

741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. On June 18, 2026, the Committee will meet in open session to discuss and make recommendations on the safety and effectiveness of MFLUSIVA (Influenza Vaccine, mRNA), manufactured by Moderna TX Inc., with a requested indication in Biologics License Application STN 125869/0 for the prevention of influenza disease caused by influenza virus subtypes A and type B represented in the vaccine, in persons 50 years of age and older.

FDA intends to make background material available to the public no later than two (2) business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before June 12, 2026, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 1:00 p.m. and 2:00 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief

statement of the general nature of the evidence or arguments they wish to present, along with the names, email addresses, and direct contact phone numbers of proposed participants, and an indication of the approximate time requested to make their presentation on or before 12 p.m. Eastern Time on June 8, 2026. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by 6 p.m. Eastern Time on June 10, 2026.

For press inquiries, please contact the HHS Press Room at www.hhs.gov/press-room/index.html or 202–690–6343. FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Cicely Reese at CBERVERBPAC@fda.hhs.gov (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–10321 Filed 5–21–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–3054]

M11 Clinical Electronic Structured Harmonised Protocol (CeSHarP); International Council for Harmonisation; 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 “M11 Clinical Electronic Structured Harmonised Protocol (CeSHarP).” The guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The guidance includes three documents: a guidance, a template, and a technical specification document. The guidance provides the rationale and recommendations for implementing a harmonized digital clinical trial protocol. The template features standardized content structure and formatting, including headers and common text elements. The technical specification document contains harmonized terminologies and standardized data fields to enable electronic exchange of clinical protocol information. The intent of the guidance is to create an internationally harmonized standard for the content and exchange of clinical trial protocol information, facilitating the review and assessment by regulators, sponsors, ethical oversight bodies, investigators, and other stakeholders. This guidance finalizes the draft guidances “M11 Clinical Electronic Structured Harmonised Protocol (CeSHarP)” issued on December 22, 2022 (87 FR 78696), and “M11 Technical Specification: Clinical Electronic Structured Harmonised Protocol” issued on June 6, 2025 (90 FR 24146).

DATES: The announcement of the guidance is published in the **Federal Register** on May 22, 2026.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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-3054 for "M11 Clinical Electronic Structured Harmonised Protocol (CeSHarP)." 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 this 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:

Regarding the guidance: Y. Veronica Pei, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6462, Silver Spring, MD 20993-0002, 240-402-7091, YangVeronica.Pei@fda.hhs.gov; or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240-402-7911.

Regarding the ICH: Brooke Dal Santo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6304, Silver Spring, MD 20993-0002, 301-348-1967, Brooke.DalSanto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "M11 Clinical Electronic Structured Harmonised Protocol (CeSHarP)." The guidance was prepared under the auspices of ICH. ICH seeks to achieve greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines enhance global drug development, improve manufacturing standards, and increase the availability of medications. For example, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, and standardized marketing application submissions.

The six Founding Members of the ICH are the FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. ICH membership continues to expand to include other regulatory authorities and industry associations from around the world (refer to <https://www.ich.org/>).

ICH works by engaging global regulatory and industry experts in a detailed, science-based, and consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In the **Federal Register** of December 22, 2022 (87 FR 78696), FDA published a notice announcing the availability of a draft guidance entitled "M11 Clinical Electronic Structured Harmonised

Protocol (CeSHarP).” The notice gave interested persons an opportunity to submit comments by February 21, 2023.

In the **Federal Register** of June 6, 2025 (90 FR 24146), FDA published a notice announcing the availability of a revised draft guidance entitled “M11 Technical Specification: Clinical Electronic Structured Harmonised Protocol.” The notice gave interested persons an opportunity to submit comments by July 7, 2025.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agencies in November 2025.

This guidance finalizes the draft guidances issued on December 22, 2022, and June 6, 2025. The guidance provides harmonized and comprehensive technical recommendations for clinical trial protocol through three key documents: the guidance, which provides the rationale and recommendations for implementing a harmonized digital clinical trial protocol; a standardized protocol template featuring standardized content structure and formatting, including headers and common text elements; and a technical specification document containing harmonized terminologies and standardized data fields to enable electronic exchange of clinical protocol information. Revisions were made to all documents addressing public comments and providing greater clarity to key terms and scope.

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 “M11 Clinical Electronic Structured Harmonised Protocol (CeSHarP).” 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 312 pertaining to clinical trial design and protocols have been approved under OMB control number 0910–0014.

III. Electronic Access

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

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–10295 Filed 5–21–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0567]

Notice of Decision Not To Designate Hepatitis Delta Virus Diseases as an Addition to the Current List of Tropical Diseases in the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: In response to a suggestion by Gilead Sciences, Inc. (Gilead) that was submitted to the public docket FDA–2008–N–0567 on February 14, 2022, the Food and Drug Administration (FDA or Agency) has analyzed whether hepatitis delta virus (HDV) infection meets the statutory criteria for designation as a “tropical disease” under Section 524 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Specifically, the Agency has analyzed whether there is “no significant market in developed nations” for drugs for HDV infections and whether HDV “disproportionately affects poor and marginalized populations,” both of which are statutory criteria for designation as a “tropical disease.” At this time, the Agency cannot conclude that HDV infection meets the statutory criteria for addition to the list of tropical diseases under the FD&C Act; therefore, FDA declines to add it to the list of tropical diseases.

DATES: May 22, 2026.

ADDRESSES: Submit electronic comments on additional diseases suggested for designation to <https://www.regulations.gov>. Submit written comments on additional diseases suggested for designation to the Dockets Management Staff (HFA–305), Food and

Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Sunita Shukla, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6334, Silver Spring, MD 20993–0002, 301–796–6406, Sunita.Shukla@fda.hhs.gov; or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

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I. Background: Priority Review Voucher Program

Section 524 of the FD&C Act (21 U.S.C. 360n), which was added by section 1102 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), uses a priority review voucher (PRV) incentive to encourage the development of new drugs, including biological products, for prevention and treatment of certain diseases that, in the aggregate, affect millions of people throughout the world. To be eligible to receive a tropical disease PRV, a sponsor must submit a human drug application that is for prevention or treatment of a “tropical disease” as listed under section 524(a)(3) of the FD&C Act. This list can be expanded by the Agency under section 524(a)(3)(S) of the FD&C Act, which authorizes FDA to designate by order “[a]ny other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations” as a “tropical disease.” Further information about the tropical disease PRV program can be found in the guidance for industry “Tropical Disease Priority Review Vouchers,” issued on October 6, 2016 (81 FR 69537), and available at <https://www.fda.gov/media/72569/download>. Additions to the statutory list of tropical diseases by an FDA final order published in the **Federal Register**