DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

October 6, 2015

Dear Soft Contact Lens Labelers:

The purpose of this letter is to inform labelers of soft (hydrophilic) contact lenses that effective October 6, FDA is granting an extension to comply with the requirements of the Unique Device Identification (UDI) system to September 24, 2017.

On September 24, 2013, the FDA published a final rule establishing a unique device identification system (the UDI Rule). The UDI Rule outlines labeling, data submission and standard date formatting requirements for all medical devices in commercial distribution in the U.S., unless an exception or alternative applies. The rule is being phased in over a 7-year period according to an established set of compliance dates. The compliance date for class III devices was September 24, 2014. The compliance date for class II devices is September 24, 2016.

On August 15, 2014, FDA notified industry that we granted a 1-year extension of the September 24, 2014, UDI compliance date for certain class III devices, including the following:

Class III Device	Product Code	Classification Regulation
Soft (hydrophilic) Contact Lens (extended wear)	LPM	21 CFR 886.5925(b)(2)

Figure 1

We granted this extension because submission of soft contact lens information to the Global Unique Device Identification Database (GUDID) based on the current industry practice of assigning a different device identifier (DI) to each prescription would have resulted in an exceptionally large number of virtually identical DI record submissions. We determined that additional time was needed to allow FDA to work with affected labelers to develop an approach to ensure that meaningful data would be submitted to the GUDID.

FDA is not contemplating a change in the labeling strategy soft contact lens labelers currently employ. FDA is developing a technical solution (the “Technical Solution”) for submitting contact lens DI record information in a manner that minimizes data redundancy while still allowing end users to search and retrieve device identification information pertinent to soft contact lenses. Any such solution will result in changes to the way DI record information is submitted to the GUDID and would also trigger modifications to the GUDID HL7 SPL schema. We anticipate that the Technical Solution would be applicable to all soft (hydrophilic) contact lenses because the DI assignment practices are similar across the industry, including for the devices identified in Figure 2.

Class II Device	Product Code	Classification Regulation
Soft (hydrophilic) Contact Lens (disposable)	MVN	21 CFR 886.5925(b)(1)
Soft (hydrophilic) Contact Lens (for color vision deficiency)	NCZ	21 CFR 886.5925(b)(1)
Soft (hydrophilic) Contact Lens (for reading discomfort)	NIC	21 CFR 886.5925(b)(1)
Soft (hydrophilic) Contact Lens (daily wear)	LPN	21 CFR 886.5925(b)(1)

Figure 2

We understand that once such a solution is developed, industry will need sufficient time to implement it. Since development of the Technical Solution is still underway, pursuant to 21 CFR 801.55(d) the FDA has determined that initiating and granting an extension beyond the September 24, 2015 compliance date for the devices in Figure 1 is in the best interest of the public health. In addition, the FDA has determined that initiating and granting an extension of the UDI compliance date for the devices in Figure 2 is also in the best interest of the public health.

Therefore, FDA grants to labelers of the devices listed in Figure 1 and Figure 2 an extension of the requirements to provide a unique device identifier (UDI) on the device label and packages, format dates on the device label according to 21 CFR 801.18, and submit data to the GUDID until September 24, 2017. FDA intends to notify industry when the Technical Solution has been developed and integrated into the GUDID production system, and we will provide the updated technical specifications to affected labelers no less than six months before this extension expires, i.e. no later than March 24, 2017; this notification will be provided through emails to industry, communication via trade associations, and via the UDI website.

Some soft (hydrophilic) contact lenses labelers may have already implemented the UDI label and date format requirements for these devices. In such cases, this extension would only apply to the requirement to submit information to the GUDID.

The agency appreciates the industry's cooperation on this issue, and we look forward to continuing to work together to implement a solution that balances the needs of both industry and the public for adequate identification of these products.

For additional information, please contact the FDA UDI Help Desk.

Sincerely yours,

Thomas P. Gross -A

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