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Sent via email to Jonette.Foy@fda.hhs.gov

June 14, 2022

Jonette R. Foy, Ph.D., Deputy Office Director
Office of Policy
Center for Devices & Radiological Health
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Building WO66, Room 5448
Silver Spring, MD 20993-0002

Re: Formal request for an extension to the unique device identifier (UDI) policy for those devices that are subject to the UDI Policy but not covered under the final UDI Update Guidance

Dear Dr. Foy,

On behalf of the Consumer Healthcare Products Association ("CHPA[1]"), I am requesting an extension to the "Immediately in Effect Guidance for Industry and Food and Drug Administration Staff: FDA Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking," referred to hereafter as the "UDI Policy." Under the UDI Policy, FDA is currently exercising enforcement discretion for the standard date formatting, UDI labeling, and GUDID data submission requirements for class I and unclassified devices, other than implantable, life-supporting, or life-sustaining (I/LS/LS) devices.

The UDI Policy is currently scheduled to expire on September 24, 2022. We understand that CDRH plans to issue a new final guidance on "Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices" ("UDI Update Guidance"), and that this guidance is on the "A-List: Prioritized Guidance Documents that CDRH Intends to Publish in FY2022."

However, it is currently uncertain which devices will be covered by the final UDI Update Guidance. The 2021 draft guidance "Select Updates for Unique Device

[1] CHPA is a 141-year-old national trade association representing the leading manufacturers and marketers of over-the-counter (OTC) medicines, consumer medical devices, and dietary supplements. CHPA is committed to empowering consumer self-care by preserving and expanding choice and availability of consumer healthcare products. (www.chpa.org)

Identification: Policy Regarding Unique Device Identification Database Requirements for Certain Devices" stated that the guidance would apply to consumer health products defined as "510(k)-exempt class I devices that are exclusively sold directly to consumers over-the-counter in both brick-and-mortar and online stores." However, as CHPA pointed out in its comments on the draft guidance, industry would benefit from clarification about what devices qualify as consumer health products. For example, it is unclear whether the Agency's intent is to limit consumer health products to those that are exclusively sold at retail, or whether they would also include class I devices sold at drug stores and also sold to healthcare facilities (such as bandages).

In light of the uncertainty about the date of issuance and scope of the final UDI Update Guidance, CHPA requests a 1-year extension to the UDI Policy. This will ensure that CHPA members are not unnecessarily spending valuable resources to prepare for compliance with a requirement that could be obsolete in the future.

Even if the UDI Update Guidance is finalized before September 24, 2022, it appears that the final guidance may not cover all of the devices that are included in the current UDI Policy. In this case, CHPA requests that FDA grant an extension to the UDI Policy for those devices that are subject to the UDI Policy but not covered under the final UDI Update Guidance.

CHPA appreciates the Agency's consideration of this extension request.

Sincerely,

Marcia D. Howard, Ph.D., CAE

Digitally signed by Marcia D. Howard, Ph.D., CAE
Date: 2022.06.14 15:39:09 -04'00'

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Attachment: CHPA comments on 2021 draft guidance "Select Updates for Unique Device Identification: Policy Regarding Unique Device Identification Database Requirements for Certain Devices

Cc: FDA UDI Help Desk at https://fdaprod.secure.force.com/UdiWebForm/