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Submitted via www.regulations.gov

December 8, 2021

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

Re: Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices; Draft Guidance for Industry and Food and Drug Administration Staff; 86 *Fed. Reg.* 57154-57156[1]; (Docket No. FDA–2017–D–6841)

Dear Sir or Madam:

The Consumer Healthcare Products Association[2] ("CHPA") submits these comments in response to the U.S. Food and Drug Administration's ("FDA's" or the "Agency's") Draft Guidance for Industry and FDA Staff, "Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices" ("UDI Draft Guidance").[3] For more than 137 years, CHPA has served as a vital advocate for the consumer healthcare products industry. A member-based trade association, CHPA represents the leading manufacturers and marketers of over-the-counter ("OTC") medical products. CHPA members provide millions of Americans with safe, effective, and affordable therapies to treat and prevent many common ailments and diseases.

CHPA applauds the Agency's efforts towards gaining "a better understanding of the devices and device characteristics for which GUDID information is particularly useful in evaluating and improving device safety throughout a product life cycle, as well as the ones for which GUDID information may be less important in this regard."[4] CHPA agrees with FDA that "the entry of UDI data into GUDID for [consumer health

[1] FDA, Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Notice of Availability, 86 Fed. Reg. 57154 (Oct. 14, 2021). Accessed from https://www.govinfo.gov/content/pkg/FR-2021-10-14/pdf/2021-22308.pdf on December 2, 2021. ("UDI Draft Guidance Notice of Availability")

[2] The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing the leading manufacturers and marketers of consumer healthcare products, including over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices. CHPA is committed to empowering self-care by ensuring that Americans have access to products they can count on to be reliable, affordable, and convenient, while also delivering new and better ways to get and stay healthy. Visit www.chpa.org.

[3] UDI Draft Guidance Notice of Availability Accessed from https://www.fda.gov/media/152917/download on December 2, 2021.

[4] *Id.* at 57156; *see also* Draft Guidance for Industry and Food and Drug Administration Staff: Select Updates for Unique Device Identification: Policy regarding Global Unique Device Identification Database Requirements for Certain Devices ("UDI Draft Guidance") at 3.

products] is burdensome to stakeholders,"[5] and that the enforcement of GUDID submission requirements for class I consumer health products is not necessary to protect the public health.[6] As discussed in our comment, CHPA believes that the same rationale applies to certain class II consumer health products.

While CHPA fully supports FDA's issuance of a final guidance and compliance policy regarding GUDID submission requirements for consumer health devices, CHPA believes that the Agency should: (1) clarify the definition of "consumer health device" used in the draft guidance; and (2) consider expanding the scope of consumer health devices covered by the guidance to not only include class I, but also certain class II and unclassified OTC devices.

Moreover, while CHPA acknowledges that the Agency defines the term "consumer health device" specifically for purposes of the UDI Draft Guidance, we believe FDA should consider to what extent this term is currently used by industry and/or the public, and whether a different definition exists that may more closely align with terminology already in use. For example, CHPA believes that the term "consumer medical device"[7] may be more readily understood as a device that is typically but not exclusively sold to consumers in a retail setting.

<u>Definition of "Consumer Health Device"</u>

CHPA requests that FDA clarify what devices qualify as a "consumer health device." In the UDI Draft Guidance, FDA explains that for purposes of the guidance, "'consumer health products' means 510(k)-exempt class I devices that are exclusively sold directly to consumers over-the counter in both brick-and-mortar and online stores."[8] FDA then describes certain categories of class I devices that "are not considered consumer health products for purposes of th[e] guidance and, therefore, do not fall within the enforcement policy described in th[e] guidance regarding GUDID data submission requirements under 21 CFR 830.300."[9] These categories include class I reserved devices, restricted devices, implantable devices, life-supporting or life-sustaining devices; and certain devices "that are distributed to professional healthcare facilities, are intended for use by healthcare professionals only, and that are devices that are: (1) reusable or reprocessed, including those that are non-sterile and sterilized on-site before use; or (2) intended for wound care."[10] The Agency explains that "[i]f a device is

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[5] *Id.*
[6] *See generally* UDI Draft Guidance.
[7] CHPA members define "consumer medical devices" (CMDs) as consumer-facing devices that are sold over-the-counter (OTC) at retail locations, including drug stores, grocery stores, convenience stores, club stores, and online. CMDs do not require a prescription from a healthcare professional nor are they distributed and used exclusively in health care settings. CMDs have established safety profiles which allow them to be used by lay persons in non-clinical environments. Consistent with other over-the-counter product categories, lay persons can use CMDs based on the labeling and accompanying instructional materials provided by the manufacturer. These devices are sufficiently user-friendly to be used by lay persons without the need for instruction or involvement from a healthcare professional. Manufacturers of CMDs rely on labeling, design, and consumer familiarity to ensure safe and effective use.
[8] UDI Draft Guidance at 4.
[9] *Id.* at 4-6.
[10] *Id.*

distributed to other types of facilities, such as grocery stores or online or brick-and-mortar pharmacies, in addition to professional healthcare facilities, it is still considered 'distributed to professional healthcare facilities' for purposes of th[e] guidance."[11]

Based on the accompanying *Federal Register* notice, CHPA understands that the categories of devices that are not considered consumer health products are included so that "a labeler of a class I device can determine if its device is one of these devices in the revised section III of this draft guidance," *i.e.*, covered by the compliance policy in the Draft UDI guidance.[12] This suggests that if a class I device is sold to consumers over-the-counter in both brick-and-mortar and online stores and does not fall within one of the categories identified by FDA, it should be considered a consumer health product for purposes of the guidance.

However, if that understanding is correct, it is unclear how to reconcile it with the requirement that a consumer health device be "*exclusively* sold directly to consumers"[13] and the explanation that a device that is sold both at retail to consumers and to professional healthcare facilities is not a consumer health product. In other words, if a class I device is sold at drug stores and also sold to healthcare facilities (*e.g.*, a bandage or a toothbrush), would it qualify as a consumer health product because it is not intended for use by healthcare professionals only? Or would it not qualify because it is not exclusively sold directly to consumers, and is also sold to professional healthcare facilities?

If the Agency's intent is to limit consumer healthcare products to those that are exclusively sold at retail (such that the bandage or the toothbrush in the example above would not fall under the definition), CHPA believes that this creates logistical burdens that are counterproductive to the Agency's efforts to eliminate overly burdensome GUDID requirements. Such an approach would require manufacturers to create two versions of each product, one for the retail channel and another for the professional healthcare channel, and would entail the need to maintain separate lots and create separate packaging and SKUs for each product. Additionally, having a retail and a healthcare version of the same product would create inventory challenges associated with the need to distinguish between products based on the sales channel. Moreover, manufacturers who typically use and rely on distributors would be faced with the impossible task of overseeing and policing the distributor activities to ensure distribution occurs into the correct channel. CHPA believes that based on the very broad definition of "professional healthcare facility,"[14] most devices that are sold at retail would also be sold to, and used in, professional healthcare facilities. For

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[11] *Id.* at 6, fn. 14.
[12] UDI Draft Guidance Notice of Availability at 57154.
[13] UDI Draft Guidance at 4 *(emphasis added)*.
[14] The UDI Draft Guidance defines "Professional healthcare facility" as "any environment where personnel with medical training are continually available to oversee or administer the use of medical devices. This includes, but is not limited to, hospitals, long-term care facilities, nursing homes, emergency medical services, clinics, physicians' offices, and outpatient treatment facilities; or a clinical laboratory." *Id.* at 6, fn. 14.

example, OTC retail devices such as toothbrushes, bandages, and incontinence products sold at retail are also used in long-term care facilities or nursing homes. The logistical burdens associated with creating two separate versions of the same product could create a disincentive for manufacturers to sell into both the retail and healthcare channels, which in turn may lead to a supply shortage in the lower volume channel.

Accordingly, CHPA proposes that the definition of "consumer health device" in the Draft UDI Guidance include devices that are sold both at retail and into healthcare settings. Such a policy is consistent with the approach the Agency took in the proposed UDI rule that included an exception from the requirement to bear a UDI identifier for "[a] device, other than a prescription device, that is made available for purchase at a retail establishment."[15] The proposed exception specifically stated that "[t]his exception shall also apply to such a device when delivered directly to a hospital, ambulatory surgical facility, nursing home, outpatient treatment facility, or other health care facility."[16]

CHPA supports the approach FDA took in the proposed rule and does not believe that there is a public health rationale to limit the applicability of the UDI compliance policy to consumer health devices sold exclusively at retail. Instead, FDA could specifically carve out certain higher risk products from the definition of consumer health device, such as the proposed categories in section B.2. of the UDI Draft Guidance, which include restricted or implantable devices, and those devices distributed to professional healthcare facilities that are intended for use by healthcare professionals only, and that are reusable or reprocessed or intended for wound care.[17] Accordingly, CHPA requests that FDA consider clarifying that those class I devices that are *typically but not exclusively* sold at retail are consumer health products, even if they are also sold to healthcare facilities, with the specific carve outs in section B.2. of the UDI Draft Guidance.

Scope of Devices Covered by the Guidance

In addition to class I devices, CHPA requests that FDA also consider including certain class II and unclassified devices that are typically sold over-the-counter directly to consumers at retail. In particular, CHPA suggests that FDA consider adding those devices that are currently subject to alternatives UDI-A160001 and UDI A-160002. Both of these alternatives apply specifically to devices that are intended to be sold over-the-counter directly to consumers exclusively at retail, and permit the use of a

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[15] FDA, Proposed Rule, Unique Identification System, 77 Fed. Reg. 40736, 40770 (July 10, 2012).
[16] *Id.* Although FDA did not include the exception in the final rule, this decision was unrelated to concerns about the sale of devices into both retail and healthcare channels. Rather, in rejecting the proposed exception in the final rule, FDA stated that "the availability of a device for purchase in retail establishments has little relationship to the potential for risk of the device," and that "devices sold through retail channels may have unusually broad distribution resulting in correspondingly broad impact when the device is defective and needs to be recalled." FDA, Final Rule, Unique Device Identification System, 78 *Fed. Reg.* 58786, 58798 (Sept. 24, 2013) ("Final UDI Rule"). This concern is fully addressed in the current draft guidance that is limited to certain lower risk devices.
[17] *See* UDI Draft Guidance at 5-6.

Universal Product Code (UPC) as the device identifier. CHPA believes it is appropriate to align the scope of these alternatives for OTC devices sold directly to consumers and the scope of the enforcement discretion for GUDID submissions for consumer health products to which the UDI Draft Guidance applies.

In the UDI Draft Guidance, FDA states that it has conducted evaluations of "high-level medical device reporting and historical recall data for class I devices," which informed the Agency's decision to issue the UDI Draft Guidance.[18] At a minimum, CHPA requests that FDA conduct the same evaluation of high-level medical device reporting and historical recall data for class II and unclassified OTC devices that are sold at retail to determine whether GUDID submission data are necessary to evaluate and improve device safety.

CHPA believes that the burden of applying the GUDID submission requirements to these class II and unclassified OTC devices outweighs the intended benefits of the UDI rule. Unlike for prescription devices used in the healthcare setting, the intended benefits of the UDI rule are only marginally realized with respect to class II and unclassified OTC devices sold at retail. The preamble to the UDI final rule outlines benefits such as reduction of medical errors by healthcare providers; more rapid and accurate identification of devices with adverse events; more rapid and more efficient resolution of device recalls; support for integration of device use information into healthcare data systems; and linkage of electronic health records (EHRs) and patient health records (PHRs).[19] These considerations have little to no relevance for OTC devices that are often used outside of healthcare facilities. For example, a reduction in medical errors is relevant to prescription devices, but not to devices that are sold at retail to consumers and provided with instructions for use. Likewise, because consumers who report an adverse event with an OTC device usually identify the device by name and brand, the UDI plays only a limited, if any, role in identifying OTC devices with adverse events. GUDID submissions also offer no additional benefit for the efficiency of OTC device recalls because consumer product companies identify and track products through the scannable UPC. Moreover, OTC devices are typically not described in healthcare data systems such as PHRs and EHRs, and therefore the UDI benefits related to healthcare systems, EHRs, and PHRs are not germane for these devices.

Additional benefits identified in the UDI rule are also largely inapplicable to OTC devices, such as providing educational and informational materials to allow readers to quickly obtain additional information.[20] Consumers looking for additional information about an OTC device sold at retail are more likely to look to a manufacturer's website or basic internet searches, not the GUDID.

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[18] *Id.* at 3.
[19] *See* Final UDI Rule at 58786–87.
[20] *Id.* at 58787.

Like class I consumer health products, class II and unclassified OTC devices sold to consumers at retail undergo frequent changes to UPCs that would require submissions to GUDID, which, as FDA acknowledged in the UDI Draft Guidance, "is burdensome to stakeholders."[21] For example, a teething ring (product code KKO) sold in different colors or promotional packaging (*e.g.*, featuring different cartoon characters) would require separate UPCs and updates to the GUDID.[22] In light of the limited benefits with respect to class II and unclassified OTC devices sold at retail, CHPA believes that requiring GUDID submissions for these devices is overly burdensome.

CHPA thanks FDA for the efforts in reducing burdens for manufacturers of consumer health products, and for the opportunity to comment on these important considerations. Please do not hesitate to contact us if you have any questions about our comments.

Respectfully Submitted,

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[21] UDI Draft Guidance at 3 ("With respect to class I devices that are consumer health products, as described above, FDA believes that the entry of UDI data into GUDID, especially given the frequent changes to the UPCs serving as the UDIs for these devices, is burdensome to stakeholders.")
[22] *See* 21 CFR §§ 830.50(b) ("Whenever you create a new device package, you must assign a new device identifier to the new device package."), § 830.310(b)(1) (requiring submission to GUDID of "[t]he device identifier portion of the UDI assigned to the version or model"), and § 830.330(b) ("The labeler of a device shall submit to FDA an update to the information required by § 830.10 whenever the information changes.")