**From:** Katz, Linda <Linda.Katz@fda.hhs.gov>
**Date:** July 5, 2016 at 1:36:45 PM EDT
**To:** Sadrieh, Nakissa <Nakissa.Sadrieh@fda.hhs.gov>
**Subject:** RE: Formaldehyde CP review draft-June 2016

Nakissa

I've read through the CP memo and provided my edits. We need to discuss it before you send it back to Tyna for revision. In general, it was well written and was reasonably easy to follow. However, it is unclear to me what information was provided by the petitioner and what information is included from information that we found on our own. When we get together tomorrow, we can go over it.

Linda

---

**From:** Sadrieh, Nakissa
**Sent:** Monday, June 27, 2016 4:28 PM
**To:** Katz, Linda
**Cc:** Sadrieh, Nakissa
**Subject:** Formaldehyde CP review draft-June 2016

Linda,

Please find attached the draft review for the formaldehyde hair straighteners CP by EWG. This is ready for your review, in order to get your initial input on whether you agree with the how I have advised the drafting of the responses and recommendations for the 3 questions posed by EWG. Please note that the section that provides the summary of our formaldehyde safety assessment, is identical to the executive summary in the safety review, after you made significant modifications to it, to reduce the length of it.

Again, I have ensured that there is more information in this review, than what will go into the response letter. however, I found it was necessary to provide the sources of the data and basis for the final recommendations and responses to the CP questions.

We are working on finalizing the formaldehyde safety review now. I will send that to you in the next couple of weeks, since you now have to review the CP review attached, and then it is ICCR.

As for the DEA CP review, that is making some progress, and I am working quite closely with John Gasper and Robeena on the content of that review. I am trying to see how I can formulate a story for denying that petition, to the extent possible. some of the same reasoning used in the attached CP review might be used in the DEA CP review as well, since the fundamental issue is the same, which is that the agency has not conducted a safety review of DEA, because the agency never has to do a safety assessment of anything, and as such, it did not take any regulatory action to restrict or

ban the use of DEA. However, in the case of DEA, there are some complicating factors, because based on further investigations that I asked Gasper to do, and input from others in the division, we now know that an FR notice was issued several years ago, and there was some enforcement "discretion" at some point, where products were being detained for nitrosamine content, and there was definitely some unofficial policy on nitrosated DEA in cosmetics. but at some point, and based on scanned emails in DCS, the "enforcement discretion" approach was changed by upper management, and there was some research done by ORS, and nothing happened afterwards, until a couple of years ago, when we had the DEA market survey done. so, some parts of the story are more solid than others, but we are putting that together now, and we will send that to you when I think that it makes sense.

Regards,
Nakissa Sadrieh, Ph.D.
Director, Cosmetics Division
Office of Cosmetics and Colors (OCAC)
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)
4300 River Road
Room 1034 (HFS-125)
College Park, MD 20740

Tel: 240-402-2194