State of California DEPARTMENT OF JUSTICE



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Via E-Mail and U.S. Mail

April 4, 2012

Josh Voorhees The Chanler Group Parker Plaza 2560 Ninth Street, Ste. 214 Berkeley, CA 94710

RE: 60-Day Notice of Violation from Anthony Held to Kiss Nail Products et al.

Dear Mr. Voorhees:

We write to you concerning the "Second Supplemental 60-Day Notice of Violation" you sent Kiss Nail Products, Inc. and several retail companies that sell Kiss products, alleging violations of Proposition 65. The notice, which you sent on behalf of Anthony Held, is dated March 29, 2012 ("March 2012 notice"). You allege violations of the Proposition 65 warning requirement based on the sale of four categories of products. Attached to the notice is a certificate of merit, signed by Clifford Chanler, in which he certifies his belief that "there is a reasonable and meritorious case for the private action." Proposition 65 requires the attorney for a private enforcer to submit this certification. (Health & Saf. Code, § 25249.7(d)(1).) As you are aware, one of the roles of our office is to review the notices and accompanying certificates of merit to ensure that they are adequate. In this case, we write to express our opinion that the notice is not adequate and should be withdrawn.

One of the categories of products you identify in the March 2012 Notice is "Cosmetic Cases/Bags" that contain Di(2-ethylhexyl)phthalate, or "DEHP." This category of products is now at issue in a case that is pending in Marin County Superior Court. Kiss has filed a motion for summary judgment in that case. Kiss claims that exposures to DEHP from the cosmetic bags and cases are below levels that require a warning. In response, you submitted to the court your own risk assessment and analysis that you claim supports a warning under Proposition 65. For

¹ DEHP is one of several phthalates listed under Proposition as a chemical known the the State of California to cause birth defects and other reproductive harm. (Cal. Code Regs., tit. 27, § 27001, subd. (c).)

the reasons discussed below, your assessment is significantly flawed and demonstrates that you do not have a valid basis for the March 2012 notice as to the category of cosmetic bags containing DEHP.

BACKGROUND

On December 21, 2010, acting on behalf of Anthony Held, your office sent a 60-day notice to Kiss Nail Products, Inc. and to Kiss Products, Inc. (collectively, "Kiss"), alleging that they sold "Cosmetic Cases/Bags containing Di(2-ethylhexyl)phthalate" without a warning, in violation of Proposition 65. The notice lists a single example of a product within the cosmetics bags category, a pedicure kit. On March 25, 2011, your client sued Kiss for the violations alleged in the notice. (Held v. Kiss Nail Products, Inc., et al., Marin County Super. Ct., No. Civ. 1101576.)

On September 1, 2011, you sent a supplemental 60-day notice to Kiss and to two retail companies that sell Kiss products. The new notice identifies the same pedicure kit as the first notice and one new example of cosmetic bags, as well as three new product categories we do not address in this letter.

In October, Kiss filed a motion for summary judgment on its affirmative defense that average users of the cosmetic bags are exposed to levels of DEHP below the Maximum Allowable Dose Level ("MADL"). (Health & Saf. Code, § 25249.10(c).) You filed the opposition to summary judgment at the beginning of March. The hearing on both motions is scheduled for April 11, 2012.

On March 29, 2012, two weeks before the motion for summary judgment hearing, you sent a second supplemental 60-day notice of violation to Kiss on behalf of Mr. Held. The new notice merely adds a new retailer that sells Kiss products, and adds three new product examples to the existing category of cosmetic bags with DEHP, products that appear to be identical in all material aspects to the product at issue in the motion for summary judgment.²

DISCUSSION

We have reviewed the analysis that you submitted to the court to support your argument that cosmetics bags containing DEHP require a warning under Proposition 65, as alleged in the March 2012 notice. At the core of your claim is an analysis of anticipated DEHP exposures by your expert, Dr. Myrta Xenaki-Petreas, which relies primarily on a report Dr. Kenneth Bogen prepared for our office several years ago to identify categories of children's products that may warrant further evaluation of potential phthalate exposures. (K. Bogen, "Technical Report: Screening-Level Hazard Assessment for Six Phthalates Under A.B. 1108 and Proposition 65"

² The remainder of the allegations in the March 2012 notice, on which we express no opinion, were already contained in a prior 60-day notice dated September 1, 2011.

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(August 2008) ("Bogen Report").) The Bogen Report states that it is only a screening level document and that it is not intended to be used for risk assessment purposes, as you have done. It is our view that Dr. Xenaki-Petreas improperly relied on the Bogen Report, since it was not intended to be used to quantify exposures for any particular products. We believe this compromises your ability to certify in the March 2012 notice that there is a reasonable and meritorious case for the private action as to cosmetic bags.

Dr. Xenaki-Petreas offered an estimate of exposures to DEHP by average users of the Kiss bags. She based the estimate almost entirely on the Bogen Report, explaining that "I conducted an exposure assessment using the assumptions and models in the AG Report for DEHP for the Kiss pedicure and manicure kit bags found to contain up to 26% DEHP...." (Xenaki-Petreas Decl. ¶ 23.) Our office, however, commissioned the Bogen Report for the very specific and narrow purpose of assessing whether further evaluation was needed to determine if children's products that comply with California's 0.1% phthalate standard might still need a warning under Proposition 65. The executive summary states:

This screening assessment addresses the extent to which full compliance with A.B. 1108 (the California "Toxic Toy" bill) implies that amounts of six phthalate plasticizers contained in plastic polyvinyl chloride products for children, as specified in that law, are very likely to result in DEHP exposures that would not require warning labels under [Proposition 65].

(Bogen Report at vii.) The report thus used a "deliberately conservative (health protective) approach," and cautions that it is not intended to identify a Proposition 65 labeling requirement for any particular product: "To make such a determination would require a much more product-detailed, specific use examination than feasible within the scope of this screening-level assessment." (*Ibid.*)

Any question about the limited function of the Bogen Report as a screening tool is resolved by examining the tables at the end of the report. The tables summarize the report's findings for the 94 categories of children's products that were considered. For each category, the final column indicates whether the "[e]stimated exposure needs further evaluation." (See, e.g., Bogen Report at 74, Table B-2a ["Estimated DEHP dose for 94 age-specific product categories, assuming 0.1% content by weight"].) Accordingly, while the tables list the investigator's "deliberately conservative" estimated exposures to children for each category, the purpose is to identify categories for further analysis. Similarly, the conclusions that Dr. Xenaki-Petreas reached based on the Bogen Report's estimated exposures are not evidence that exposures at this level will occur. Rather, they indicate areas for "further evaluation."

Your analysis in support of the new notice appears to be further flawed by your argument that any risk assessment must be based on a dermal Maximum Allowable Dose Level rather than the MADL for oral exposure that is set by regulation (410 ug/day). (Cal. Code Regs., tit. 27, § 25805(b).) This is incorrect. The oral MADL is proper because the MADL for dermal exposures, as a comparable exposure pathway to intravenous exposures, would be higher than

the oral MADL.³ In addition, your expert suggests that in assessing the risk to a pregnant woman you must rely on the 20 ug/day MADL that has been set for exposures to infants, rather than the adult MADL of 410 ug/day. (Xenaki-Petreas Decl. ¶ 27-28.) Under the Proposition 65 regulations, however, DEHP exposures to adults that fall below the safe harbor level for adults are deemed to be below the MADL, which has been set at a level low enough to protect against potential harm to the fetus. (Cal. Code Regs., tit. 27, §§ 25803(a)(1), 25805

Additionally, in rejecting Kiss's product use assumptions (that the hypothetical adult woman would hold a Kiss bag with both hands (of adult male size) for 15 minutes a day), you incorrectly argue that a defendant must use actual data to determine who are "average users" of the product.⁴ Neither the regulations nor the law require the use of actual data on average users in every instance. Moreover, the assumption that average users of the pedicure kit are adults who handle the kits with both hands for 15 minutes every day seems both reasonable and conservative. Unless you have evidence to show that average users of the pedicure bags are children, or that people handle the bags for more than 15 minutes a day, we do not agree that the absence of actual data on Kiss's part, alone, is a basis to reject its exposure estimate.

Accordingly, it appears that your March 2012 notice concerning cosmetic bags containing DEHP is based on an improper use of the Bogen report, and on flawed and erroneous assumptions (including that the risk assessment must be based on a dermal rather than the oral MADL, that it should apply the 20 ug/day MADL for an infant, rather than the 410 ug/day MADL for an adult, and that it must utilize actual data to determine who are the "average users" of the products). Because of these flaws, we conclude that you cannot certify in good faith that the claims in the March 2012 Notice as to cosmetic bags containing DEHP are reasonable and meritorious.

CONCLUSION

Normally when our office reviews a certificate of merit for a sixty-day notice, we assess the prima facie evidence of exposure presented by the noticing party and do not assess the party's ability to withstand any affirmative defense. In this case, however, given that briefing has been submitted to the court, we have reviewed the basis for your analysis and legal position concerning the exposure to DEHP from Kiss cosmetic bags. In light of our review, it appears that you can not certify, as required by the statute, that there is a "reasonable and meritorious case for the private action" set forth in your March 2012 notice concerning cosmetics bags containing DEHP. Apparently, you do not have independent evidence to overcome the showing

³ The adult MADL for intravenous exposures to DEHP is 4,200 ug/day. (Cal. Code Regs., tit. 27, § 25805(b).)

⁴ The regulations state that "[f]or exposures to consumer products, the level of exposure shall be calculated using the reasonably anticipated rate of intake or exposure for average users of the consumer product, and not on a per capital basis for the general population." (Cal. Code Regs., tit. 27, § 25821, subd. (c)(2).)

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Kiss has made or you would have presented it to the court. Accordingly, we request that you withdraw the March 2012 notice as to those products.

Sincerely,

HARRISON M. POLLAK Deputy Attorney General

For KAMALA D. HARRIS Attorney General

cc: Malcolm Weiss (for Kiss Nail Products)

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