



April 1, 2026

Dr. Marty Makary  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Springs, MD 20993

Dr. Michelle Tarver  
Director  
Center for Devices and Radiological Health  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Drs. Makary and Tarver,

We are writing on behalf of AIM North America to express our strong support for the comments submitted by GS1 US in regard to the Food and Drug Administration (FDA) to enhance the Recall Enterprise System (RES) to discretely store the Unique Device Identifier (UDI) of recalled medical devices in distinct fields.

Since 1970, AIM has served as the neutral authority for technologies that capture, manage, and integrate data to improve business processes. As a chapter of AIM, Inc., AIM North America promotes the adoption of AIDC technologies through education and strategic advocacy. We work alongside industry leaders—including the FDA, DOW, GS1, and MHI—to define standards and enhance connectivity.

AIM serves as the secretariat for the U.S. Technical Advisory Group (TAG) to ISO/IEC JTC 1/SC 31, driving international standards for Automatic Identification and Data Capture (AIDC) techniques. We formulate U.S. positions on data structures, encoding, and capture technologies that power inter-industry applications and global trade.

AIM North America provides unrivaled expertise in asset tracking technologies, from RFID and IoT to advanced barcode systems. We stand ready to support the FDA in navigating technical AIDC requirements, ensuring robust standards and seamless implementation.

Sincerely yours,

A handwritten signature in black ink that reads "Don Ertel".

Don Ertel  
AIM North America Board Chair

A handwritten signature in blue ink that reads "Jay Crowley".

Jay Crowley  
AIM North America UDI Work Group Chairperson

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## **INTRODUCTION**

As the global voice of AIDC technologies, AIM Global represents technology providers, integrators, and users across the supply chain. We foster excellence in automatic identification—spanning barcodes, NFC, and RFID—by advocating for standards that ensure accurate, interoperable data and enhanced product traceability.

AIM North America, a key chapter of AIM Global, drives the adoption of AIDC technologies by advocating for, educating on, and implementing industry mandates in cooperation with regulatory bodies. Our UDI Work Group brings together a dedicated coalition of manufacturers, distributors, hospitals, and industry stakeholders to advance compliance and best practices

We support the GS1 US comments to enhance the Recall Enterprise Systems (RES) to improve the efficiency of medical device recalls by utilizing the Unique Device Identifier (UDI).

## **COMMENTS**

While the RES lists recalled medical devices, it presents UDIs in a static, free-text format rather than a machine-readable format. Updating this to a machine-readable system would revolutionize data liquidity, transforming how recalled items are tracked. By scanning a device, clinicians could receive immediate, automated recall alerts, providing a vital safety check at the point of care that directly prevents the use of compromised products.

We agree with GS1 US that without automated systems, providers must rely on manual processes prone to human error. Currently, staff must manually scan dozens of weekly recall notices, searching for UDIs to match against inventory and patient usage. Complex, text-heavy notices listing multiple UDIs further complicate this process. These manual workflows create critical delays in identifying dangerous devices, potentially preventing timely patient notification.

To improve data interoperability, the FDA should create a discrete UDI field in the RES. This allows software to 'locate' the UDI directly, ensuring that data sent via the Medical Device Recalls API is properly rendered and legible for receiving systems.

This request supports 2021 FDA Patient Engagement Advisory Committee recommendations to strengthen how medical device recall information is communicated to patients and the public.

Implementing this change is a low-burden, high-impact update, as manufacturers already include this information in recalls. By mandating a discrete field, the FDA will drastically improve recall interoperability—a critical step that will save lives.

We strongly encourage the FDA to implement this enhancement, which is vital for improving the interoperability of life-saving recall information. Strengthening this infrastructure is key to ensuring meaningful recall dissemination and reinforces our shared commitment to patient safety.