

NYC HEPATITIS B POLICY AND ELIMINATION UPDATES

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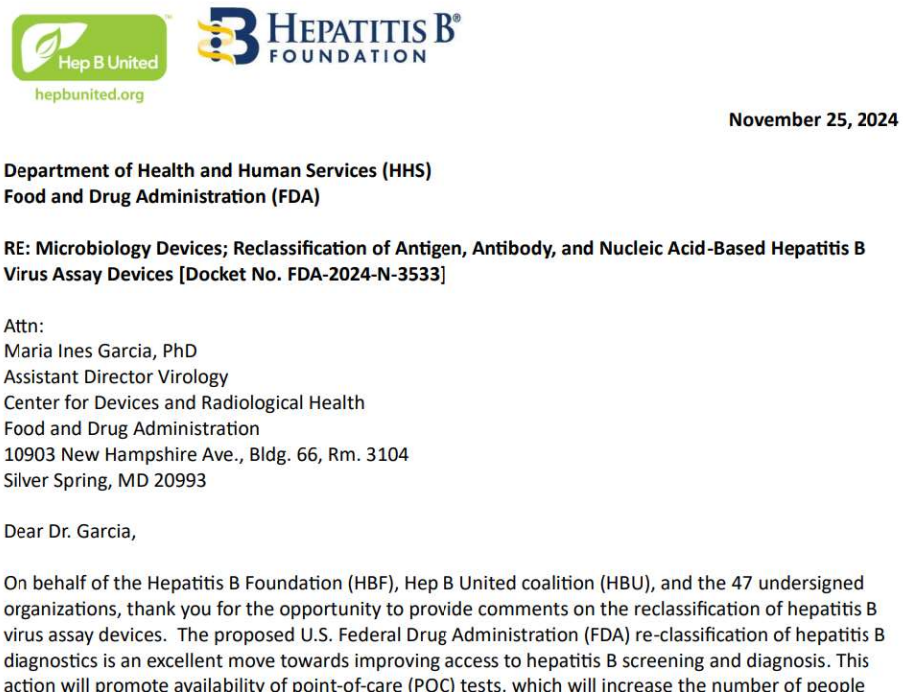
NYC HEPATITIS B POLICY UPDATE



Hep B United
hepbunited.org

HEPATITIS B FOUNDATION

November 25, 2024

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)

RE: Microbiology Devices; Reclassification of Antigen, Antibody, and Nucleic Acid-Based Hepatitis B Virus Assay Devices [Docket No. FDA-2024-N-3533]

Attn:
Maria Ines Garcia, PhD
Assistant Director Virology
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 66, Rm. 3104
Silver Spring, MD 20993

Dear Dr. Garcia,

On behalf of the Hepatitis B Foundation (HBF), Hep B United coalition (HBU), and the 47 undersigned organizations, thank you for the opportunity to provide comments on the reclassification of hepatitis B virus assay devices. The proposed U.S. Federal Drug Administration (FDA) re-classification of hepatitis B diagnostics is an excellent move towards improving access to hepatitis B screening and diagnosis. This action will promote availability of point-of-care (POC) tests, which will increase the number of people

The NYC Health Department joined the Hep B United letter to HHS and the FDA on the proposed down classification of hepatitis B virus assay devices.

- Proposed rule promotes availability of point-of-care (POC) hepatitis B tests.
- Supports NYC VHE goal to reduce premature deaths among people with chronic hepatitis B by 65% by 2030.
- 47 organizations endorsed the letter.

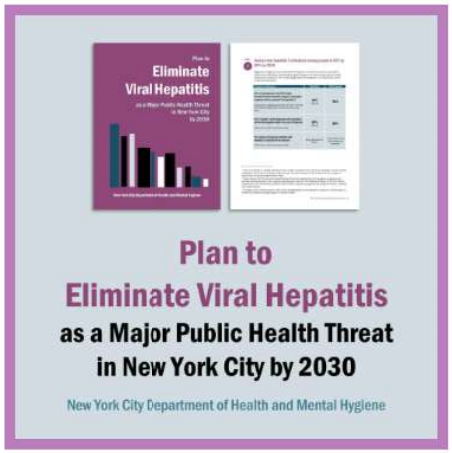
NYC VIRAL HEPATITIS ELIMINATION HUB

NYC's Plan to Eliminate Viral Hepatitis by 2030

A network building capacity to preve

The Plan to Eliminate Hep B and C in NYC

In 2021, the NYC Health Department released the Plan to Eliminate Viral Hepatitis as a Major Public Health Threat in New York City by 2030, a set of strategies to reduce Hep C infection, improve the health of people with Hep B and C, and reduce health inequities related to viral hepatitis infection in NYC.



An estimated 329,000 people are living with Hep B and/or C in NYC, according to the NYC Health Department's 2022 Hep A, B, and C Annual Surveillance Report. Without care and treatment, people with Hep B or C may progress to serious liver disease, liver cancer or premature death.

The NYC Viral Hepatitis Elimination Plan was developed with local Hep B and C advocates and stakeholders and implementation of the plan will include quarterly community engagement and planning through the Hep Free NYC Coalition. Eliminating viral hepatitis in NYC is ambitious, but with

CONTACT INFORMATION

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