March 30, 2017

Dear Soft Contact Lens Labelers:

The purpose of this letter is to inform labelers of soft (hydrophilic) contact lenses that, effective March 30, 2017, FDA is granting an extension to comply with the requirements of the Unique Device Identification system.

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 was September 24, 2016.

FDA has previously granted two extensions to the soft contact lens industry. The first, dated August 15, 2014, granted a one-year extension of the September 24, 2014, compliance date for class III soft contact lens devices. The second, dated October 6, 2015, granted an additional two-year extension for class III soft contact lens devices, and a one-year extension of the September 24, 2016, compliance date for class II soft contact lens devices. The extensions granted by the second letter expire on September 24, 2017.

We granted these extensions 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 had expected that, during the extension periods, we would develop a technical solution that would allow contact lens DI record information to be submitted in a manner that minimizes data redundancy while still allowing end users to search and retrieve device identification information pertinent to soft contact lenses (Technical Solution). Unfortunately, given resource limitations, we have been unable to develop the Technical Solution and need more time to develop an approach that ensures that meaningful data will be submitted to GUDID.

Therefore, pursuant to 21 CFR 801.55(d), FDA grants to labelers of the devices listed in Figure 1 below 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 one year after FDA 1) develops and fully integrates the Technical Solution into the GUDID production system, 2) provides any necessary updated technical specifications to affected labelers, and 3) notifies industry that the extension will expire , through emails to industry, communication via trade associations, and via the UDI website. FDA has determined that initiating and granting an extension for the devices listed in Figure 1 under the parameters described in this letter is in the best interest of public health. Please continue to be assured that FDA remains committed to developing a solution that does not require a change in the labeling strategy soft contact lens labelers currently employ.

U.S. Food & Drug Administration
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Class III Device	Product Code	Classification Regulation
Soft (hydrophilic) Contact Lens (extended wear)	LPM	21 CFR 886.5925(b)(2)
Class II Device	Product Code	Classification Regulation
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)	LPL	21 CFR 886.5925(b)(1)
Soft (hydrophilic) Contact Lens (disposable)	MVN	21 CFR 886.5925(b)(1)

Figure 1

Some soft (hydrophilic) contact lenses labelers 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 greatly appreciates the industry's cooperation and patience on this issue. 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,
/s/
Thomas P. Gross, MD, MPH
Director
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
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