of these medicated feeds through distribution channels.

FDA believes that sponsors may request voluntary withdrawal of those specific therapeutic indications as a way to keep their products in the less restrictive Category I when the recategorization of a drug to Category II is triggered by a therapeutic indication for a minor species. For certain drug products, the only therapeutic indications requiring a withdrawal period that would remain following the voluntary withdrawal of approval of production uses are those for minor species. The loss of therapeutic indications for minor species would adversely affect the availability of therapeutic medicated feeds necessary for the health of minor species, which is a matter of significant concern for the Agency.

This foreseeable adverse effect on the health of minor species would directly undermine the intent of Congress in passing the Minor Use and Minor Species Animal Health Act of 2004 (Pub. L. 108–282) as well as to our intent in establishing the implementing regulations under that statute. The Category I drugs likely to be affected have been safely used in this category for decades, and we have no reason to believe they would not continue to be safely used in this category moving forward.

Under the current category definitions in § 558.3 for feed use drugs, a drug will be included in Category II if the lowest use level of the drug in any approved species requires a withdrawal period. This approach equates the existence of a withdrawal period for a particular use with the potential risk that edible tissues from animals administered a medicated feed might contain a residue of concern.

However, the toxicological analysis of animal drugs used to calculate a withdrawal period is based on lifetime exposure by humans to potential drug residues. This assessment of lifetime exposure does not consider the lower risk to the public health from the use of these same new animal drugs in food-producing minor species attributable to the lower human consumption over time of edible tissues from food-producing minor species (Refs. 1 and 2). For this reason, FDA does not at this time believe this revision of the category definitions presents a risk to the public health.

In a manner similar to its effect on drug indications that are already approved, CVM believes the existing categorization scheme would pose a significant disincentive for future development of additional minor species therapies for existing Category I drugs if those new uses would require a withdrawal period and thus trigger a change to Category II for that drug.

Given the potential for implementation of GFI #213 to result in the foreseeable consequence of the withdrawal of approval of needed therapeutic indications for minor species, the definitions of the two categories of new animal drugs used in medicated feeds in § 558.3 are being revised to base category assignment only on uses in major species. This revision is expected to preserve the availability of drugs intended for therapeutic use in minor species and also prevent a significant disincentive for future development of additional therapies for minor species without compromising public health.

III. Provisions of the Regulation

We are amending paragraphs (b)(1)(i) and (ii) of this Agency's regulations at § 558.3 (*Definitions and general considerations applicable to this part.*) to base the definition for each of the two categories of new animal drugs (Category I and Category II) used in medicated feeds only on approved uses in major species. Section 558.3(b) is further amended to add definitions for ''major species'' and ''minor species'' that are identical to the definitions of those terms found in FDA's regulations for new animal drugs for minor use and minor species (21 CFR 516.3). We are revising the feed drug category definitions in § 558.3 to preserve the availability of medicated feeds intended for use in minor species and prevent a

likely disincentive for development of additional therapies for minor species.

IV. Direct Final Rulemaking

FDA has determined that the subject of this rulemaking is suitable for a direct final rule. FDA is amending § 558.3(b)(1) by revising the definitions of Category I and Category II new animal drugs administered in or on medicated feed. This rule is intended to make noncontroversial changes to existing regulations. The Agency does not anticipate receiving any significant adverse comments on this rule.

Consistent with FDA's procedures on direct final rulemaking, we are publishing elsewhere in this issue of the **Federal Register** a companion proposed rule. The companion proposed rule and this direct final rule are substantively identical. The companion proposed rule provides the procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of any significant adverse comment. The comment period for this direct final rule runs concurrently with the comment period of the companion proposed rule. Any comments received in response to the companion proposed rule will also be considered as comments regarding this direct final rule.

FDA is providing a comment period for the direct final rule of 75 days after the date of publication in the **Federal Register**. If FDA receives a significant adverse comment, we intend to withdraw this direct final rule before its effective date by publication of a notice in the **Federal Register** within 30 days after the comment period ends. A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants withdrawing a direct final rule, the Agency will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553).

Comments that are frivolous, insubstantial, or outside the scope of this direct final rule will not be considered significant or adverse under this procedure. For example, a comment recommending a regulation change in addition to those in the rule would not be considered a significant adverse comment unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision can be severed from the remainder of the rule, FDA may adopt as final those provisions of the rule that are not the subject of a significant adverse comment.

If FDA withdraws the direct final rule, all comments received will be considered under the companion proposed rule in developing a final rule under the usual notice-and-comment procedures under the APA (5 U.S.C. 552 *et seq.*). If FDA does not receive a significant adverse comment in response to the direct final rule, the Agency will publish, within 30 days after the comment period ends, a document in the **Federal Register** confirming the effective date of the final rule. The Agency intends to make the direct final rule effective December 1, 2016.

A full description of FDA's policy on direct final rule procedures may be found in a guidance document announced in the **Federal Register** of November 21, 1997 (62 FR 62466). The guidance document may be accessed at: *http://www.fda.gov/RegulatoryInformation/Guidances/ucm125166.htm.*

V. Legal Authority

We are issuing these regulations under the legal authority provided by section 512 of the FD&C Act relating to new animal drugs and section 701(a) of the FD&C Act. Section 512 gives FDA the authority to approve new animal drug applications (NADAs). Such approval establishes conditions of use under which the drug can be used in a safe and effective manner. Categorization of new animal drugs used in medicated feeds is one such condition of use. In addition, section 701(a) of the FD&C Act gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act.

VI. Economic Analysis of Impacts

We have examined the impacts of the direct 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 us 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 direct final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this direct final rule would not impose any compliance costs on the sponsors of animal drug products that are currently marketed or in development, we certify that this direct final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''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 $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This direct final rule would not result in an expenditure in any year that meets or exceeds this amount.

This direct final rule allows certain new animal drugs approved for use in animal feed that would otherwise be recategorized as Category II drugs under the current definitions in § 558.3 following withdrawal of approval of production indications during GFI #213 implementation to remain in Category I if the change to Category II would have been triggered by a minor species indication.

Based on the revised definitions of the two feed drug categories, there is one drug, sulfamerazine for control of furunculosis in trout (21 CFR 558.582), that will be recategorized from Category II to Category I as a result of this direct final rule. No compliance costs will be incurred due to this recategorization because no changes to the approved application are required for continued marketing of the drug.

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) 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.

VIII. Paperwork Reduction Act of 1995

This direct final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

IX. Federalism

We have analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. We have determined that this direct final 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 this direct final 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.

X. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. U.S. Department of Agriculture, ''Livestock & Meat Domestic Data,'' *http://www.ers.usda.gov/data-products/livestock-meat-domestic-data* (accessed on June 23, 2016).
2. ''Food Fish Production and Sales by Species, by Size Category, by State and United States: 2005,'' *http://www.agcensus.usda.gov/Publications/2002/Aquaculture/aquacen2005_08.pdf* (accessed on June 23, 2016).

List of Subjects in 21 CFR Part 558

Animal drugs, animal feeds.

Therefore, under the Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc–1, 371.

■ 2. In § 558.3, revise paragraphs (b)(1)(i) and (ii); and add paragraphs (b)(13) and (14) to read as follows:

§ 558.3 Definitions and general considerations applicable to this part.

* * * * *

(b) * * *

(1) * * *

(i) Category I—These drugs require no withdrawal period at the lowest use level in each major species for which they are approved or are approved for use only in minor species.

(ii) Category II—These drugs require a withdrawal period at the lowest use level for at least one major species for which they are approved, or are regulated on a ''no-residue'' basis or with a zero tolerance because of carcinogenic concern regardless of whether a withdrawal period is required in any species.

* * * * *

(13) ''Major species'' means cattle, horses, swine, chickens, turkeys, dogs, and cats.

(14) ''Minor species'' means animals, other than humans, that are not major species.

Dated: August 18, 2016.

Jeremy Sharp,

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

[FR Doc. 2016–20148 Filed 8–23–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0814]

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 U.S. 70/Alfred A. Cunningham Bridge across the Trent River, mile 0.0, at New Bern, NC. The deviation is necessary to facilitate safe participation in the Multiple Sclerosis Society's Historic New Bern Bike Ride. This deviation allows the bridge to remain in the closed-to-navigation position.

DATES: The deviation is effective from 8 a.m. on Saturday, September 10, 2016, to 9:30 a.m. Sunday, September 11, 2016.

ADDRESSES: The docket for this deviation, [USCG–2016–0814] 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. Michael Thorogood, Bridge Administration Branch Fifth District, Coast Guard, telephone 757–398–6557, email *Michael.R.Thorogood@uscg.mil.*

SUPPLEMENTARY INFORMATION: The North Carolina Department of Transportation, who owns and operates the U.S. 70/Alfred A. Cunningham Bridge, has requested a temporary deviation from the current operating regulations set out in 33 CFR 117.843(a), to ensure the safety of the cyclists and spectators that are associated with the Multiple Sclerosis Society's Historic New Bern Bike Ride.

Under this temporary deviation, the bridge will be maintained in the closed position from 8 a.m. to 9:30 a.m. on Saturday, September 10, 2016, and from 8 a.m. to 9:30 a.m. on Sunday, September 11, 2016. The bridge is a double bascule drawbridge and has a vertical clearance in the closed position of 14 feet above mean high water.

The Trent River is used by small commercial vessels and recreational vessels. The Coast Guard has carefully considered the nature and volume of vessel traffic in publishing this temporary deviation.

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

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule 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: August 17, 2016.

Hal R. Pitts,

Bridge Program Manager, Fifth Coast Guard District.

[FR Doc. 2016–20232 Filed 8–23–16; 8:45 am]

BILLING CODE 9110–04–P