drug labeling under the PLR (21 CFR 201.57(c)(13)) and provides guidance on the inclusion of clinical recommendations based on clinical pharmacology findings in other sections of the labeling. The guidance is also intended to ensure consistency, as appropriate, in labeling of the CLINICAL PHARMACOLOGY section for all prescription drug products approved by FDA.

This guidance provides a general framework and set of recommendations that should be adapted to specific drugs and their conditions of use. Not all of the information identified in this guidance for inclusion in the CLINICAL PHARMACOLOGY section of product labeling will be applicable for every drug. For the purposes of this notice, all references to drugs include both human drugs and biological products unless otherwise specified.

The guidance outlines the use of subsections, headings, and subheadings to provide organization for the CLINCAL PHARMACOLOGY section in labeling. The guidance also emphasizes the importance of providing variability measures related to pharmacokinetic measures and parameters, pharmacodynamic measures, and other clinical pharmacology study results.

In addition to clarifications and edits throughout the guidance on various subsections of section 12, some notable changes from the revised draft guidance include:

- Addressing whether applicants are expected to revise current approved labeling if reserved sections 12.4 and 12.5 have already been used for other topics, and
- Providing revised recommendations on the inclusion of pregnancy and lactation information to be consistent with recommendations in FDA's ''Pregnancy and Lactation Labeling Rule'' (*https://www.federalregister.gov/documents/2014/12/04/2014-28241/content-and-format-of-labeling-for-human-prescription-drug-and-biological-products-requirements-for*) (December 2014) and draft guidance for industry entitled ''Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products—Content and Format'' (*http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm425398.pdf*) (December 2014).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on inclusion of clinical pharmacology information in section 12 CLINICAL PHARMACOLOGY of product labeling. 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 requirement of the applicable statutes and regulations.

III. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572; the collections of information related to pharmacogenomic data have been approved under OMB control number 0910–0557.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov.*

Dated: November 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–29125 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–2009–D–0600]

Health Document Submission Requirements for Tobacco Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a revised guidance for industry entitled ''Health Document Submission Requirements for Tobacco Products.'' The guidance provides information to assist persons making health document submissions to FDA as required by the Family Smoking Prevention and Tobacco Control Act. We received several comments to the draft guidance, and those comments were considered as the guidance was finalized.

DATES: 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: 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–2009–D–0600 for ''Health Document Submission Requirements for Tobacco Products.'' 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.

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.*

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