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 guidance document.

FOR FURTHER INFORMATION CONTACT: Aimée Phillippi-Taylor, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, 240–402–0601, *aimee.phillippi-taylor@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of final GFI #113 (VICH GL20) entitled ''Effectiveness of Anthelmintics: Specific Recommendations for Felines.'' It should be read in conjunction with GFI #90 (VICH GL7), ''Effectiveness of Anthelmintics: General Recommendations,'' which should be referred to for discussion of broad aspects for providing pivotal data to demonstrate product anthelmintic effectiveness. The purpose of this guidance is: (1) to be more specific for certain specific feline issues not discussed in GFI #90 (VICH GL7); (2) to highlight differences with GFI #90 (VICH GL7) on effectiveness data recommendations; and (3) to give explanations for disparities with GFI #90 (VICH GL7). 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 founding 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 standing members 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.

In the **Federal Register** of August 12, 2022 (87 FR 49855), FDA published the notice of availability for a draft guidance entitled ''International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Effectiveness of Anthelmintics: Specific Recommendations for Felines (Revision 1); Draft Guidance for Industry; Availability'' giving interested persons until October 11, 2022, to comment on the draft guidance. After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the VICH Steering Committee and endorsed by the regulatory agencies in October 2024. The guidance announced in this notice finalizes the draft guidance dated August 2022.

This VICH guidance document is intended to provide study design recommendations that will facilitate the universal acceptance of the generated effectiveness data to fulfill the national/regional requirements for anthelmintic drugs in animal species.

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 Effectiveness of Anthelmintics: Specific Recommendations for Felines. 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 21 CFR part 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the 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.

[FR Doc. 2026–12685 Filed 6–23–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–D–6539]

Quantitative Systems Pharmacology (QSP)-Based Dose Selection for Minimum Anticipated Biological Effect Level (MABEL) in First-in-Human (FIH) Trials; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled ''Quantitative Systems Pharmacology (QSP)-Based Dose Selection for Minimum Anticipated Biological Effect Level (MABEL) in First-in-Human (FIH) Trials.'' The guidance is intended to provide recommendations in the application of quantitative systems pharmacology (QSP) modeling when a minimum anticipated biological effect level (MABEL) in first-in-human (FIH), phase 1 trials for drugs and biological products is recommended. This guidance focuses on drugs and biological products for which the MABEL approach can be used to guide starting doses for FIH trials. This includes, but is not limited to, drugs and biological products that may cause cytokine release, T-cell activation, or other potent pharmacological reactions.

DATES: Submit either electronic or written comments on the draft guidance by July 24, 2026 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–6539 for ''Quantitative Systems Pharmacology (QSP)-Based Dose Selection for Minimum Anticipated Biological Effect Level (MABEL) in First-in-Human (FIH) Trials.'' 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 draft 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Qi Liu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993, *Qi.Liu@fda.hhs.gov,* 301–796–1568.

SUPPLEMENTARY INFORMATION:

I. Background

Historically, FIH starting doses were often derived from animal toxicology studies and have been based on the highest non-adverse effect level observed in animals (NOAEL), highest severely toxic doses in 10% of rodents (STD10), or highest non-severely toxic doses in non-rodent species (HNSTD), converted to a human equivalent dose. Although these approaches have been appropriate for many drugs and biological products, there are limitations for certain high-risk products (*e.g.,* immunostimulatory monoclonal antibodies). In response, the concept of MABEL was developed. MABEL is defined as a dose expected to produce a minimal biological effect in humans. Determining MABEL typically involves using pharmacologic activity and receptor binding data (human cell lines), while also integrating any other relevant data (*e.g.,* animal safety and pharmacokinetic data), as appropriate, to predict a dose that is just at the onset of biological activity.

QSP has emerged as a tool to model disease progression and complex drug–biological system interactions. QSP merges an understanding of biological systems and a drug's exposure-response, enabling modeling and simulation of how a drug engages its target and triggers downstream biological responses in a mechanistic, quantitative manner. Over the past decade, there has been a notable increase in regulatory submissions (*e.g.,* investigational new drug applications (INDs), biologics license applications (BLAs), and new drug applications (NDAs)) that include QSP modeling to support various decisions, such as informing FIH dose selection, particularly for drugs and biological products where traditional methods may fall short. For example, certain drugs and biological products have highly specific targets that only exist in humans and can elicit steep pharmacodynamic responses (*e.g.,* cytokine release or T-cell activation) that are difficult to predict from animal studies alone. In many cases, the relevant target may be absent or differently expressed in animal species, limiting the translational relevance of animal toxicity data. Standard allometric scaling of doses also might not account for such pharmacological differences. Therefore, a model-based approach that considers all available data (*e.g.,* in vitro, in vivo, disease progression, clinical experience from

compounds with both similar structure and similar mechanism of action, and in silico) may be more appropriate to estimate a starting dose in the FIH trial. In addition, QSP modeling may derive potential efficacy- and safety-related information and balance them in a quantitative manner to inform FIH dose selection. This guidance specifically addresses those needs by outlining how QSP models can be developed and used to estimate a MABEL for drugs and biological products entering FIH trials.

This 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 ''Quantitative Systems Pharmacology (QSP)-Based Dose Selection for Minimum Anticipated Biological Effect Level (MABEL) in First-in-Human (FIH) Trials.'' 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 document contains no new collections 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 21 CFR part 312, including the submission of rationale and dose determination, as set forth in part 312.23; the submission of detailed technical information, as set forth in part 312.31; and the submission of meeting requests and supporting documentation, as set forth in part 312.47, have been approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the internet may obtain the draft 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.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–12619 Filed 6–22–26; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Council of Councils.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Council of Councils.

Date: July 13, 2026.

Time: 03:00 p.m. to 04:00 p.m.

Agenda: To review and evaluate grant applications.

Address: Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, National Institutes of Health, Building 1, Room 260, 1 Center Drive, Bethesda, MD 20892.

Meeting Format: Virtual.

Contact Person: Robin I. Kawazoe, Deputy Director, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, National Institutes of Health, Building 1, Room 260, 1 Center Drive, Bethesda, MD 20892, 301–402–9852, *kawazoer@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Council of Council's home page: *http://dpcpsi.nih.gov/council/* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: June 18, 2026.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–12617 Filed 6–23–26; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2026 Notice of Supplemental Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, Department of Health and Human Services (HHS).

ACTION: Notice of intent to award supplemental funding.

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) is supporting an administrative supplement in scope of the parent award for one eligible grant recipient funded in FY 2024 under the Prevention Technology Transfer Centers Cooperative Agreements, Notice of Funding Opportunity (NOFO) SP–24–002. The recipient may receive up to $1,198,000. The recipient has a project end date of September 29, 2029. The supplemental funding supports the implementation of a substance use prevention fellowship program. The program will be developed in collaboration with national-level state and community organizations and aims to develop and sustain a highly trained and knowledgeable workforce of prevention professionals drawn from communities that have faced challenges in maintaining sufficient prevention staffing to meet the full scope of community needs. Fellows will be equipped to understand, apply, and exemplify the core principles and evidence-based best practices of substance use prevention. This program will support a state level fellowship program and a community level program. This program will also prepare fellows to achieve certification from the International Certification and Reciprocity Consortium (IC&RC). The supplemental funding will support fellows in the following areas: hands-on experience working in state agencies and community organizations while