



SEP 29 2005

Henry Kiwarkis, President
Sue Ismiel & Daughters US, Inc.
21250 Hawthorne Blvd., Suite 700
Torrance, CA 90503

Dear Mr. Kiwarkis:

This letter concerns your April 22, 2005, time and extent application (TEA) requesting that oil of *Melaleuca alternifolia* (tea tree oil) be considered for inclusion in the monograph for OTC pediculicide drug products (21 CFR part 358, subpart G).

We have completed our review of your TEA and determined that this condition is not eligible for inclusion in the OTC drug monograph system at this time. To be considered eligible for the monograph system, a drug must have been marketed for a particular indication for a material time and to a material extent as set forth in 21 CFR 330.14(b)(2) (§ 201(p) of the Federal Food, Drug, and Cosmetic Act). Tea tree oil has been marketed for a material time as a pediculicide, having been marketed directly to consumers for at least 5 continuous years in the same country (*i.e.*, Australia). However, we do not consider tea tree oil to have been marketed to a material extent. Only 418,000 dosage units have been sold in three countries. This number is inadequate compared to the number of dosage units sold for other conditions found eligible for inclusion in the OTC drug monograph system via the TEA process. The average number of dosage units marketed for products switched from Rx-to-OTC status is typically in the tens of millions. We have determined that more marketing experience is necessary to detect serious but infrequent adverse events and meet the "material extent" requirement of § 330.14(b)(2) and § 201(p) of the Federal Food, Drug, and Cosmetic Act. We will require evidence that several million units of tea tree oil-containing pediculicides have been sold prior to re-evaluating eligibility.

If you have any questions regarding this letter, please contact Dr. Walter Ellenberg, regulatory health project manager, at 301-796-2090 or via e-mail: Walter.Ellenberg@fda.gov.

Sincerely,

Charles J. Ganley, M.D.

Director,

Office of Nonprescription Products
Center for Drug Evaluation and Research