

Questions to the Dermatologic and Ophthalmic Drugs Advisory Committee:

- 1) What would be appropriate indication(s) for Lotrisone Lotion?
- 2) Possible wording for inclusion in labeling may be: "Minimally inflamed tinea pedis, corporis, and cruris not requiring a corticosteroid component may be effectively treated with a topical anti-fungal drug product not containing corticosteroid." What statement, if any does the Committee recommend for labeling and/or advertising for Lotrisone Lotion?
- 3) None of the trial subjects treated with Lotrisone Lotion were infected with *Microsporum canis*. A small series of therapeutic failures using Lotrisone Cream in the treatment of *M. canis* infection has been reported (Rosen and Elewski, 1995). Should *Microsporum canis* be deleted from the list of dermatophytes for which Lotrisone Lotion is indicated, pending Phase 4 studies to demonstrate clinical efficacy in the treatment of *M. canis*?
- 4) In addition to the labeling common to super-potent topical corticosteroids, the Sponsor proposed Pediatric Use labeling for Lotrisone Lotion [NDA 20-010]:

Pediatric Use: LOTRISONE Lotion is not recommended for use in children under 12 years of age as the safety and effectiveness have not been established in well-controlled clinical studies in pediatric patients under 12 years. NOT TO BE USED UNDER THE AGE OF 12 AND NOT TO BE USED IN DIAPER DERMATITIS.

Is the labeling for pediatric use of Lotrisone Lotion [NDA 20-010] as proposed by the Sponsor sufficient? Should the label be further strengthened, i.e. via alternative language, additional statements in the Warnings or Contraindications section, and placement of warnings on the product tube itself?

- 5) Current Pediatric Use labeling for Lotrisone Cream [NDA 18-827] states:

Pediatric Use Safety and effectiveness in children below the age of 12 have not been established with LOTRISONE Cream...

The use of LOTRISONE Cream in diaper dermatitis is not recommended.

Should the pediatric section, in addition to other labeling sections, for Lotrisone Cream [NDA 18-827] be changed to mirror labeling for Lotrisone Lotion as discussed in the above questions?

- 6) Does the Committee have recommendations regarding additional ways to address the issue of use of products containing super-potent topical corticosteroids in children and infants?