the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Mai Huynh, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0669, *mai.huynh@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry GFI #286 (VICH GL60) entitled ''Good Manufacturing Practice for Active Pharmaceutical Ingredients Used in Veterinary Medicinal Products.'' The objective of this guidance is to provide recommendations regarding GMP for the manufacturing of APIs under an appropriate system for managing quality. It is also intended to help ensure that APIs meet the requirements for quality and purity that they purport or are represented to possess.

FDA has participated in efforts to enhance international harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify, and then reduce, differences in technical requirements for drug development among regulatory agencies in different countries. FDA has actively participated in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission and European Medicines Agency; AnimalhealthEurope; FDA—Center for Veterinary Medicine and U.S. Department of Agriculture—Center for Veterinary Biologics; the U.S. Animal Health Institute; the Japanese Ministry of Agriculture, Forestry and Fisheries; and the Japanese Veterinary Products Association. There are 10 observers to the VICH Steering Committee: one representative from government and one representative from industry of Australia, New Zealand, Canada, South Africa, and the United Kingdom. The World Organisation for Animal Health is an associate member of the VICH. The VICH Secretariat, which coordinates the preparation of documentation, is provided by HealthforAnimals.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Good Manufacturing Practice for Active Ingredients Used in Veterinary Medicinal Products.'' 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032; and the collections of information in section 512(n)(1) of the FD&C Act (21 U.S.C. 360b(n)(1)) have been approved under OMB control number 0910–0669.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: January 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–01441 Filed 1–24–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0092]

Revising Abbreviated New Drug Application Labeling Following Revision of the Reference Listed Drug Labeling; Final Guidance for Industry; 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 final guidance for industry entitled ''Revising ANDA Labeling Following Revision of the RLD Labeling.'' This guidance provides recommendations for updating labeling for abbreviated new drug applications (ANDAs) following revisions to the labeling of a reference listed drug (RLD), including information on how to identify RLD labeling updates and how to submit labeling updates to both unapproved and approved ANDAs to conform to RLD labeling updates. This guidance finalizes the draft guidance for industry of the same title issued on January 27, 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on January 25, 2024.

ADDRESSES: You may submit electronic or written comments on Agency guidance at any time 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):* 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–2022–D–0092 for ''Revising ANDA Labeling Following Revision of the RLD Labeling.'' 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 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 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 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jonathan Hughes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1688, Silver Spring, MD 20993–0002, 301–796–9291, *Jonathan.Hughes@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Revising ANDA Labeling Following Revision of the RLD Labeling.'' This guidance provides recommendations for updating labeling for ANDAs following revisions to the labeling of an RLD, including information on how to identify RLD labeling updates and how to submit labeling updates to both unapproved and approved ANDAs to conform to RLD labeling updates.

A generic drug is generally required to have the same labeling as the RLD, except for changes required because of differences approved under a suitability petition (see section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)) (21 U.S.C. 355(j)(2)(C) and 21 CFR 314.93) or because the generic drug and the RLD are produced or distributed by different manufacturers (see *e.g.,* section 505(j)(2)(A)(v) of the FD&C Act and § 314.94(a)(8)(iv) (21 CFR 314.94(a)(8)(iv))). FDA will refuse to approve an ANDA if, among other things, it does not include such information regarding the proposed labeling (see *e.g.,* § 314.127(a)(7)). FDA regulations provide examples of permissible differences in labeling that may result when a proposed generic drug and the RLD are ''produced or distributed by different manufacturers,'' including the omission of an indication or other aspect of labeling protected by patent or exclusivity and ''labeling revisions made to comply with current FDA labeling guidelines or other guidance'' (§ 314.94(a)(8)(iv)).

An ANDA holder is expected to update its labeling after FDA has approved relevant changes to the labeling for the corresponding RLD. Prompt revision, submission to the Agency, and implementation of revised labeling are important to ensure that the generic drug continues to be as safe and effective as the corresponding RLD. Because the labeling of a generic drug must be the same as the labeling for the RLD, except for permissible differences, the revision should be made at the earliest time possible.

In this guidance, FDA is providing information on how ANDA applicants and holders should monitor for changes to RLD labeling, procedures for the electronic submission of labeling updates, information describing the type of submission that should be made to FDA, as well as other considerations for submitting a labeling update to FDA.

This guidance finalizes the draft guidance for industry of the same title issued on January 27, 2022 (87 FR 4252). The January 2022 draft guidance revised the final guidance for industry entitled ''Revising ANDA Labeling Following Revision of the RLD Labeling'' issued in April 2000. FDA considered comments received on the January 2022 draft guidance as the guidance was finalized. Minor revisions from the draft to the final guidance were made to improve clarity.

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 ''Revising ANDA Labeling Following Revision of the RLD 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 requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521).

The collections of information in part 314 (21 CFR part 314) for the submission of ANDAs (including the content and format of ANDAs and supplements and amendments) have been approved under OMB control number 0910–0001 and in part 314 (included under the 21 CFR parts 10 through 16 hearing regulations) under OMB control number 0910–0191.

The collections of information pertaining to the electronic submission of labeling changes have been approved under OMB control number 0910–0045. The collections of information pertaining to the content and format requirements for human prescription

drugs and biological products and the submission of such labeling have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: January 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–01442 Filed 1–24–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–E–0448]

Determination of Regulatory Review Period for Purposes of Patent Extension; VOCABRIA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for VOCABRIA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application 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 drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by March 25, 2024. 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 July 23, 2024. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 25, 2024. 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–2022–E–0448 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; VOCABRIA.'' 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 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 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 § 10.20 (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: 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 or biologic product, animal drug product, medical device, food additive, or color additive) was subject to