



U.S. Department of Transportation Pipeline and Hazardous Materials Safety Administration

January 8, 2021

Dr. Jeanne Santoli, M.D. Centers for Disease Control and Prevention (CDC) NCIRD/ISD/VSAB 1600 Clifton Road, NE Atlanta, GA 30333

Reference No. 21-0002

Dear Dr. Santoli:

This letter is in response to your January 4, 2021 email and January 8, 2021, telephone call with several members of the Office of Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration (PHMSA) requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to the classification of "wasted" or otherwise expired COVID-19 vaccines. Specifically, you ask whether the unopened vaccine vials would be regulated as a hazardous material under the HMR for purposes of mailing them back to the centralized distribution depots.

Under 49 CFR 173.134(b)(1) a material that does not contain an infectious substance or that is unlikely to cause disease in humans or animals is not subject to the requirements of the HMR as a Division 6.2 material. In the absence of another hazardous material, unopened but expired or otherwise "wasted" vials of COVID-19 vaccines do not meet the definition of a hazardous material and are not subject to the HMR.

I hope this information is helpful. Please contact us if we can be of further assistance.

Sincerely,

Shane C. Kelley

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Director, Standards and Rulemaking Division