

LOG OF MEETING

U.S. CONSUMER PRODUCT SAFETY COMMISSION  
OFFICE OF COMMISSIONER MARY SHEILA GALL

11/10/94 RZ

X Reelitz

**SUBJECT:** COMBE, INC.

**DATE OF MEETING:** SEPTEMBER 12, 1994, 2:30 P.M.

**PLACE:** CPSC Headquarters/Room 714

**LOG ENTRY SOURCE:** Bruce C. Navarro

**DATE OF ENTRY:** October 17, 1994

**COMMISSION ATTENDEES:**

Commissioner Mary Sheila Gall  
Bruce Navarro  
Patricia Semple  
Suzanne Barone

**NON-COMMISSION ATTENDEES:**

Andrew S. Krulwich  
Julie Jacobs  
David Johnson

**SUMMARY OF MEETING:**

Combe's representatives, in essence, summarized issues raised in the attached letter. Commissioner Gall raised questions pertaining to toxicity and packaging size and feasibility.

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September 8, 1994

## VIA HAND-DELIVERY

Eric A. Rubel, Esquire  
General Counsel  
U.S. Consumer Product Safety Commission  
4330 East-West Highway  
Bethesda, Maryland 20814

Re: Requirements for Child-Resistant Packaging; Proposed Requirements for Products Containing Lidocaine or Dibucaine (57 Fed. Reg. 34274): Combe, Inc. Request for an Exemption for OTC Topical Lidocaine-Containing Products

Dear Mr. Rubel:

The purpose of this letter is to summarize, and in some cases, expand upon the points made in our meeting with you today on behalf of Combe, Inc. ("Combe"), a manufacturer of lidocaine-containing topical ointment. We appreciated the opportunity to meet with you.

Combe manufactures and distributes in the United States an OTC triple antibiotic/lidocaine ointment combination product which is packaged in 1/2 ounce and 1 ounce collapsible aluminum tubes.

In response to the Consumer Product Safety Commission's ("CPSC") August 4, 1992 proposed rule regarding lidocaine and dibucaine products (57 Fed. Reg. 34274), Combe submitted a comment to CPSC requesting an exemption from child resistant packaging ("CR packaging") for OTC topical lidocaine preparations. In its draft final rule contained in the August 3, 1994 Briefing Package to the Commission, the staff did not directly address the arguments raised in Combe's request for an exemption. Indeed, the staff has not even presented the Commission with the option to vote to

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grant the exemption. This, in itself, raises legal issues because an agency is obligated under the Administrative Procedures Act to consider and respond to comments. See Williams Natural Gas v. FERC, 872 F.2d 438 (D.C. Cir. 1989); Action on Smoking and Health v. C.A.B., 699 F.2d 1209, 1216 (D.C. Cir. 1983). Most importantly, however, there are important public policy and legal issues raised by the inclusion of OTC topical lidocaine preparations that appear to have been overlooked. We respectfully urge the Commission to revisit Combe's request for an exemption from CR packaging for OTC topical lidocaine-preparations for the following reasons as set forth more fully below.<sup>1</sup>

Specifically,

- There have been no serious incidents with OTC topical lidocaine despite the fact that an estimated 6.2 million units were sold in 1992. The only serious lidocaine incidents have been with prescription, viscous formulations. Tens of millions of units of the OTC topical products have been sold over the last ten years without one serious illness or fatality reported. And, it is "serious personal injury or serious illness" that the statute expressly is designed to prevent. 15 U.S.C. § 1472(a)(1). (Emphasis added).
- The staff does not contest these facts. Indeed, the staff readily admits, and the data shows, that lidocaine is far less toxic than dibucaine, which the staff calls "one of the most potent and toxic local anesthetics."
- The only basis given in the Briefing Package for including topical lidocaine is that there have been serious incidents with the far more toxic topical dibucaine and, in the staff's view, this shows that ointments and creams can possibly be ingested. Briefing Package, Memorandum to the Commission from Ronald L. Medford and Suzanne Barone at 3-4 (hereinafter "Staff Memorandum"). Therefore, the staff apparently reasons, topical lidocaine should be included.

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<sup>1</sup> We are requesting the exemption for all OTC topical lidocaine-containing products (e.g., ointments, creams, and gels). We would note that in Combe's prior comment to the agency, the company only referred to an exemption for lidocaine-containing ointments and creams. However, Combe would like to clarify that any such exemption should apply to all OTC topical lidocaine-containing products.

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- However, this is lumping together apples and oranges. The staff has, in essence, improperly grouped lidocaine and dibucaine, as well as prescription and OTC lidocaine products, together in this rulemaking. The law places the burden on the Commission to demonstrate that the hazard from the particular substance by reason of its packaging requires special packaging to protect against serious injury or illness. 15 U.S.C. 1472(a)(1). There is no finding or evidence in the record that supports the proposition that OTC topical lidocaine-containing products, not dibucaine formulations, present serious injury because of their packaging.
- The recommendation to include topical lidocaine OTC formulations is over-regulation in its starkest form, especially since (i) the staff has no present child-resistant packaging it can turn to right now for these products and (ii) the proposal will, at best, impose hundreds of thousands of dollars in costs and, as the staff readily admits, impose substantial financial loss on some small businesses. Briefing Package, Tab A, Draft Final Rule for Requirements for Child-Resistant Packaging at 30-31 (hereinafter "Draft Final Rule"). This last point is astounding. For the Commission to impose substantial financial loss where there is little, if any, risk, has been unheard of since the mid-1970's when the Commission was roundly criticized by Congress and others for its insensitivity in allegedly causing a company to go out of business.
- As a matter of policy, this result is unjustifiable. As a matter of law, it fails to meet the requirements of the Act which place the burden on the Commission to demonstrate both the serious hazard from this product as well as technically feasible, practicable and appropriate alternatives. The fact is that there is very little, if any, risk and, as the staff admits, it is "not aware of any commercially available reclosable CR feature for a (2 ounce or less) metal or plastic tube." The staff's attempt to shift the burden of proof on the industry to show such factors as the instability of plastic tubes and the unavailability of technically feasible and practicable packaging is unlawful.

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I. **THE STAFF HAS NOT DEMONSTRATED THAT OTC TOPICAL LIDOCAINE PREPARATIONS, BY REASON OF THEIR PACKAGING, POSE A SUFFICIENT RISK TO CHILDREN TO REQUIRE SPECIAL PACKAGING.**

The Poison Prevention Packaging Act ("PPPA") provides that in order to establish standards for the special packaging of a product, the Commission must find that:

the degree or nature of the hazard to children in the availability of the substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance. . . . 15 U.S.C. § 1472(a)(1).

As the legislative history of the PPPA indicates, the Commission "must find that the substance is responsible for serious personal injury to, or illness of, children and that such illness or injury arises because children are enabled by its packaging to obtain access to the substance." S. Rep. No. 91-845, 2nd Sess. at 10 (hereinafter "S. Rep."). Thus, CPSC bears the burden of proving that the particular substance at issue is responsible for serious injury to or illness of children by reason of its packaging. The Commission has not satisfied this burden with respect to topical lidocaine-containing products.

Specifically, the staff has offered no data to show that there have been any confirmed deaths or serious injuries associated with OTC topical lidocaine products. Indeed, the staff concedes in its recent briefing package to the Commission that ". . . no accidental deaths of children have been attributed to OTC formulations of lidocaine. . . ." despite the fact that 6.2 million units of lidocaine-containing ointment and cream were sold in 1992 and generally comparable amounts for more than ten years. Staff Memorandum at 3. Moreover, the staff concedes that lidocaine and dibucaine exposures in general "do not have serious outcomes." *Id.* at 3.

The only basis the staff gives to include OTC topical lidocaine products in this rulemaking is to incorrectly lump together both lidocaine and dibucaine as well as prescription and OTC lidocaine formulations in the same rulemaking despite the

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obvious differences between these ingredients and dosages. Draft Final Rule at 33-34; Staff Memorandum at 3-4. To group lidocaine and dibucaine together overlooks the different toxicity risks between the two ingredients. As the staff itself notes, "(d)ibucaine is one of the most potent and toxic local anesthetics [with] (s)ystemic toxicity . . . includ[ing] serious effects on both the central nervous system and the cardiovascular system." 57 Fed. Reg. 34277 (August 4, 1992). Indeed, the staff concedes that a "10-fold adjustment from levels of regulation for lidocaine to levels of regulation for dibucaine is reasonable . . . ." Briefing Package, Tab F, Memorandum from Susan Aitkin, Division of Poison Prevention and Scientific Coordination to Suzanne Barone, July 19, 1994 at 4.

In addition, topical OTC lidocaine-containing products should not be grouped together with prescription formulations such as viscous and liquid dosage forms (the dosage forms in which some serious injuries with lidocaine have been observed) since the potential for toxicity differs greatly between these varying product formulations.

Thus, the proposal to include lidocaine-containing ointments, creams and gels smacks of overregulation especially in light of the fact that, as discussed below, the staff has not presented any technically feasible or appropriate CR alternatives. Further, this proposal is equally unjustifiable given that the staff admits that the costs associated with designing new CR packaging for such products may range from \$145,000 - \$585,000 and could take 27-36 months to develop. Draft Final Rule at 30-31.

### II. CR PACKAGING FOR LIDOCAINE-CONTAINING OINTMENTS, CREAMS AND GELS IS NOT TECHNICALLY FEASIBLE, PRACTICABLE, APPROPRIATE OR REASONABLE.

The staff itself concedes that it is not aware of any technically feasible, practicable or appropriate CR packaging alternatives with respect to OTC topical lidocaine preparations. The options listed by the staff boil down to a hope chest. They would be nice; but, they are either technically unfeasible or impractical. Indeed, the staff admits that this rule will impose "substantial disruption and financial loss" on some small companies with limited product lines (Draft Final Rule at 30-31) thereby

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threatening to place the Commission in an untenable position where there is little, if any risk of injury.<sup>2</sup>

A. Technically Feasible

The legislative history behind the PPPA indicates that:

(i)n order to find that special packaging is 'technically feasible', the Secretary must determine that technology exists to produce packaging conforming to the standard. This requirement prevents establishment of a standard that cannot be satisfied in practice. S. Rep. at 10. (emphasis added).

In a memorandum from Charles Wilbur, Division of Poison Prevention and Scientific Coordination, to Suzanne Barone, Project Manager, Health Services, regarding the technical feasibility, practicability, and appropriateness of the lidocaine/dibucaine rulemaking, the staff notes that it is "not aware of any commercially available reclosable CR feature for a (2 ounce or less) metal or plastic tube . . . ." Briefing Package, Tab G, Memorandum of Division of Poison Prevention and Scientific Coordination, July 27, 1994 at 4 (emphasis added).

The three options the staff presents are untenable. First, use of a threaded plastic cap with a hinged snap cap is not technically feasible since such a cap is not currently available in the marketplace and, as the staff admits, would therefore have to be designed from scratch at a cost in the hundreds of thousands of dollars and several years of development time. Staff Memorandum at 11; Draft Final Rule at 30-31. In

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<sup>2</sup> In the late 1970's, the Commission was routinely quizzed in Congressional budget and oversight hearings because of accusations that it had driven a small toy company, Marlin Toys, out of business. Our point here is not whether or how the Commission actually caused the company to go out of business. Rather, the point is that regardless of how it is done, driving a company out of business is an extreme act for a regulatory agency to take and can make the Commission vulnerable. It should only be done -- especially knowingly -- where there is a demonstrated likelihood of serious illness or injury. This is not the case here.

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addition, it may be possible that a small child could bite off the child resistant cap. The staff does not address this risk.

Similarly, use of a 22mm closure would require the increase of Combe's current 1/2 oz. Lanabiotic™ tube from 3/4 x 4 1/2 inches to 1 1/2 x 4 1/2 inches which would mean that Combe would have to sell 3 ounces of product in order to avoid slack-fill or in other words, 6 times more product than the current 1/2 ounce tube. This would be a marketing impossibility. In addition, the staff bears the burden of demonstrating that stability can be achieved through the use of a plastic tube alternative. The staff incorrectly tries to shift the burden to manufacturers by claiming that manufacturers failed to present any data demonstrating the instability of lidocaine packaged in a plastic tube. See Staff Memorandum at 8. However, it is the staff, and not manufacturers, which bears the burden of coming forward with stability data. The staff has failed to do this.

Finally, a CR single-use metal tube is not technically feasible since dose units are not applicable to lidocaine (i.e., a container which is intended to be used at one time is not compatible with topical lidocaine preparations since these products lack a specific dosage.) The staff appears to recognize this fact. *Id.* Moreover, a 1/2 oz. tube of lidocaine-containing ointment is re-used frequently. If Combe had to market the product in single-use packages, the company would have to market numerous single-use tubes which is costly and totally impracticable to a consumer's need for a single, easy-to-store product.

In addition, a new CR closure could not be easily developed since, as the staff itself concedes, the development costs associated with designing a new CR package may range from \$145,000 to \$585,000 and could take 27-36 months to develop. Draft Final Rule at 30-31. It is noteworthy that the staff recommends that because "(a)dditional time may be needed to develop new packaging, stability test (sic), obtain molds, and initiate production" manufacturers should be given the option of requesting a temporary exemption for a minimum period of time from CPSC. Staff Memorandum at 13-14.

Thus, as the staff itself admits, CR packaging for lidocaine-containing ointments, creams and gels may take 27-36 months. The PPPA, however, provides that no regulation should take effect later than one year from the date such regulation is final. 15 U.S.C. § 1471n. Thus, the staff is conceding that it will take 2-3 times longer to develop CR packaging for topical lidocaine-containing products than Congress

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had in mind. By definition, this clearly means that CR packaging for such products is neither technically feasible, practicable or appropriate. Permitting a temporary extension of time is not a lawful dodge around the statutory requirement for technically feasible, practicable or appropriate packaging.

In sum, the Commission has not met its burden of demonstrating that a technically feasible CR package exists or could be easily developed for lidocaine-containing ointments, creams or gels.

B. Practicability

The legislative history behind the PPPA provides that "(i)n order to find that special packaging is 'practicable', the Secretary must determine, for example, whether special packaging meeting the standard would be susceptible to modern mass-production and assembly-line techniques." S. Rep. at 10. As discussed above, the staff asserts that manufacturers should be able to solve the technical problems inherent in the CR packaging for lidocaine-containing ointments, creams and gels. The staff's hopeful assumption that manufacturers will eventually find feasible and practicable CR alternatives is simply not realistic. It does not suffice as a matter of law.

Moreover, the costs associated with developing new CR closures do not suggest that requiring such packaging would be "practicable". Indeed, the staff itself admits that, increased costs of up to \$4.40 per tube are estimated if individual companies undertook the costs of such development. Draft Final Rule at 31. The staff notes that since most lidocaine and dibucaine ointments and creams are sold to pharmacies at prices ranging from less than \$1.00 to approximately \$6.00, these increased costs may "outweigh" the cost of such preparations thereby demonstrating the impracticability of such a special packaging standard. *Id.*

C. Appropriateness

The legislative history underlying the PPPA provides that in order for the Commission to find that special packaging is "appropriate", the Secretary

must examine the substance under consideration and find that packaging complying with the standard is not detrimental to the integrity of the substance and does not interfere with its storage or use. S. Rep. at 10.

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Although the staff may have found that child-resistant packaging could be accomplished for dibucaine or prescription lidocaine, the legislative history clearly indicates that the Commission bears the burden of proving the appropriateness of special packaging for each particular substance involved in the rulemaking. The staff has not satisfied this burden since it has not offered any data to solve the problem of stability of topical lidocaine-containing products packaged in plastic tubes nor has the staff provided any other technically feasible, practicable or other appropriate CR option.

D. Reasonableness

Despite the fact that 6.2 million units of lidocaine ointments and creams were sold in 1992 with no confirmed reports of deaths or serious injuries, the staff asserts that a special packaging rule for lidocaine-containing ointments, creams and gels would be "reasonable." 57 Fed. Reg. 34278 (August 4, 1992.) However, the staff cannot fulfill its statutory mandate to "consider the reasonableness" of a special packaging rule without offering any explanation as to why such a rule would be reasonable. 15 U.S.C. § 1472(b)(1).

The three options which the staff indicates manufacturers can choose under the rule (i.e., reformulate the product, develop CR packaging, or discontinue marketing the product) are all equally unreasonable. First, as the staff itself recognizes, "reformulation may result in the loss of a market 'niche' held by a specific preparation." Draft Final Rule at 30. Moreover, reformulation may involve significant costs and time. Thus, manufacturers may face substantial competitive harm or costs under this "option".

Second, as set forth above, development of child-resistant packaging for lidocaine-containing ointments, creams and gels is not technically feasible, practicable or appropriate.

Third, to discontinue marketing the product is hardly a reasonable option given that it could cause significant competitive harm and costs to manufacturers. Nor is going out of business a reasonable option in light of the fact that approximately 6.2 million units of lidocaine-containing ointment and cream formulations were sold in 1992 with no confirmed incidents of serious injury or illness, it does not seem "reasonable" to give manufacturers the option of discontinuing marketing of such a product or going out of business.

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In conclusion, we respectfully urge the Commission to reevaluate Combe's request for an exemption. The staff has not made a showing of a public interest for CR packaging for this particular product that would warrant the severe economic consequences of this rule. There is no showing of technical feasibility, practicability or appropriateness as required by the statute.

Put simply, the staff has made no showing of risk of serious injury or illness with these particular products. At best, the staff presents hypothetical concerns with what they admit is a product to which no accidental deaths or serious illness have been attributed. This places the Commission in a position that the staff concedes may put some companies out of business with little benefit to public safety. The Commission simply has not met the burdens the law places on it.

Due to the time constraints regarding this matter, we are sending a copy of this letter to each of the Commissioners.

Thank you for your consideration.

Respectfully submitted,



Andrew S. Krulwich  
Julie Jacobs

Counsel to Combe, Inc.

ASK/mlp

cc: Chairman Ann Brown  
Commissioner Jacqueline Jones-Smith  
Commissioner Mary Sheila Gall  
Office of the Secretary