Locke Lord LLP

750 Lexington Avenue
New York, NY 10022
Telephone: 212-308-4411
Fax: 212-308-4844
www.lockelord.com

Sharon A. Blinkoff
Direct Telephone: 212-912-2893
sharon.blinkoff@lockelord.com

October 28, 2015

Via E-mail Submission

Monet Vela
Regulations Coordinator
Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, CA 95812

Re: Petition for Administrative Rulemaking to Repeal or Amend Proposition 65 Regulations Pertaining to the Maximum Allowable Dose Level for Lead

Dear Ms. Vela:

Thank you for the opportunity to provide written comments on the Center for Environmental Health's ("CEH") Petition for Administrative Rulemaking to Repeal or Amend Proposition 65 Regulations Pertaining to the Maximum Allowable Dose Level for Lead (the "Petition") and the Draft Pre-Regulatory Language for Section 25805 (the "draft rule").

As counsel for the non-profit trade association Independent Cosmetic Manufacturers and Distributors ("ICMAD"), I write to inform you of ICMAD's significant concerns with both the Petition and the draft rule. ICMAD is an organization whose membership is composed of small entrepreneurial and emerging growth companies in the cosmetics and personal care industries. ICMAD's membership, small businesses that innovate and provide jobs, are the type of companies that will bear the brunt of any changes to the existing Maximum Allowable Dose Level ("MADL") for lead.

ICMAD was disappointed to hear the view expressed in certain oral comments that the concerns of small businesses about changes to the MADL are irrelevant because the MADL is an optional safe harbor level. ICMAD was further alarmed that the Center for Environmental Health's position continues to be that the MADL should be repealed in its entirety. ICMAD does not believe that doing so protects or informs consumers. ICMAD therefore submits the following comments.

I. Small Businesses and Consumers Rely Upon MADLs to Appropriately Gauge Risks.

Determining whether a product is required to carry a warning label, absent a MADL, can be prohibitively expensive for small businesses. Even when a company performs such analysis,

they remain vulnerable to the type of bounty hunter litigation that has developed around enforcing warning label requirements. The costs of defending against these cases, even when the company makes an appropriate determination on the warning label, are high. While major manufacturers are able to absorb such costs, small companies cannot. In some instances these costs can drive companies out of business. In other instances, companies will be forced to choose between passing these costs on to consumers in the form of higher prices or providing fewer product choices. In fact, it is this disproportionate impact on small businesses that often drives bounty hunter litigators to specifically target smaller companies to try and secure payouts. Such behavior does nothing to improve product safety or inform consumers of risks.

CEH's proposal to entirely eliminate the MADL is particularly odd in that it will likely result in the opposite effect of what they intend. CEH's position is that there is no safe level of exposure to lead. (CEH Petition, p. 11.) Under current regulations, manufacturers have an incentive to keep exposure below 0.5 micrograms/day in order to avoid Proposition 65 labeling requirements. This level is 1/1000th of the level at which no observable effect exists. However, eliminating the MADL entirely also eliminates the incentive to ensure that products stay below this level. CEH's proposal might actually result in products with higher lead content as manufacturers find it cheaper to put a warning label on a product rather than to self-certify a safe level or reduce lead content and exposure.

An established MADL for lead benefits both consumers and producers. If a product does not have a warning label, consumers will know that a product presents a lead exposure risk at less than 1/1000th of the level at which no observable effect exists. If a product contains a warning label, consumers will know the concrete number at which a warning is required rather than guessing at what level the product has been self-certified as safe. In other words, a MADL does more to inform consumers as to actual risks than the absence of a MADL. Producers, such as ICMAD's members, benefit because they can rely on the MADL to avoid the prohibitive costs of self-certifying a safe level and defending themselves from unwarranted litigation over safe products.

II. OEHHA Has Failed to Adequately Explain the Scientific Basis for Reducing the MADL.

In response to the Petition, OEHHA has proposed lowering the MADL from a lead exposure level of 0.5 micrograms per day to 0.2 micrograms per day in its draft rule. ICMAD is concerned that OEHHA has failed to adequately explain the scientific basis for this reduction.

At this point, the research OEHHA relied upon and the MATLAB data that purports to support the reduced level has only been available to the public for two weeks. This is an inadequate period of time to determine whether OEHHA's conclusions have a generally-accepted scientific basis. The only publicly available explanation of the scientific basis is the slideshow presented at the October 14, 2015 Hearing.

Typically, because this is a pre-rulemaking proceeding, this failure to adequately explain the science relied upon would not be a major issue. OEHHA would be expected to present a robust defense of its science as it moves to the rulemaking phase. Here, however, as explained by OEHHA's counsel at the October 14, 2015 Hearing, it is expected that this will be an abbreviated rulemaking because OEHHA is currently in litigation over the existing MADL with

Mateel Environmental Justice Foundation. As a result of that litigation, OEHHA has indicated that it will move forward to a final rule rather quickly. ICMAD hopes that despite this expedited process, OEHHA will provide a more detailed explanation of the scientific basis for the rule.

III. ICMAD is Concerned that the Proposed Rule Will Confuse Consumers as to Actual Risks Associated with the Products Produced by its Members.

ICMAD's members produce and distribute cosmetic products, including lipstick. The source of lead in cosmetic products is primarily from natural sources and typically comes from color additives. Those color additives, under the Federal Food, Drug, and Cosmetic Act, must obtain pre-market approval. The FDA limits lead in color additives to maximum specified levels protective of human health. The FDA has conducted several extensive studies on the lead content of lipstick, and has determined that "[l]ipstick, as a product intended for topical use with limited absorption, is ingested only in very small quantities. [The FDA does] not consider the lead levels [it] found in the lipsticks to be a safety concern."[1]

The vast majority of lipsticks fall well within the safe harbor level established by the existing MADL even under an assumption that under regular use all lead content is ingested (which is not the case). Under the new MADL, however, a number of small lipstick manufacturers might feel the need to put a warning label on a product that the FDA has determined presents no safety concerns related to lead levels simply to avoid the costs associated with bounty hunter litigation. Doing so misinforms consumers as to the actual risks associated with a product found to be safe by the FDA. Such a result is particularly egregious as OEHHA has failed to fully explain the scientific basis for the MADL proposed in its draft rule.

IV. Conclusion

ICMAD appreciates the opportunity to present written comments on the Petition and draft rule. Its membership has significant concerns about the path being charted by OEHHA. A rule is being promulgated without adequate explanation of its scientific basis. This rule will have a disproportionate impact on small business such as ICMAD's members without reducing risks to human health or properly informing consumers. As currently proposed, the rule has the potential to confuse consumers as to the risks associated with their product choices. ICMAD urges OEHHA to preserve the current MADL.

Locke Lord LLP

By: _____
Sharon A. Blinkoff

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[1] FDA, *Lipstick & Lead: Questions & Answers*, <http://www.fda.gov/Cosmetics/ProductsIngredients/Products/ucm137224.htm> [as of October 28, 2015.]