April 3, 2017

Ashley A. Mills, CEO
The Vision Council
225 Reinekers Lane, Suite 700
Alexandria, VA 22314

Dear Ms. Mills,

This letter is in response to the Unique Device Identification (UDI) issues raised in The Vision Council's September 18, 2015, letter to FDA; the October 2, 2015, meeting with Dr. Jeffrey Shuren, Director of the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA); and follow-up communications with CDRH staff on August 2, 2016 and November 10, 2016. The Vision Council questioned the applicability of UDI requirements as they may pertain to the optical industry entities involved in the production of prescription spectacle lenses.

Overview of the prescription lens supply chain

Prescription lenses are regulated as class I devices that are 510(k) exempt. They are classified under 21 CFR § 886.5844, "Lens, Spectacle, Non Custom (Prescription)" with a FDA Product code HQG, and defined as "[a] prescription spectacle lens is a glass or plastic device that is a lens intended to be worn by a patient in a spectacle frame to provide refractive corrections in accordance with a prescription for the patient."

Based on the information provided by The Vision Council, prescription lenses exist in three production states:

1. Lens blanks which are semi-finished lenses where one surface has been shaped or molded to a specific base curve and the lenses have yet to be ground or edged;
2. Uncut lenses, where both surfaces have been optically worked but not yet edged; and
3. Finished prescription lenses, where both surface and edging operations have been completed, and coating and treatment for impact resistance has been applied.

The process of producing prescription lenses typically involves three types of parties:

1. Prescription lens manufacturers produce lens blanks or uncut lenses for further processing;
2. Optical laboratories finish and cut lens blanks into prescription lenses and often insert the cut, finished lenses into spectacle frames; and
3. Prescriptions for individual patients are provided by eye care professionals; some eye care professionals also perform the services of optical laboratories.

Assignment of UDI responsibilities

Device labelers are responsible for meeting the labeling and data submission requirements of the UDI System rule, finalized in the Federal Register on September 24, 2013 (78 FR 58786). 21 CFR 801.3 defines a labeler as:

1. Any person who causes a label to be applied to a device with the intent that the device will be commercially distributed without any intended subsequent replacement or modification of the label; and
2. Any person who causes the label of a device to be replaced or modified with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label, except that the addition of the name of, and contact information for, a person who distributes the device,

without making any other changes to the label, is not a modification for the purposes of determining whether a person is a labeler.

Due to the identification of three distinct types of parties in the prescription lens supply chain, each type of party must be evaluated independently to determine whether UDI requirements apply.

UDI Responsibilities of Prescription Lens Manufacturers

According to information provided by The Vision Council, prescription lens manufacturers package lens blanks in individual boxes or envelopes. The packaging contains a label that contains basic information about the product, including the information needed to fulfill the requirements of 21 CFR 801.1.

When the lens is matched with the prescription for finishing at the optical lab, the lens blank packaging with its label is discarded and does not further accompany the lens in the processing and distribution chain. After the optical lab completed its processing, the lens is accompanied by an invoice describing the lens prescription and the associated costs for distribution to the eye care professional.

Although prescription lens manufacturers do place a label on the container of the device in accordance with the requirements of 21 CFR 801.1, the device is not intended to be commercially distributed without replacement or modification of the label. In fact, it is a longstanding, standard business practice within the optical lens industry for the label to be discarded as the lens moves through the distribution chain. As a result, prescription lens manufacturers do not meet the definition of “labeler” in 21 CFR 801.3. Prescription lens manufacturers are therefore not responsible for meeting UDI requirements for these devices.

UDI Responsibilities of Optical Laboratories

According to information provided by The Vision Council, optical laboratories are firms that receive lens blanks or uncut lenses from lens manufacturers. In general, they process the lens blanks into finished lenses manufactured to meet the prescription requested by the eye care professional for a given patient. The laboratory matches the appropriate blank with the tendered prescription and often, when processing is complete, inserts the finished lens into the selected frames. The eyeglasses at this point are sent to the eye care professional or ordering patient accompanied by an invoice describing the prescription and costs, with no label.

Based on the unique characteristics of the prescription optical lens distribution chain and FDA’s current interpretation of the FD&C Act and implementing regulations, optical laboratories do not meet the definition of “labeler” in 21 CFR 801.3. Optical laboratories are therefore not responsible for meeting UDI requirements for these devices.

UDI Responsibilities of Eye Care Professionals

According to information provided by The Vision Council, eye care professionals prescribe and sell finished prescription eyewear to patients. They submit a prescription to an optical laboratory for processing. Once the lenses have been transformed into the appropriate prescription, they may be tendered to the eye care professional or to the patient. The finished spectacles may contain the invoice from the optical laboratory, or the invoice information may be entered into the eye care professionals’ electronic systems. The invoice may or may not reach the patient, though the information regarding the prescription will generally be provided in some

form. No label is created by the eye care professional for 21 CFR 801 purposes.

Based on the unique characteristics of the prescription optical lens distribution chain and FDA's current interpretation of the FD&C Act and implementing regulations, eye care professionals do not meet the definition of "labeler" in 21 CFR 801.3. Eye care professionals are therefore not responsible for meeting UDI requirements for these devices.

Summary

The labeler of each device is responsible for meeting the labeling and data submission requirements in the UDI System rule. Based on the information you provided to FDA and FDA's current interpretation of the FD&C Act and its implementing regulations, prescription lens manufacturers, optical laboratories, and eye care professionals are not labelers, and therefore are not responsible for meeting UDI requirements for these devices.

It should be noted that an entity's status as a labeler does not relieve or otherwise change the other applicable FDA responsibilities for these entities. Additionally, this analysis is based on the longstanding, unique characteristics of the prescription optical lens distribution chain. Should business practices within the spectacle lens distribution chain evolve to be materially different from the practices described above, labeler obligations for these entities would need to be reevaluated. Further, the UDI system is in nascent stages, and FDA is still working through many issues related to implementation. Should FDA's interpretation of the FD&C Act or its implementing regulations change in a way that affects the responsibilities of prescription lens manufacturers, optical laboratories, or eye care professionals described in this correspondence, FDA will notify The Vision Council and the public well in advance, consistent with Federal law.

If you have additional questions, please contact the UDI Help Desk at GUDIDSupport@fda.hhs.gov.

Sincerely,

Linda A. Sigg -S

Digitally signed by Linda A. Sigg -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Linda A. Sigg -S, 0.9.2342.19200300.100.1.1=1300080209
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Linda Sigg
Associate Director of Informatics
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
Food and Drug Administration