



March 23, 2022

Dockets Management Staff (HFA-305)
Food and Drug Administration,
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: **Initial Comments** of AIM North America UDI Work Group on: The Food and Drug Administration's Draft Guidance for Transition Plan for Medical Devices Issued Emergency Use Authorization (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency
Docket No. FDA-2021-D-1149

We respectfully submit this endorsement for the comments recently provided by the Association for Health Care Resource & Materials Management (AHRMM), Learning UDI Community (LUC), as well as some additional comments relative to the critical use of Unique Device Identifiers (UDIs), and the Global UDI Database (GUDID) in EUAs as outlined in the FDA's Notice in the above-captioned docket. These comments were prepared by members of the AIM North America UDI Work Group.

Founded in 1970, AIM is an industry trade association that represents the providers and users of technologies, systems, and services that capture, manage, and integrate accurate data into larger information systems that improve processes enterprise-wide. AIM North America is a chapter of AIM, Inc. In this role we advocate, educate, and coordinate with other subject matters experts including the FDA, GS1, MHI, AHRMM, RPA, AIAG, and others, to further the adoption of AIDC usage in industry.

AIM serves as the secretariat for the U.S. Technical Advisory Group (TAG) ISO/IEC JTC 1/SC 31 | Automatic Identification and Data Capture Techniques. This group formulates the U.S. position on all work related to the standardization of data formats, syntaxes, structures, and encoding, along with capture technologies for automatic identification and data capture and their associated devices utilized in inter-industry applications and international business interchange.

As subject matter experts in asset tracking technologies including Barcodes (1D & 2D Symbols), Radio Frequency Identification (RFID), Real Time Location System (RTLS), Internet of Things (IoT), and other technologies. AIM North America stands ready to support the FDA on any AIDC technical requests, including standards or implementation.

Sincerely yours,

Handwritten signature of Jeanne Duckett in black ink.

Jeanne Duckett
AIM North America Board Chair

Handwritten signature of Patti Blessing in black ink.

Patti Blessing
AIM Board Member
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INTRODUCTION

AIM, Inc. is a global industry and standards trade association, established in 1970, comprised of manufacturers, distributors, and system integrators of Automatic Identification & Data Collection (AIDC) technology systems that capture, manage, and integrate accurate data into information systems to further the adoption and usage of AIDC in industry. AIM, Inc. is a recognized body for standards development of AIDC technologies, and an advocate for AIDC design, application, and implementation.

AIM North America is a chapter of AIM, Inc. and in this role, we work to advocate, educate, and implement AIDC based industry mandates in coordination with the ruling body. The AIM North America [UDI Work Group](#) is comprised of AIM Members (technologists in data carriers, data capture & data utilization), Medical Device Manufacturers & Distributors, Hospitals, and other industry Trade Associations and stakeholders.

We appreciate the opportunity to submit comments in response to the Food and Drug Administration's (FDA) Draft Guidance for Transition Plan for Medical Devices Issued Emergency Use Authorization (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, Docket No. FDA-2021-D- 1149.

The AIM North America UDI Work Group echo's and endorses the comments recently submitted by the Association for Health Care Resource & Materials Management (AHRMM), Learning UDI Community (LUC); a collaboration of stakeholders from across the health care field including providers, manufacturers, distributors, software application providers, standards organizations, the FDA, and other interested participants. Please see Appendix A for a quick reference to the AHRMM comments.

COMMENTS

- We understand the unique situation the FDA faced while responding to the emergency medical crisis that COVID-19 created, and we commend the approach of releasing Emergency Use Authorization (EUA) medical devices and products to address and respond to the urgent and dire needs in order to save lives.
- Although we fully support all comments submitted by AHRMM, we specifically underscore their last comment on their submission relative to the need to require future EUAs to meet the FDA UDI Regulation, a proven system to identify medical devices from manufacturing through distribution, to patient care intended to ultimately improve patient safety, modernize device post market surveillance, and facilitate medical device innovation. Requiring the inclusion of the UDI Regulation on future EUAs will support an automated, downloadable and more transparent communication tool that health systems can use to better track EUA devices in their inventory and other IT systems.
- Experience during the COVID pandemic has highlighted the risks associated with counterfeit and sub-standard medical devices & products. Currently, the FDA does not have a means to monitor performance and safety of EUAs since UDI was not required. We recommend that future EUAs be required to comply with the UDI Regulation in order to bring clarity and transparency to this segment of devices/products.
- Additionally, we recommend that EUAs should be required to submit a minimal set of device identification data to the Global UDI database (GUDID) to provide a single repository of data for all medical devices. We suggest that the GUDID should be expanded to include EUA request number and the EUA termination date as required fields to aid in the EUA transition process. GUDID is intended to serve as a comprehensive

database of all regulated medical devices. If a product is being distributed to the general public, it should be trackable in a public database.

- Industry stakeholders feel that requiring EUAs to meet the basic tenants of the UDI Rule for unique identification and submission to GUDID is less burdensome than the risk to patient safety associated with these devices when there is no record of them in the established medical device repository.
- Documented examples exist where the packaging label on some of the current EUAs in circulation have caused confusion for multiple parties, including manufacturers, supply chain and consumers because they do not follow FDA UDI requirements (examples will be shared with the FDA upon request). Enforcement of, at a minimum, the UDI requirements of unique identification and submission to the GUDID on future EUAs will alleviate confusion, mistrust, and maintain package label authenticity.
- Medical device companies currently trading products within the United States have been operating utilizing UDI for many years (the final Class I compliance date is September 2022). Industry believes those same companies introducing an EUA product or device into the market would not encounter significant delay to market release in order to comply with the necessary UDI labeling requirements they already have in place.

APPENDIX A

AHRMM Learning UDI Community

Comments to the Food and Drug Administration's Draft Guidance Transition Plan for Medical Devices Issued Emergency Use Authorization (EUAs) During Coronavirus Disease 2019 (COVID-19) Public Health Emergency
FDA-2021-D- 1149

INTRODUCTION:

The following comments to the Food and Drug Administration's Draft Guidance for Medical Devices Issued Emergency Use Authorization (EUAs) During Coronavirus Disease 2019 (COVID-19) Public Health Emergency FDA-2021-D- 1149, are being made by the Association for Health Care Resource & Materials Management (AHRMM), Learning UDI Community (LUC).

The AHRMM LUC is a collaboration of stakeholders from across the health care field including providers (physicians, clinicians, and supply chain professionals), manufacturers, distributors, software application providers, standards organizations, the FDA, and other interested participants. Its purpose is to expand adoption and utilization of the Unique Device Identifier (UDI) and the data in the Global UDI Database (GUDI) and other global UDI databases (UDIDs). It accomplishes this through the creation of multi-disciplinary workgroups that identify barriers and develop consensus-based leading practices to overcome those barriers.

Based on the input from health care providers, manufacturers, distributors, solution providers and other stakeholders, the following comments are offered.

COMMENTS:

- We appreciate that FDA values a proactive approach to ensuring a seamless transition from policies and operations that were implemented during the COVID-19 public health emergency to a post emergency status for all stakeholders across the health care supply chain. Health care providers, distributors and in some cases, patients need time to adjust their systems and make plans to ensure they have access to necessary medical devices and equipment. Therefore, it is critical they are informed, as soon as possible, of the manufacturer's intent to submit marketing submissions or discontinue production.
- Guidelines need to be established and communicated, ensuring that there is adequate time for manufacturers to know what they need to do if they want to continue to operate in this space as well as giving hospitals/health systems a clear understanding of timing for purposes of managing supply on-hand and future ordering.
- Having manufacturers include a plan for notifying customers of their intentions to the list of information being submitted to the CDRH document control center outlined in section VA: "Notification of Intent for Certain Reusable Life Supporting or Life Sustaining Devices" line 195 while helpful, would not be sufficient.
- Section VC: "If manufacture does not intend to continue distributing its devices after EUA termination date" provides four examples of how various categories of devices are to be dealt with by the manufacture. The section does not clarify whose responsibility it is to communicate this information to hospital providers, distributors, or patients and attempting to create a standardized method of notification would be manual and time consuming for all parties.
- Likewise in section VI: Examples, none include explicit expectations regarding communication with hospital providers, distributors, and other customers. The key to having a smooth transition from the current EUA environment to a post EUA environment will be the strength of the communication between all stakeholders within the supply chain. This will be equally true with the Single Use Device (SUD) EUA transition process

- A significant concern with the current EUA process is that it does not require a manufacturer to meet UDI regulations (i.e. apply a properly formed UDI to the device label and submit a minimal set of device identification data to the Global UDI database). To support an automated, downloadable more transparent communication tool that health systems can use to better track EUA devices in their inventory and other IT systems we recommend the following:
 - In situations where the manufacturer voluntarily included the UDI on EUA devices, the UDI should meet UDI regulatory requirements and the switch from EUA to marketing submission should not be a UDI-DI trigger.
 - In situations where the manufacturer did not include UDI on a EUA device and is transitioning to market approval, the manufacturer should be required to enter the original EUA request date and the EUA expiration date in the Global UDI database (GUDID).
 - A more efficient and effective means of communication to device stakeholders is to enhance GUDID to include a separate field in for EUA request number and EUA termination date.
 - In situations where the manufacturer did not include the UDI on a EUA device, and is not transitioning to market approval, FDA should post the product manufacturer, product name, product ID, original EUA request date and EUA expiration date in a public database that is in a format that can be downloaded (e.g. .csv or .xls).