



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 18 2000 7:38:20 OCT 16 P1:25

Hulon W. McCain, Ph.D.
Director, Regulatory Affairs/Toxicology
Whitehall-Robins Healthcare
Five Giralda Farms
Madison, New Jersey 07940-0871

Re: Docket No. 98N-0337
Comment No. APP10

Dear Dr. McCain:

This letter is in response to your Application for Exemption dated September 11, 2000, requesting an exemption from certain provisions of the labeling requirements for over-the counter (OTC) drug products (21 CFR 201.66) for Chap Stick lip balm products based on small package size.

The basis for your request is that loose sticks and tubes placed at checkout counters in retail stores account for a significant portion of Chap Stick product sales and provide a convenience for consumers. You state that "front-end" lip balm merchandising is responsible for dramatic recent increases in retail sales. You further state that retailers allow limited placement of blister-carded products at the front end of their stores due to space limitations. You estimate that the inability to market loose sticks would result in a significant loss in sales.

You state that the product has a high therapeutic index, an established safety profile, and represents an extremely low risk for consumers. Therefore, you request to be allowed to omit the "Directions" required by § 201.66(c)(6) and the "Inactive Ingredients" required by § 201.66(c)(8). In addition, you request to modify the "Drug Facts" title in § 201.66(c)(1), the "Purpose" heading in § 201.66(c)(3), and the format of the headings and information under the "Active ingredient" and "Warnings" sections in § 201.66(d)(6). You state that although the proposed labeling differs from 21 CFR 201.66, the required information can be presented with less complexity and still communicate the appropriate and safe use of the product.

98N-0337

ANS 10

We have completed our review of your request and have the following comments:

Generally, the agency will not routinely grant an exemption for packages that are too small to meet the labeling requirements of the final rule. Manufacturers seeking an exemption on the basis of limited labeling space should include specific information detailing their efforts to comply with the rule by increasing available label space or package size.

Further, the agency is unlikely to grant exemptions based solely on financial considerations. The final rule has already addressed the fact that there will be cost increases to some manufacturers to comply with the new labeling requirements and that some products will need to be repackaged or may disappear from the market. While FDA is not likely to grant exemptions based on the limits of existing packaging to accommodate the required content and format, the agency will consider requests for deferral of time to allow manufacturers to change over to a larger or alternative package style.

The inclusion of inactive ingredients in OTC labeling is required by the amendment to section 502(e) of the Federal Food, Drug and Cosmetic Act under section 412 of the Food and Drug Administration Modernization Act of 1997 (FDAMA), which is implemented by 21 CFR 201.66. See the discussion in the final rule establishing the new labeling requirements for OTC human drugs (March 17, 1999, 64 FR 13254 at 13263). Thus, the Division cannot grant your request to omit this information through the current exemption process at this time.

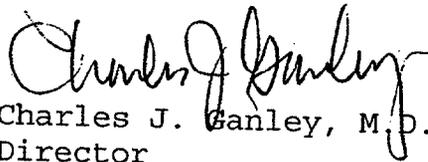
There currently is no final monograph for OTC skin protectant drug products. Thus, your company is not required to comply with 21 CFR 201.66 at this time. Further, skin protectants have been identified as a category of OTC drug products that may have reduced label content. The skin protectant final monograph will likely include specific exemptions for small packages such as lip balm products. While the agency encourages early implementation of the new Drug Facts labeling, until the skin protectant final monograph is published, we are unable to disclose what exemptions it might contain. The skin

protectant final rule may also include a comment period regarding reduced label content for these products. You would be able to submit comments regarding this issue at that time. The agency hopes that the skin protectant final rule will be published in the FEDERAL REGISTER within the next 6 to 9 months.

For the reasons stated above, we must deny your Application For Exemption at this time. You may resubmit an Application, if necessary, after the skin protectant final monograph is published.

If you have any questions, please contact Elizabeth F. Yuan, R.Ph., Regulatory Health Project Manager at 301-827-2222.

Sincerely yours,



Charles J. Ganley, M.D.
Director

Division of OTC Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research