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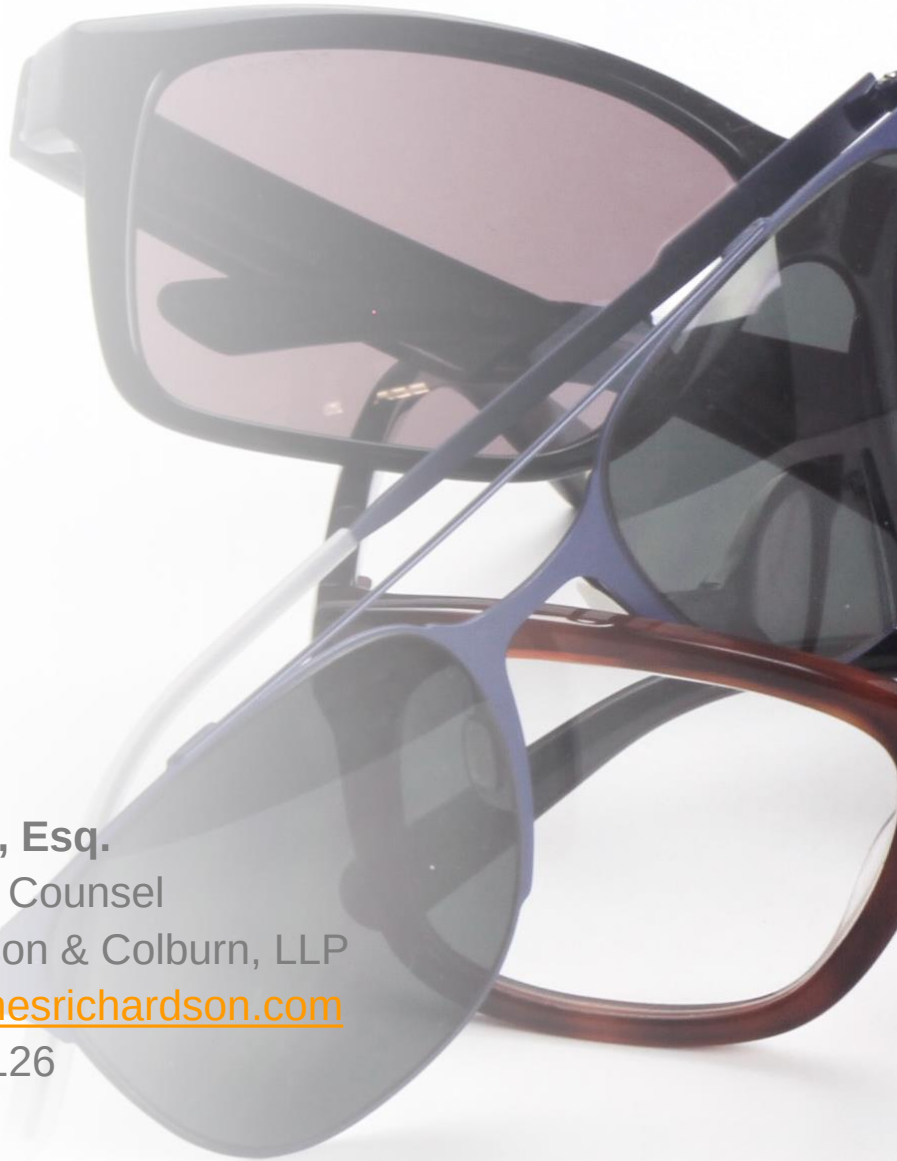

Government & Regulatory Affairs Update
COLA – April 26, 2019

Michael C. Vitale, ABOM
Senior Technical Director
& Lens Division Liaison
The Vision Council
mvitale@thevisioncouncil.org
703-548-2684

Rick Van Arnam, Esq.
Regulatory Legal Counsel
Barnes, Richardson & Colburn, LLP
rvanarnam@barnesrichardson.com
212-725-0200, x126

California Prop 65 SUD Efforts

- December 2, 2016, TVC submitted an SUD application to OEHHA for BpA in our members products
- Testing occurred on 129 eyewear samples across a variety of eyewear categories
  - Prescription and Sunglass lenses,
  - Ophthalmic and Sunglass frames,
  - temples,
  - safety eyewear
  - nose pads

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OEHHA
SCIENCE FOR A HEALTHY CALIFORNIA

California Prop 65 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 vast 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 (>15ppb)
- Toxicology testing reported;
  - 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

California Prop 65 SUD Efforts

- Asked OEHHA to issue a completeness determination of our SUD application in early 2017
- Once an SUD application is deemed complete then no NOVs can be filed against the product category in question
- OEHHA issued follow up questions in May of 2017
- TVC staff and counsel met with OEHHA on August 1st, 2017 to discuss their follow up questions
- The issues were around the presentation of the data from ATS Testing Facility
- Concerns regarding the “broad” scope of the SUD request was also raised
- The updated SUD application was submitted on 7/17/2018
- Our application was deemed complete on 3/8/2019!!!

California Prop 65 SUD Efforts

- **Next Steps**
  - Approximately 60 days for determination?

In the mean time, continue to label!!!

  - Also, please remember, this application is for BpA and not any other chemicals that may be in your products!

Prop. 65 Update

- New warning language must be used for all products made on or after August 31, 2018 if products contain listed substance(s)
- Products made before August 31, 2018 may use either new warning language or old warning language on products that contain listed substance(s)
- New warning language must be used for all occupational or environmental exposures of listed substance(s)
- Guidance document on Prop 65 changes --

https://www.thevisioncouncil.org/sites/default/files/TVC_Prop65_ChangesMemo_06_27-mcv-final.pdf

FDA Lab Registration Issue

- Still waiting on decision
- Met with FDA on November 28, 2017
- Submitted supporting documents on March 13, 2018
- Several email pings after submission
- March 1, 2019 – matter being reassigned
- Do not register lab at this time unless you are doing something more than typical lab processing
- Registration fee increased in 2018 to $4,624.00 from $3,382.00

Intro to CGMPs

- **Current Good Manufacturing Practices**
  - **Quality systems to insure safe, effective and compliant medical devices**
  - **Regulated by FDA at 21 CFR § 820**
  - **Covers manufacturers – broad concept, can even include importers**
  - **Processes and procedures covering design, monitoring and control**
  - **Class I devices not excused from CGMPs. Subject of FDA audit**
  - **Written policies and procedures, with buy-in at C-suite level**
  - **Procedures are to be audited.**

QUESTIONS?