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Eye to Eye

FDA Proposes Changes To Eyewear Regs

By Brenda Fishbaugh

In all the hubbub about the FDA's Proposed Rule concerning UV exposure times and the under-18 ban, you may have missed their suggestion that current eye protection regulations be dramatically changed. In fact, 25% of the proposed changes involve adjusting current eye protection regs in an effort to "harmonize" with a European standard.

So, why would the FDA attempt to change a rule that has been in place since 1979?

The FDA explained that a new standard would prevent eye burns and ocular melanoma caused by sunlamp exposure. Footnoting research done 12 years ago in Australia, the FDA cited eye injury as the main focus for changing the eye protection standard. The research they cited included welders and indoor tanners, though respondents were not asked if the injury resulted from not wearing eye protection. Note the word "respondents;" that's right – the FDA research relied on phone surveys!

The question is: If you wear FDA-compliant eyewear, do you eliminate that risk? I would certainly hope so; however, the FDA's research does not differentiate between injury that occurred with and without it.

Industry veteran, Joe Schuster, assisted me in researching the FDA's Proposed Rule. Joe dug into the Center of Disease Control statistics (NEISS) regarding sunbed injuries requiring ER visits. Interestingly, those injuries dropped dramatically from 2003 (6,487) to 2012 (1,957) and eye injury made up 5.8% of the 1,957. That's 110 tanning related eye injuries in a year, with no data on whether they occurred with or without eye protection. These injuries, spread across millions of UV sessions each year, depict a relatively small number. Additionally, we don't know if FDA-compliant eye protection was worn, or whether they tanned at home or in a supervised, professional tanning salon.

I spoke about this with both leading tanning salon insurance providers. Insurtec shared that about 1% of claims involve eye damage, and again, it's inconclusive whether the tanner wore eye protection. So, where is the consumer safety issue that is causing the FDA to demand such an extensive change in regs and new, extensive reporting requirements? A new law of this type would also require a reference on eye protection packaging.

The FDA Proposed Rule also cites that by changing the standard to harmonize with the European standard, ocular melanoma can be reduced. Ocular melanoma! Joe Schuster learned from the Ocular Melanoma Foundation website that they don't think UV light even plays a role in causing ocular melanoma. I contacted our ophthalmologist consultant, Dr. Mark Kimpel, who cited several medical research articles, again, showing that UV light is not thought to cause ocular melanoma. He worked at the Mayo Clinic in Rochester, MN and explained that ocular melanoma is extremely rare, according to specialists. Of course, UV light contributes to other eye damage; however, we believe that wearing FDA-compliant eyewear dramatically reduces that risk.

Joe and I spent over two months researching FDA claims and learning more about the suggested European eyewear standard contained in EN 60335-2-27:2015 and changes that are in play, which have not yet been finalized. Joe corresponded with Sharon Miller of the FDA, as well as several lamp manufacturers and other eyewear makers to get as much info as possible. Our response to the FDA included several areas of concern, and also suggestions for better methods of protective eyewear use.

On March 14, we published our results and response on the FDA.gov website, and also provided our info to the ITA (Indoor Tanning Association) to buttress their response to the eye protection portion of the FDA Proposed Rules, to revise the current standard of 21CFR1040.20.

It will be some time before we learn what the FDA may or may not modify on the Proposed Rules. Certainly, we will all be impacted, even as far as the eyewear you can sell in your salons. However, it will not be for lack of due diligence on our part to fully understand the FDA's position and current and proposed European laws that will influence the U.S. indoor tanning industry. ■



About the Author:

Tanning industry veteran Brenda Fishbaugh is president of Eye Pro, Inc., makers of disposable eyewear. She travels extensively training salons on the effects of UV light on vision.

