



April 25, 2017

Daren Nygren, President  
Contact Lens Manufacturers Association  
P.O. Box 29398  
Lincoln, NE 68529

Dear Mr. Nygren:

This is in response to the Contact Lens Manufacturers Association (CLMA) letter dated March 2, 2015, in which CLMA requests FDA to confirm that it considers the manufacturers of contact lens blanks rather than the fabricating laboratories to be the labeler as that term is defined in 21 CFR 801.3. CLMA asks that this clarification apply to rigid gas permeable (RGP) lenses fabricated from contact lens blanks specifically for an individual patient named in a prescription.

The RGP contact lens industry has a unique regulatory structure in that the lens material manufacturer is the holder of the 510(k)/PMA for the finished device and the lens material manufacturer contracts with fabricating laboratories to complete the manufacturing process. Although the laboratory fabricates the finished device out of the lens blank and provides the finished and labeled device to the practitioner, it is the lens blank manufacturer that is ultimately responsible for the finished product, as well as quality assurance activities. Additionally, in this industry, the lens material is more relevant to device safety and for adverse event reporting and device recalls than the way an individual device is fabricated for a single patient.

A major principle underlying 21 CFR Part 801, Subpart B is that every version or model of a device is required to bear a different device identifier (DI) to allow for the adequate identification of devices at the point of distribution and at the point of use that includes the availability of key information. While it is the responsibility of the labeler to determine whether a change in a device is a different version or model for the purposes of UDI compliance, FDA does not believe it would further the objectives of the UDI program for each individual patient's finished lens to be assigned a separate DI. Such an approach would create an exceptionally large number of DIs for each type of lens blank, diluting the ability to adequately identify such lenses and leading to a similarly large number of virtually identical DI record submissions in the Global Unique Device Identification Database (GUDID), which would undermine the collection of meaningful device identification data.

For these reasons, FDA agrees that the lens blank manufacturer should be considered the "labeler" for the purposes of compliance with the UDI rule, rather than the fabricating laboratory with whom the manufacturer contracts to finish its lenses. Thus, the lens blank manufacturer should comply with the requirements to provide a unique device identifier (UDI) on the device label and packages (21 CFR Part 801 subpart B), format dates on the device label (21 CFR 801.18), and submit data to the GUDID (21 CFR 830). This interpretation applies to the devices listed in Figure 1:

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)

In addition, to ensure the unique device identifier (UDI) is available for the end user, i.e. the prescriber or the patient, the lens blank manufacturer will provide the UDI for a given lens blank to the fabricating laboratory in a form by which the laboratory can thereafter accurately convey the UDI on the label or immediate container of the finished lens.

If you have any questions, please contact the UDI Help Desk at [GUDIDSupport@fda.hhs.gov](mailto:GUDIDSupport@fda.hhs.gov).

Sincerely yours,

Linda Sigg  
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