IANA
INTERMODAL ASSOCIATION OF NORTH AMERICA

President & CEO – Anne Reinke

June 30, 2026

Kyle Diamantas, J.D.
Acting Commissioner
U.S. Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. FDA-2026-N-4268, Medical Devices; Exemptions From Premarket Notification: Certain Class II Devices

Dear Commissioner Diamantas:

On behalf of the Intermodal Association of North America (IANA), the leading transportation trade association representing the combined interests of the intermodal freight industry, I am writing today regarding Docket No. FDA-2026-N-4268. IANA supports the United States Food and Drug Administration's (FDA) intention to modernize federally mandated drug testing by removing regulatory barriers through this notice.

IANA's membership roster of over 1,000 corporate members includes intermodal and over-the-road motor carriers, as well as railroads (Class I, short-line, and regional), ocean carriers, port authorities, intermodal marketing and logistics companies, and suppliers to the industry such as equipment manufacturers, leasing companies, and technology firms. IANA's associate (non-voting) members include shippers (defined as the beneficial owners of the freight being shipped), academic institutions, government entities, and non-profit trade associations.

Safety is at the forefront of IANA's mission and our members' work. Our industry is tasked with the important role of moving essential freight across the nation and around the world. About 6.5 million private sector workers regulated by the Department of Transportation are tested annually to comply with federal workplace requirements. To maintain a high level of safety on our nation's transportation networks, IANA supports modernizing federal workplace drug testing oversight. To that end, IANA supports the FDA's proposal to expand the 510(k) exemptions to include regulated workplace testing programs.

While urine-based testing is the standard for federally regulated workplace testing, the rate of subversion is rising. Directly observed testing methods, including oral fluid and hair testing, are less susceptible to tampering, yet regulatory barriers prevent their use in federally regulated workplace testing.

Oral fluids were approved for federally regulated workplace testing in 2023, but due to the FDA's burdensome 510(k) clearance requirement, there are no certified labs in the United States to conduct this testing. The lack of available testing tools is particularly troubling as fentanyl, xylazine, and methadone use are on the rise but are not currently detected by the Department of

Health and Human Services' (HHS) five-panel test. Federally regulated workplace testing must adapt to emerging threats.

IANA looks forward to working with you and would welcome the opportunity to further engage with your office. If you or your staff have any questions, please do not hesitate to contact me at areinke@intermodal.org or 301-982-3400.

Sincerely,

Anne C Reinke

Anne Reinke
President and CEO
Intermodal Association of North America