

OPTICAL LABS DIVISION G&R UPDATE

2016 Vision Expo West

September 14, 2016

Topics to Cover

- > **Update on UDI**
 - > **Status of Exemption Request**
 - > **Prep for Sept 23, 2018**

- > **Update on Prop 65**
 - > **Safe Harbor**
 - > **SUD efforts**

Update on Unique Device Identifier

- > Labeling law; allows for product traceability
- > Code on label/packaging
 - > Readable plain text
 - > Automatic identification and data capture (AIDC) format
 - > Device identifier/Product Identifier
- > GUDID reporting
- > Most TVC products are Class I medical devices
 - > **September 25, 2018 for Class I devices**
 - > Existing inventory gets three year exemption

UDI and Class I Medical Devices

- > **UPC code will satisfy the UDI labeling requirement**
- > **Will OPC work?**
- > **Still must populate GUDID**

TVC Efforts for UDI Relief

- > Request for Exception**
 - > Seeks to exempt lenses from UDI requirements**
 - > Concerted effort to coordinate timing**
- > Submitted Sept. 2015**
 - > Met with FDA in October 2015**
 - > Follow up conference call in Jan 2016**
 - > Responded to additional questions in Aug 2016**
 - > Seeking new meeting after Oct 2016**

BpA Safe Harbor

- > Issue for CA labs or labs doing business in CA.**
- > 3 micrograms per day based on exposure testing**
- > Limited to exposure**
 - > Does not cover inhalation or ingestion**
- > October 1, 2016**

SUD Efforts and TVC

- > **The TVC SUD application**
 - > **Scope of application**
 - > **Status of application**
 - > **Expected timetable**
- > **Goals**
 - > **Deter possible frivolous law suits**
 - > **Approve test methodology**

Questions

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