prevention of West Nile virus disease? (3) Are there proposed changes or considerations that you recommend the government consider when finalizing the draft target product profile? This input is a valuable component in developing a useful target product profile.

III. How To Submit Your Response

Please respond concisely, in plain language, and in narrative format at *www.regulations.gov* or via mail. You may respond to some or all of the topic areas covered in the RFI, and you may suggest other factors or relevant questions. You may also include links to online material or interactive presentations. Clearly mark any proprietary information and place it in its own section or file.

Noah Aleshire,

Chief Regulatory Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2026–1685]

Target Product Profile for Monoclonal Antibodies for West Nile Virus Disease Prevention: Request for Information

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announces the opening of a docket to obtain comment on the proposed *Target Product Profile for Monoclonal Antibodies for West Nile Virus Disease Prevention.* This Request for Information (RFI) invites comments and suggestions on the proposed target product profile. The objective of the target product profile is to describe key minimal and optimal attributes for a West Nile virus monoclonal antibody product that can be provided to patients at higher risk for severe West Nile virus disease as pre- or post-exposure prophylaxis. This input is a valuable component in developing a useful target product profile.

DATES: Written comments must be received on or before January 15, 2027.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2026–1685, by either of the methods listed below. Do not submit comments by email. CDC does not accept comments by email.

Federal eRulemaking Portal: *www.regulations.gov.* Follow the instructions for submitting comments.

Mail: Dr. Randall Nett, Branch Chief, Arboviral Diseases Branch, Division of Vector-Borne Diseases, Centers for Disease Control and Prevention, 3156 Rampart Rd., MS–PO2, Fort Collins, CO 80521.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Randall Nett, Branch Chief, Arboviral Diseases Branch, Division of Vector-Borne Diseases, Centers for Disease Control and Prevention, 3156 Rampart Rd., MS–PO2, Fort Collins, CO 80521; Telephone: 970.221.6400; Email: *vectorpolicy@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. In addition, CDC invites comments specifically on the questions for consideration in section II of this document.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near-duplicate examples of a mass-mail campaign. Do not submit comments by email. CDC does not accept comments by email.

I. Background

CDC has developed a proposed *Target Product Profile for Monoclonal Antibodies for West Nile Virus Disease Prevention.* Statutory authority for this effort is located in Public Health Service Act Sections 301(a) [42 U.S.C. 241(a)] and 317U [42 U.S.C. 247b–23].

Target product profiles are tools used to establish priorities and expectations for a pharmaceutical product development process. A target product profile summarizes the characteristics of a product intended to meet an unmet clinical need, including the minimally acceptable and preferred performance characteristics. All comments will be considered in the final target product profile. We anticipate publishing the target product profile in a peer-reviewed scientific journal in the next six months. Following publication, the target product profile will be available on the journal's website.

The proposed target product profile is included as supplemental information in docket CDC–2026–1685 on *https://www.regulations.gov.*

II. Information Requested/Questions

CDC invites input from stakeholders throughout the scientific research, advocacy, and clinical practice communities, as well as the general public, on the proposed target product profile for monoclonal antibodies for West Nile virus disease prevention. Additionally, we request input on the following questions:

(1) Would monoclonal antibodies used as pre- or post-exposure prophylaxis be important for preventing West Nile virus disease? (2) Does a commercial market likely exist for monoclonal antibodies for prevention of West Nile virus disease? (3) Are there proposed changes or considerations that you recommend the government consider when finalizing the draft target product profile?

This input is a valuable component in developing a useful target product profile.

III. How To Submit Your Response

Please respond concisely, in plain language, and in narrative format in *www.regulations.gov* or via mail. You may respond to some or all of the topic areas covered in the RFI, and you may suggest other factors or relevant questions. You may also include links to online material or interactive presentations. Clearly mark any proprietary information and place it in its own section or file.

Noah Aleshire,

Chief Regulatory Officer, Centers for Disease Control and Prevention.

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