

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.

Submit written requests for single copies of the guidance to the Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Katherine Collins, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002, 1-877-287-1373, email: [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a revised guidance for industry entitled "Health Document Submission Requirements for Tobacco Products."

The revised guidance includes guidance for manufacturers or importers of newly deemed tobacco products that are subject to chapter IX of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 387). Cigarettes, cigarette tobacco, roll-your-own, and smokeless tobacco were immediately subject to chapter IX of the FD&C Act, including section 904(a)(4), which requires the submission of certain health documents. Section 901(b) of the FD&C Act grants FDA authority to deem all other tobacco products subject to chapter IX of the FD&C Act as well. Pursuant to that authority, FDA issued a final rule deeming all other products that meet the statutory definition of "tobacco product," set forth in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), except for accessories of those products, subject to the Chapter IX of the FD&C Act (81 FR 28973). FDA published the final rule on May 10, 2016 (81 FR 28973) and it became effective on August 8, 2016. Therefore, manufacturers and importers of such tobacco products are now required to comply with chapter IX of the FD&C Act, including section 904(a)(4).

**II. Significance of Guidance**

FDA is issuing this guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on health document submission requirements. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

**III. Paperwork Reduction Act of 1995**

This guidance also refers to previously approved collections of information found in FDA statute. The guidance includes information and recommendations for how to provide health document submissions. The collections of information in section 904(a)(4) of the FD&C Act have been approved under OMB control number 0910-0654.

**IV. Electronic Access**

Persons with access to the Internet may obtain an electronic version of the guidance at either <http://www.regulations.gov> or <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>.

Dated: November 29, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-29117 Filed 12-2-16; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-1999-D-1875]

**Compliance Policy Guide Sec. 615.115 on Extralabel Use of Medicated Feeds for Minor Species; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised Compliance Policy Guide (CPG) 615.115 entitled "Extralabel Use of Medicated Feeds for Minor Species." In advance of the January 1, 2017, date on which we anticipate that a number of drugs will convert from over-the-counter (OTC) to veterinary feed directive (VFD) status, this revised CPG clarifies policy and regulatory action guidance to FDA staff on the Agency's exercise of regulatory discretion with regard to the extralabel use of medicated feeds containing those drugs in minor species.

**DATES:** The Agency is soliciting public comment, but is implementing this CPG immediately because the Agency has determined that prior public participation is not feasible or appropriate. You may submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** You may submit comments as follows:

*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):* 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-1999-D-1875 for “Compliance Policy Guide Sec. 615.115 Extralabel Use of Medicated Feeds for Minor Species.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://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 <https://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 <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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the CPG to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the CPG.

**FOR FURTHER INFORMATION CONTACT:** Amber McCoig, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5556, [Amber.McCoig@fda.hhs.gov](mailto:Amber.McCoig@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The revised CPG is intended to clarify policy and regulatory action guidance to FDA staff on the Agency’s exercise of regulatory discretion with regard to the extralabel use of medicated feed in minor species. We are implementing this CPG without prior public comment because we have determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)). Although this CPG is immediately in effect, it remains subject to comment in accordance with FDA’s good guidance practices regulation.

The treatment of minor species is especially challenging for two reasons. First, many minor species, such as fish and game birds, have very few drugs approved for their use. As a result, veterinarians often times have to treat these species in an extralabel manner, using drugs that are not approved for them. Further, some minor species cannot practically be medicated in any way other than through the use of medicated feeds. Because extralabel use of medicated feeds is not permitted, veterinarians face an additional challenge to prevent unnecessary suffering and death of minor species.

In 2001, FDA published CPG 615.115 to provide guidance to FDA staff concerning the Agency’s exercise of regulatory discretion with regard to the extralabel use of medicated feeds in minor species. The CPG was silent regarding the different marketing statuses of medicated feeds and did not explicitly address situations involving feeds containing VFD drugs.

In the **Federal Register** of December 12, 2013, FDA announced Guidance for Industry (GFI) #213 entitled “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 Guidance for Industry #209” (78 FR 75570). As a result of GFI #213, FDA anticipates that, beginning January 1, 2017, a number of drugs, including some drugs used in medicated feeds, will convert from OTC marketing status to VFD marketing status. As this conversion occurs, drugs that previously were available OTC for producers and veterinarians for use in medicated feed will become VFD drugs. Because the current CPG is silent regarding the different marketing statuses of medicated feeds, to avoid potential confusion and harm to minor species requiring treatment with certain drug products converting from OTC to VFD, the Agency has decided to revise CPG 615.115 to explicitly clarify our intent to exercise regulatory discretion over both OTC and VFD feeds. In order to inform stakeholders before January 1, 2017, of the Agency’s expectations regarding the extralabel use of VFD feeds in minor species, we are implementing this CPG immediately. We are soliciting public comment on this CPG, but immediate implementation will give stakeholders the opportunity to operate under the provisions of this CPG before they submit comments.

**II. Significance of Guidance**

This CPG is being issued as a level 1 guidance for FDA staff consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The CPG represents the current thinking of FDA on the extralabel use of medicated feeds for minor species. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

##### III. Electronic Access

Persons with access to the Internet may obtain the CPG at either <http://www.fda.gov/AnimalVeterinary/>

*GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or <http://www.regulations.gov>.

Dated: November 18, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-29133 Filed 12-2-16; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2016-E-0617; FDA-2016-E-0619]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; BEXSERO

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for BEXSERO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

**DATES:** Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by February 3, 2017. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 5, 2017. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** You may submit comments as follows:

#### *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):* 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 Nos. FDA-2016-E-0617 and FDA-2016-E-0619 for "Determination of Regulatory Review Period for Purposes of Patent Extension; BEXSERO." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://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 <https://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 <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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award