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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-D-7233]

Target Animal Safety Evaluation for Veterinary Monoclonal Antibody Products; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GFI) #298 (VICH GL62) titled "Target Animal Safety Evaluation for Veterinary Monoclonal Antibody Products." This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft guidance contributes to the international harmonization of methods used for the target animal safety (TAS) evaluation of veterinary monoclonal antibody products (VMAPs) and aids in preparing and conducting VMAP TAS studies under laboratory and field conditions. A harmonized standard is intended to aid in development of mutually acceptable VMAP TAS programs.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any 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-2026-D-7233 for "Target Animal Safety Evaluation for Veterinary Monoclonal Antibody Products; Draft Guidance for Industry; Availability." 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 Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740. Send one self-addressed adhesive label to assist that office in

processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Joy Rachel Ganchingco, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, 301-837-7327, joyrachel.ganchingco@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft GFI #298 (VICH GL62) titled "Target Animal Safety Evaluation for Veterinary Monoclonal Antibody Products."

Currently, no VICH GL specifically supports marketing applications for VMAPs in the regions participating in the VICH. The VICH GLs available for TAS (i.e., VICH GL43 for pharmaceutical products and VICH GL44 for vaccines) do not fully address the TAS evaluation for a VMAP. Furthermore, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) S6 (R1) for the preclinical safety evaluation of biotechnology-derived pharmaceuticals is not fully applicable to VMAPs. Hence, there is a need for specific guidance on the TAS evaluation of a VMAP. Therefore, this guideline summarizes scientifically acceptable general principles for the TAS evaluation of a VMAP and should be used in conjunction with VICH GL43.

This guideline is for VMAPs intended for use in companion animals and livestock animals. The active ingredient of a VMAP is a monoclonal antibody (mAb) or a mAb fragment, which could be engineered to be specific for a target animal and target(s). When needed, advice should be sought from the relevant regulatory authority for specific guidance on the design of the TAS study(ies) prior to their initiation or if the applicant determines an alternative approach to the TAS evaluation of a VMAP may be more appropriate.

FDA has participated in efforts to enhance 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 Conference on Harmonization of Technical Requirements for Approval of 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 goal of the VICH is to develop harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and receives input from both regulatory and industry representatives.

The VICH Steering Committee is composed of founding member representatives from the European Commission and European Medicines Agency; AnimalhealthEurope; FDA's Center for Veterinary Medicine; U.S. Department of Agriculture's 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 standing members to the VICH Steering Committee: 1 representative from government and 1 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 level 1 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 "Target Animal Safety Evaluation for Veterinary Monoclonal Antibody 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.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

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 section 512(n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(n)(1)) and in 21 CFR part 514 have been approved under OMB control number 0910-0032. The collections of information in 21 CFR part 511 have been approved under OMB control number 0910-0117.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.regulations.gov.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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