

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-471

APPROVABLE LETTER

4. In *Warnings*, add the following warning: "Do not use on [bullet] broken skin [bullet] serious burns." This warning is necessary because (1) application to broken or burned skin is likely to increase systemic absorption and (2) submitted safety studies reflect use only on intact skin.
5. Revise the statement of identity (i.e., "sunscreen") so that it appears in bold face type on the principal display panel (PDP) and in a size reasonably related to the most prominent printed matter on the PDP, in accordance with § 201.61(c). In addition, you may want to increase the font size of the following statements in order to enhance consumer awareness of important information:

- "Water Resistant"
- "SPF 20"

6. Remove the following terms from all primary and secondary container labeling:

- _____
- _____
- _____

Consumers may interpret these terms as superiority claims. Such claims are unsubstantiated.

7. Remove statements identifying these products as ' _____ ' and/or ' _____ ' .
The submitted studies do not support these claims.
8. Remove claims that these products are ' _____ ' or " _____ ." No data were submitted to support these claims.
9. Revise the dosage form from _____ " to "cream."
10. Revise any statements indicating the product " _____ ;" against UV damage so that the statements indicate the product "helps protect."
11. Remove any reference to UVA radiation as the "skin-aging" UV radiation, including reference to wrinkling, fine lines, age spots, etc.
12. Remove or revise statements indicating that UVA rays cause _____ .
_____ . FDA is not aware of definitive evidence from the literature supporting these statements.
13. To prevent consumer confusion, include the USAN name "ecamsule" wherever the trademark name "Mexoryl SX" appears. Similarly, include the USP name "avobenzone" wherever the registered name "Parsol" appears.
14. Remove the statement _____ The statement may imply a superiority claim (over sunscreens that do not contain this statement), even though data have not been submitted to substantiate a superiority claim.
15. Remove the statement _____ No data were submitted to support this claim.
16. Remove the statement _____ ' from the following Vichy PDP statement:

BROAD SPECTRUM
UVA/UVB PROTECTION

17. Revise the labeling where it implies that a product provides _____ protection. No data were submitted to support this claim.

In addition, you may wish to include the trade name modifier "20" to further distinguish the SPF 15 sunscreens in NDAs 21-501 and 21-502 from the SPF 20 sunscreens in NDA 21-471.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

Within 10 days after the date of this letter, you are required to amend these applications, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw these applications under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

These drug products may not be legally marketed until you have been notified in writing that these applications are approved.

If you have any questions, call Elaine Abraham, Regulatory Project Manager, at (301) 796-0843.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Office of Nonprescription Products
Center for Drug Evaluation and Research

Sincerely,

{See appended electronic signature page}

Julie Beitz, M.D.
Acting Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Susan Walker
7/25/2006 02:50:43 PM

Andrea Segal
7/25/2006 03:05:40 PM
Dr. Ganley delegated the responsibility for signing this action
letter to me.