

DRAFT

FOOD AND DRUG ADMINISTRATION CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

*Joint Meeting of the
Non-Prescription Drugs and Dermatologic and Ophthalmic Drugs Advisory Committee
May 6-7, 2004*

Issues for the Committee

Clinical Efficacy

- 1) Please comment on what is the lowest acceptable rate of cure that is clinically meaningful for a topical OTC drug product for the treatment of tinea pedis, using complete clinical and mycological clearance as definition of “cure”? Please discuss your rationale.
- 2) Dose response studies are not conducted in the development programs of antifungal products for the treatment of tinea pedis. Given the efficacy of products currently marketed, should topical antifungal drug development programs for tinea pedis evaluate safety and efficacy at different concentrations, dosing durations, and dosing frequencies?
- 3) FDA has received numerous reports of lack of effect for topical antifungal products. It is not clear if this is a reflection on the actual efficacy of the products or a reflection of consumer expectations regarding cure of tinea pedis.
 - a. Should FDA consider adding information to labeling on the following:
 - i. Cure rate (e.g. complete cure) or effective treatment
 - ii. Expectation of symptom relief
 - iii. Delay in response relative to the end of treatment
 - b. Are there claims on the current labeling that may mislead consumers to have greater expectations of benefit than are merited by the efficacy data available?

Clinical Microbiology

- 4) Given the efficacy rates observed in the clinical trials, should antifungal drug resistance be a concern?
- 5) Should antifungal minimum inhibitory concentrations, (MICs) be determined for clinical isolates during drug development and submitted with the NDA?

Safety

- 6) Is the risk of secondary infections (e.g., bacterial cellulitis), related to inadequately treated tinea pedis, of sufficient frequency and severity as to merit communication in OTC consumer labeling?
 - a. Are there specific subpopulations at risk for secondary infections that should be identified on the label?

complete cure = negative culture plus no signs or symptoms

² Effective Treatment = negative culture and mild or no signs and symptoms

³ Mycological cure = negative culture

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