



September 22, 2016

Dear Rigid Gas Permeable Contact Lens Companies:

The purpose of this letter is to inform materials manufacturers and finishing laboratories of class II and class III rigid gas permeable contact lenses that FDA is issuing an extension to comply with 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 Global Unique Device Identification Database (GUDID) (collectively UDI requirements) 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 UDI 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. Individual extensions were granted to class III rigid gas permeable contact lens companies to extend the compliance date to September 24, 2016. The compliance date for class II devices is September 24, 2016.

Under the UDI Rule, the labeler, as defined under 21 CFR 801.3, is responsible for compliance with UDI requirements. For rigid gas permeable contact lenses, FDA intends to clarify the entity within the manufacturing chain (i.e., the material manufacturer or the finishing laboratory) that is the labeler for purposes of 21 CFR 801.3 and 830.3.

FDA is issuing to labelers of the devices listed in Figure 1 an extension to September 24, 2017 to meet requirements to provide a 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, so that FDA may issue policy clarifying the entity within the manufacturing chain that is the labeler for purposes of 21 CFR 801.3 and 830.3.

Figure 1

Device	FDA Product Code	Classification Regulation
Rigid Gas Permeable Contact Lens (daily)	HQD, MUW	21 CFR 886.5916(b)(1)
Rigid Gas Permeable Contact Lens (extended wear)	NUU, MWL	21 CFR 886.5916(b)(2)

For additional information, please contact the [FDA UDI Help Desk](#).

Sincerely yours,  
/s/  
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