

CDC to conduct surveillance and monitoring of disease trends. CDC used current evidence to draft the proposed Laboratory Recommendations for Syphilis Testing in the United States to improve laboratory testing for syphilis and aid laboratorians and clinicians in the diagnosis of the disease.

Dated: March 31, 2023.

Tiffany Brown,

Acting Executive Secretary, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-D-0592]

Human User Safety in New and Abbreviated New Animal Drug Applications; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry #278 (GFI #278) entitled “Human User Safety in New and Abbreviated New Animal Drug Applications.” Human User Safety (HUS) is an integral component of the overall safety evaluation of proposed new animal drugs. FDA is issuing this guidance to clarify the current approaches and recommendations of FDA’s Center for Veterinary Medicine (CVM) for HUS assessment and submission of HUS information to support the overall safety of proposed new animal drugs prior to approval.

DATES: Submit either electronic or written comments on the draft guidance by June 5, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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-2023-D-0592 for “Human User Safety in New and Abbreviated New Animal Drug Applications.” 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 (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. 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: Karen Sussman, Center for Veterinary Medicine (HFV-114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0876, karen.sussman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of draft GFI #278 entitled “Human User Safety in New and Abbreviated New Animal Drug Applications.” This draft guidance is intended for sponsors interested in pursuing the approval, or conditional approval, of new animal drugs (including new generic animal drugs). This guidance addresses general principles of HUS assessment for new animal drugs, sources of data, mitigation strategies for proposed new animal drugs, potential recommendations to address HUS concerns, and how HUS information should be submitted to CVM.

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 “Human User Safety in New and Abbreviated New Animal Drug Applications.” 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 511 have been approved under OMB control number 0910–0117; in 21 CFR part 514 have been approved under OMB control numbers 0910–0032 and 0910–0284; in 21 CFR part 516 have been approved under OMB control numbers 0910–0605 and 0910–0620; and in section 512(n)(1) of the Federal Food, Drug, and Cosmetic 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: March 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; The National Health Service Corps and Nurse Corps Interest Capture Form—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA’s ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than May 5, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call 301–594–4394.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The National Health Service Corps and Nurse Corps Interest Capture Form OMB No. 0915–0337—Revision.

Abstract: The National Health Service Corps (NHSC) and the Nurse Corps Scholarship and Loan Repayment Programs of HRSA are both committed to improving the health of the nation’s underserved by uniting communities in need with caring health professionals and by supporting communities’ efforts to build better systems of care. The NHSC and Nurse Corps Interest Capture Form, which can be accessed on the HRSA website at <https://bhwh.hrsa.gov/about-us/ask-question>, is an optional form that a health profession student, licensed clinician, faculty member, clinical site administrator, or other interested individual can complete and submit to HRSA online. The purpose of the form is to enable individuals and clinical sites to ask questions about the NHSC and/or Nurse Corps Scholarship and Loan Repayment Programs, and to provide their contact information so that HRSA may provide them with periodic program updates and other general information via email. Completed forms

will contain information such as the names and roles of the individual(s), their phone number(s) and email address(es), and the HRSA program(s) in which they are interested or about which they have questions.

The revisions in this ICR are as follows:

a. The discontinuation of the print version of the NHSC and Nurse Corps Interest Capture Form, previously used by HRSA staff for sharing HRSA program information with health profession students and providers at national and regional conferences and campus recruiting events.

b. The addition of an online version of the NHSC and Nurse Corps Interest Capture Form, located on the HRSA website at <https://bhwh.hrsa.gov/about-us/ask-question>.

A 60-day notice published in the **Federal Register** on January 11, 2023, vol. 88, No. 7; pp. 1600–01. There were no public comments.

Need and Proposed Use of the Information: The need and purpose of this information collection is to share resources and information regarding the NHSC and Nurse Corps Scholarship and Loan Repayment Programs with interested HRSA website (<https://www.hrsa.gov/>) visitors.

Likely Respondents: Individuals and potential service sites interested in the NHSC or Nurse Corps Scholarship and Loan Repayment Programs.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.