DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

July 10 2015

Dear Intraocular Lens Labelers:

The purpose of this letter is to inform labelers of intraocular lenses (IOLs) that they may resume submission of IOL device identifier (DI) records to the Global Unique Device Identification Database (GUDID).

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

Device	Product Code	Classification Regulation
Intraocular lens (IOL)	HQL	21 CFR 886.3600
Multifocal Intraocular lens	MFK	
Accommodative Intraocular lens	NAA	
Toric Optics Intraocular lens	MJP	
Phakic Intraocular Lens	MTA	
Iris Reconstruction Lens	NIZ	

Fig 1

We believed at the time the labeling strategy being employed for the devices listed in the letter to industry would result in an extremely large number of DI record submissions to the GUDID. Not only would the volume of submissions greatly exceed the best estimates previously available to the FDA, but also many of these submissions would be virtually identical files. We determined that the additional time provided by the extension would allow us to work with affected labelers to develop an approach to ensure that meaningful data would be submitted to the GUDID. We informally asked the affected labelers to refrain from submitting their data for these devices to the GUDID until such an approach was developed.

After requesting and receiving further information from a significant number of the labelers of the devices listed in Fig. 1 above, we learned that the labeling strategy being employed by these labelers would result in a relatively small number of DI record submissions to GUDID.

For this reason, we are now withdrawing our request that the labelers of the devices listed in Fig. 1 refrain from submitting their data to the GUDID. You may continue your original UDI labeling strategy and submit your DI records for these devices to the GUDID at any time. Please

bear in mind that your DI records for these devices are required to be submitted to the GUDID no later than September 24, 2015.

The further information we received from labelers of these devices also indicated that the DI record information for different versions or models within a particular device brand would likely be virtually identical without further description. To lessen the impact of the repetitiveness of the DI records and improve the utility of the GUDID information, we encourage to you to describe device parameters specific to a particular device version or model in that device's DI record, using the "Device Description" field. Examples would include a description of cylinder power, optical diameter, and diopter.

We would like to express our thanks to all labelers covered by the August 15, 2014, letter to industry, including the IOL labelers, for working with us so diligently on this complex issue. We greatly appreciate your cooperation and look forward to our further collaboration.

Sincerely yours,

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