the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 117 have been approved under OMB control number 0910–0751.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/FoodGuidances or http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: *August 18, 2016.*

Jeremy Sharp,

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

[FR Doc. 2016–20177 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: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, we) proposes to amend 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. The proposed 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: Submit either electronic or written comments by November 7, 2016.

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, email: *david.edwards@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Proposed Rule

FDA proposes 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 revision is being proposed 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.

The proposed revisions would revise the category definitions such that they would be based only on whether a withdrawal period is required for a major species.[1] Under the proposed definition, a Category I Type A medicated article would 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 would move to Category II.

The purpose of the proposed revision is to preserve the present availability of medicated feeds intended for therapeutic use in minor species and to prevent a significant disincentive for future development of additional therapies for minor species. We believe the proposed 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 Proposed Rule

FDA proposes to amend 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

We are proposing these regulations based on our authority under the new animal drug provisions in section 512 (21 U.S.C. 360b) and section 701 (21 U.S.C. 371) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) 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 proposed rule are intended to preserve the availability of medicated feeds intended for therapeutic use in minor animal species. In addition, these proposed 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 proposing 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 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

[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.

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, we propose to revise the definitions of the two categories of new animal drugs used in medicated feeds in § 558.3 to base category assignment only on uses in major species. This proposed 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. Proposed Regulation

FDA proposes to amend 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 (Category I and Category II) of new animal drugs used in medicated feeds only on approved uses in major species. We further propose to amend § 558.3(b) by adding 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 proposing to revise the feed drug category definitions in § 558.3 to preserve the availability of medicated feeds intended for use in minor species and to prevent a likely disincentive for development of additional therapies for minor species.

IV. Companion Document to Direct Final Rulemaking

This proposed rule is a companion to the direct final rule published elsewhere in this issue of the **Federal Register**. FDA proposes to amend § 558.3(b)(1) to revise the definitions of Category I and Category II new animal drugs administered in medicated feed. This proposed rule is intended to make

noncontroversial changes to existing regulations. The Agency does not anticipate receiving any significant adverse comment 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 direct final rule. The direct final rule and this companion proposed rule are substantively identical. This 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 proposed rule runs concurrently with the comment period of the companion direct final rule. Any comments received in response to the companion direct final rule will also be considered as comments regarding this proposed rule.

FDA is providing a comment period for the proposed rule of 75 days after the date of publication in the **Federal Register**. If FDA receives a significant adverse comment, we intend to withdraw the 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 (5 U.S.C. 553).

Comments that are frivolous, insubstantial, or outside the scope of the proposed 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 proposed rule would not be considered a significant adverse comment unless the comment states why the proposed rule would be ineffective without the additional change.

If FDA does not receive significant adverse comment in response to the companion 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 on 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 proposing 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 proposed 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 proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule would not impose any compliance costs on the sponsors of animal drug products that are currently marketed or in development, we propose to certify that this proposed 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 proposing ''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 proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

This proposed 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 would be recategorized from Category II to Category I as a result of this proposed rule, if finalized. No compliance costs would 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 will 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 proposed 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 proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed 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 the proposed 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, it is proposed that part 558 be 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. 2016–20149 Filed 8–23–16; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 70

[EPA–HQ–OAR–2016–0194; FRL–9951–09–OAR]

RIN 2060–AS61

Revisions to the Petition Provisions of the Title V Permitting Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) proposes to revise its regulations to streamline and clarify processes related to submission and review of title V petitions. This notice covers five key areas, each of which should increase stakeholder access to and understanding of the petition process and aid the EPA's review of petitions. First, the EPA is proposing regulatory provisions that provide direction as to how petitions should be submitted to the agency. Second, the EPA is proposing regulatory provisions that describe the expected format and minimum required content for title V petitions. Third, the proposal clarifies that permitting authorities are required to respond to significant comments received during the public comment period for draft title V permits, and to provide that response with the proposed title V permit to the EPA for the agency's 45-day review period. Fourth, guidance is provided in the form of ''recommended practices'' for various stakeholders to help ensure title V permits have complete administrative records and comport with the requirements of the Clean Air Act (CAA or Act). Fifth, to increase familiarity with the post-petition process, this notice presents information on the agency's interpretation of certain title V provisions of the CAA and its implementing regulations regarding the steps following an EPA objection in response to a title V petition, as previously discussed in specific title V orders.

DATES: *Comments:* Comments must be received on or before October 24, 2016.

Public Hearing: If anyone contacts EPA requesting a public hearing on or before September 6, 2016, we will hold a public hearing. Additional information about the hearing would be published in a subsequent **Federal Register** notice.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2016–0194, to the *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, Cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Questions concerning these proposed rule revisions should be addressed to Ms. Carrie Wheeler, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Air Quality Planning Division, (C504–05), Research Triangle Park, NC 27711, telephone number (919) 541–9771, email at *wheeler.carrie@epa.gov.* To request a public hearing or information pertaining to a public hearing on the proposed regulatory revisions, contact Ms. Pamela Long, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Air Quality Policy Division, (C504–01), Research Triangle Park, NC 27711; telephone number (919) 541–0641; fax number (919) 541–5509; email address: *long.pam@epa.gov* (preferred method of contact).

SUPPLEMENTARY INFORMATION: The information presented in this document is organized as follows: