THE VISION COUNCIL

COLA 2017

Technical & Regulatory Update

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The Vision Council

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COLA 2017
Technical Update

- UDI Update
  - > Exemption Granted
    - » *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 the FDA and FDA's current interpretation of the FD&C Act and its implementing regulations, prescription lens manufacturers, optical laboratories, and eyecare professionals are not labelers, and therefore are not responsible for meeting UDI requirements for these devices."*

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Technical Update

- Prop 65
  - SUD Efforts
    - *April 2016, retained the services of William N. Hall of Venable, LLP to explore the possibility of receiving a SUD covering BpA in optical products (lenses, frames, sunglasses, OTC readers and safety glasses). Hall and Venable has a very strong background and SUD track record –*
    - *Mr. Hall and his firm have been involved in 2 of the 3 SUDs granted by OEHHA.*
    - *June 28 a TVC delegation met with the leadership of OEHHA to discuss the status of our SUD application and to answer questions.*
    - *OEHHA scientists reacted positively our the testing approach and pleased that BpA was not detectable in optical products*
    - *Questions related to the representation of the Frame Sample*
    - *Pleased with the Lens Sample*
    - *Asked for more OTC Readers and Safety Frames to be tested*
    - *Questions on BpA extraction protocols*
    - *Asked for details on the test lab*

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- SUD Efforts
  - *Summer and Fall of 2016 at the request of OEHHA additional testing / analysis occurred.*
  - *December 2, 2016 our final SUD application was sent to OEHHA.*
  - *Testing occurred on 129 eyewear samples across a variety of eyewear categories*
    - *prescription lenses,*
    - *sunglass lenses,*
    - *frames,*
    - *temples,*
    - *safety eyewear, and*
    - *nose pads*

> SUD Efforts

- » *Results showed total BPA content in these samples ranged from not detected ("ND") 15 parts per billion ("ppb") to only 302 parts per million ("ppm"), with a great majority below 10 ppm*
- » *When tested using an artificial perspiration extraction method not one of the 129 eyewear samples showed any migration of BPA from the samples to the leachate*
- » *If BPA migrated into the artificial perspiration at the detection limit, the theoretical estimated exposure posed by the BPA is significantly less than the Maximum Allowable Dose Level ("MADL") of 3 micrograms per day ("µg/day") and a BPA concentration of 302 ppm in eyewear does not result in a detectable exposure to BPA.*
- » *Asked OEHHA to issue a completeness determination of our SUD application in early 2017.*
- » *When SUD application is deemed complete then no NOVs can be filed against the product category in question*

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- Labeling and Language Changes
  - *More restrictive*
  - *Includes symbols and different warning language*
  - ***Must identify listed substance in product***
    - ***"WARNING: This product can expose you to a chemical such as phthalates known to the State of California to cause cancer [or birth defects or reproductive harm]. For more information go to www.P65 Warnings .ca.gov".***

- Also required for environmental and occupational exposures
  - *No later than August 30, 2018*
  - *Update Guidance Document*

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- ANSI ASC/Z80 - 26 Active standards
  - > Under revision
    - » *ANSI Z80.31 – Ready Readers*
      - *Remove "single vision"*
    - » *Z80.1-2020*
- ANSI Z87.1
  - > ANSI Z87.1-2015-Personal Eye and Face Protection Devices
    - » *Bio Hazards*
- ISO/TC172 – 28 Active standards
  - > 21987 and 8980-1&2
    - » *At the FDIS stage*
- ISO/TC94 – 12 Active standards
  - > Safety and Sunglasses

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