Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T–367 JOPES, AK TO CABGI, AK [NEW]

JOPES, AK	WP	(Lat. 62°03′33.30″ N, long. 163°17′07.68″ W)
WOMEV, AK	WP	(Lat. 62°18′43.29″ N, long. 162°57′55.67″ W)
JERDN, AK	WP	(Lat. 63°44′57.33″ N, long. 160°44′31.91″ W)
HALUS, AK	WP	(Lat. 64°41′43.78″ N, long. 162°04′03.53″ W)
FEMEP, AK	WP	(Lat. 65°14′24.15″ N, long. 160°58′41.58″ W)
JIGUM, AK	WP	(Lat. 65°59′34.37″ N, long. 161°56′53.01″ W)
Kotzebue, AK (OTZ)	VOR/DME	(Lat. 66°53′08.46″ N, long. 162°32′23.77″ W)
CABGI, AK	WP	(Lat. 68°52′16.94″ N, long. 166°04′50.37″ W)

* * * * *

Issued in Washington, DC, on January 3, 2022.

Scott M. Rosenbloom,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2022–00004 Filed 1–12–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA–2021–N–1326]

Scientific Data and Information Related to the Residue of Carcinogenic Concern for the New Animal Drug Carbadox; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public hearing on scientific data and information related to the residue of carcinogenic concern for the new animal drug carbadox, a carcinogenic new animal drug used in swine feed.

DATES: The public hearing will be held virtually on March 10, 2022, from 1 p.m. to 5 p.m., Eastern Time. Persons interested in attending this public hearing must register no later than 11:59 p.m. Eastern Time on March 9, 2022. Persons interested in making oral presentations and comments at the public hearing must submit requests by February 18, 2022. Submit either electronic or written comments on this hearing by April 11, 2022. See the **SUPPLEMENTARY INFORMATION** section for registration dates and information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 11, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 11, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2021–N–1326 for ''Scientific Data and Information Related to the Residue of Carcinogenic Concern for the New Animal Drug Carbadox; Public Hearing; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- 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 our 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Kelly Covington, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, *CarbadoxPublicHearing2022@fda.hhs.gov,* 240–402–5661.

SUPPLEMENTARY INFORMATION:

I. Background and Purpose of Hearing

Under the Delaney Clause (section 512(d)(1)(I) (21 U.S.C. 360b(d)(1)(I)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)), FDA generally cannot approve a new animal drug application (NADA) if the drug that is the subject of that application induces cancer in humans or animals. An exception to this general rule is commonly known as the Diethylstilbestrol ''DES'' Proviso, which allows for the approval of a carcinogenic new animal drug where FDA finds that under the approved conditions of use: (1) The drug will not adversely affect the animals treated with the drug and (2) no residues of the drug will be found by an approved regulatory method in any edible tissues of, or in any foods yielded by, the animal (section 512(d)(1)(I) of the FD&C Act).

On July 20, 2020, the Agency published a notice in the **Federal Register** proposing an order to revoke the approved method for detecting residues of carbadox, a carcinogenic new animal drug used in swine feed. (85 FR 43853, July 20, 2020; Docket No. FDA–2020–N–0955, ''Phibro Animal Health Corp.; Carbadox in Medicated Swine Feed; Revocation of Approved Method.'') The currently approved method measures quinoxaline-2-carboxylic acid (QCA) as a marker residue to detect the presence of the residue of carcinogenic concern. (Determination of Carbadox (as Quinoxaline-2-Carboxylic [QCA]) Residues in Swine Liver and Muscle Tissues After Drug Withdrawal, *https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room.*) The proposal to revoke the approved method for carbadox is based on CVM's determination that the method is inadequate to monitor residue of carcinogenic concern in compliance with FDA's regulations in part 500, subpart E (21 CFR part 500, subpart E). These regulations set out the requirements for demonstrating that no residues of the drug will be found by an approved regulatory method in any edible tissues of or in any foods obtained from the animal, as required to meet the requirements of the DES Proviso. The purpose of the public hearing is to gather additional data and information related to the residue of carcinogenic concern for the new animal drug carbadox.

II. Notice of Hearing Under 21 CFR Part 15

This public hearing will be held in accordance with part 15 (21 CFR part 15). Pursuant to § 15.1(a) and authority delegated from the Commissioner of Food and Drugs as referenced in the FDA Staff Manual Guide 1410.21(1)(B)(6) and (1)(D), the FDA Acting Chief Scientist concludes, as a matter of discretion, that it is in the public interest to permit persons to present information and views at a public hearing on this matter. The hearing will be conducted by a presiding officer, who will be accompanied by other United States Government employees serving as a panel in conducting the hearing. Under § 15.30(f), the hearing is informal, and the rules of evidence do not apply. Only the presiding officer and panel members can pose questions; they can question any person during or at the conclusion of each presentation. To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

III. Topics for the Public Hearing

We encourage public comments and presentations at the public hearing. We are particularly interested in receiving comments, data, and information about the topics listed below. In submitting comments, data, and information to the docket, please identify available references for the data and information, as well as the specific item number listed below, if applicable. Please reference, but do not resubmit, any information already contained in Docket No. FDA–2020–N–0955, ''Phibro Animal Health Corp.; Carbadox in Medicated Swine Feed; Revocation of Approved Method.''

1. Data to inform our knowledge of the residue of carcinogenic concern not summarized in the Freedom of Information summary for the 1998 supplemental approvals, including additional data regarding the fraction of noncarcinogenic residues in the total radiolabeled residues of carbadox.

2. For any given concentration of a marker residue, the corresponding concentration of the residue of carcinogenic concern.

3. Additional information not already contained in Docket No. FDA–2020–N–0955, ''Phibro Animal Health Corp.; Carbadox in Medicated Swine Feed; Revocation of Approved Method'' related to the adequacy of the current approved method to measure QCA as a marker residue for the residue of carcinogenic concern for the new animal drug carbadox.

4. Any method, other than the current approved method, that demonstrates ''no residue'' for the new animal drug carbadox in conformance with part 500, Subpart E.

5. Detailed information on the conduct and quality of studies providing data to support the points above, including information on the extraction process and the stability of residues being analyzed.

IV. Participating in the Public Hearing

Registration: To register to attend the virtual public hearing, on ''Scientific Data and Information Related to the Residue of Carcinogenic Concern for the New Animal Drug Carbadox; Public Hearing; Request for Comments'' please register at *https://fda.zoomgov.com/j/1600135012?pwd=MFdjMW9FRXg4RGllc3FHWVhkWVAyZz09* by March 9, 2022. If you have any questions, you can contact *CarbadoxPublicHearing2022@fda.hhs.gov* (See **DATES** and **ADDRESSES**). Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Request for Oral Presentations: During online registration, you may indicate if you wish to make a formal presentation (with accompanying slide deck) or present oral comments during the public hearing session (with no slide deck). If you decide you wish to make a presentation after registering online, you may submit a request to *CarbadoxPublicHearing2022@fda.hhs.gov.* All requests to make presentations must be received by February 18, 2022. FDA will do its best to accommodate requests to make public presentations. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations. FDA will determine the amount of time allotted to each presenter and the approximate time each presentation is to begin and will select and notify participants by February 23, 2022.

If selected for a formal oral presentation (with a slide deck), each presenter must submit an electronic copy of their presentation (PowerPoint or PDF) to *CarbadoxPublicHearing2022@fda.hhs.gov* with the subject line ''Scientific Data and Information Related to the Residue of Carcinogenic Concern for the New Animal Drug Carbadox; Public Hearing; Request for Comments'' on or before March 4, 2022. No commercial or promotional material will be permitted to be presented or distributed at the public hearing.

Persons notified that they will be presenters are encouraged to be online early. Actual presentation times may vary based on how the hearing progresses in real time. An agenda for the hearing and any other background materials will be made available no later than 5 days before the hearing at *https://www.fda.gov/animal-veterinary/workshops-conferences-meetings/part-15-public-hearing-scientific-data-and-information-related-residue-carcinogenic-concern-new.*

Transcripts: Please be advised that as soon as a transcript of the public hearing is available, it will be accessible at *https://www.regulations.gov.* It may also be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the Agency's website at *https://www.fda.gov/animal-veterinary/workshops-conferences-meetings/part-15-public-hearing-scientific-data-and-information-related-residue-carcinogenic-concern-new.*

Dated: January 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–00475 Filed 1–12–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Part 559

RIN 3141–AA76

Facility License; Correction

AGENCY: National Indian Gaming Commission, Department of the Interior.

ACTION: Proposed rule; correction.

SUMMARY: This document corrects the preamble to a proposed rule published in the **Federal Register** of December 1, 2021, regarding Facility Licenses. The document contained incorrect dates for submitting comments. This correction clarifies that comments are due January 31, 2022.

FOR FURTHER INFORMATION CONTACT: Michael Hoenig, 202–632–7003.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of December 1, 2021, in FR Doc. 2021–25845, on page 68200, in the third column, change the **DATES** caption to read:

DATES: Written comments on this proposed rule must be received on or before January 31, 2022.

Dated: January 6, 2022.

Michael Hoenig,

General Counsel.

[FR Doc. 2022–00625 Filed 1–12–22; 8:45 am]

BILLING CODE 7565–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2021–0428; FRL–9374–01–R4]

Finding of Failure To Attain the 2010 Sulfur Dioxide Standard; Tennessee; Sullivan County Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to determine that the Sullivan County, Tennessee sulfur dioxide (SO_2) nonattainment area failed to attain the 2010 1-hour SO_2 primary National Ambient Air Quality Standard (NAAQS or standard) by the applicable attainment date of October 4, 2018, based upon a weight of evidence analysis of available quality-assured and certified SO_2 ambient air monitoring data and SO_2 emissions data from January 2015 through December 2017. If EPA finalizes this determination as proposed, the State of Tennessee will be required to submit revisions to the Tennessee State Implementation Plan (SIP) that, among other elements, provide for expeditious attainment of the 2010 SO_2 standard.

DATES: Comments must be received on or before February 14, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2021–0428 at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* 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 whose disclosure 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. 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 *https://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Evan Adams, Air Regulatory