Frazier, Tia

From: Jackson, Michelle
Sent: Monday, December 30, 2002 1:35 PM
To: Frazier, Tia
Subject: FW: Docket Numbers 78N-183H, 75N-183F, and 96N-0277

-----Original Message-----
From: Lumpkins, Debbie L
Sent: Tuesday, October 29, 2002 3:25 PM
To: 'Roslyn.Prinsley@rirdc.gov.au'
Subject: Docket Numbers 78N-183H, 75N-183F, and 96N-0277

Dear Dr. Prinsley:

This is in response to your to your letters requesting: (1) Clarification of agency letters dated April 19 and June 20, 2002 and (2) an extension of the period for filing a Time and Extent Application (TEA) to support the eligibility of tea tree oil for the over-the-counter (OTC) drug review. Your letter states that you have no record of the citizen petition (CP) coded as CP1 in Docket number 75N-183H that is the subject of the agency's April 19, 2002 letter, and you suggest that this may be a typographical error. You also assert that there is ample marketing history of tea tree oil in the United States.

The agency's April 19, 2002, letter was not in error. The letter refers to a petition that was submitted by Mitech Laboratories in collaboration with the American Tea Tree Oil Association (ATTA) and the Australian Tea Tree Oil Association (ATTIA) to support the general recognition of tea tree oil (2 to 10 percent) as a safe and effective OTC topical antimicrobial for use by healthcare professionals. The petition, dated January 20, 1995, was signed by Martha Smith of Mitech Laboratories. The responsibility for the CP was transferred from Mitech Laboratories to C&S Laboratory Consultants in a letter from ATTA and ATTIA dated March 23, 1995. We were subsequently informed that C&S Laboratory Consultants was no longer coordinating activities concerning the evaluation of tea tree oil. From the correspondence it appeared that all of the submissions on this subject were associated with the ATTA and ATTIA. The last address that we had for the ATTA and ATTIA was the one to which the letter was sent. However, there is apparently no record of this CP with your organization.

Concerning the marketing history of tea tree oil in the United States: For an ingredient to be eligible for the OTC drug review it must have been marketed to a material time and extent in the United States for the condition for which it is to be evaluated. In other words, for tea tree oil to be evaluated in the OTC drug review as a healthcare professional antiseptic, e.g., a patient preoperative skin preparation, surgical handscrub, or healthcare personnel handwash, it must have been marketed to a material time and extent in the United States for these uses. We were unable to find any evidence of the marketing of tea tree oil for these indications in this country. Hence, the conversion of CP1 to a TEA which would allow for the submission of foreign marketing experience to support the evaluation of tea tree oil as a healthcare antiseptic in the OTC drug review. This TEA process described in the April 19, 2002 letter applies only to this CP.

The agency has been able to locate a marketing history of tea tree oil as a first aid antiseptic in this country. Thus, tea tree oil is eligible for the OTC drug review for this indication. The citizen petition for this use (CP3 in Docket 75N-183F) can be evaluated as part of the OTC drug review and a TEA submission is not needed. The evaluation of the petition can proceed as agency resources permit. There are also a number of other submissions for this ingredient to the first aid antiseptic rulemaking that will be considered as part of that rulemaking.

In summary, over the past several years there have been a number of submissions requesting that the agency generally recognize tea tree oil as safe and effective for use as a healthcare professional antiseptic and as a first aid antiseptic. There have been citizen petitions submitted to support both uses. An evaluation of the CP on the use of tea tree oil for OTC healthcare professional use provided no evidence of marketing in the United States for these uses. The April 19, 2002 letter indicated that foreign marketing experience may be provided to demonstrate eligibility for the OTC drug review. However, if there is no interest on the part of your organization for this use of the ingredient, no further action on your part is necessary. The CP on the use of the ingredient as a first aid antiseptic is eligible for the evaluation under the OTC drug review based on its history of marketing in this country. Additional data demonstrate marketing in foreign countries is not needed.

Docket No. 96N-0277 is the Docket number for the agency's foreign marketing rulemaking.

I hope this information is helpful. Please let me know if you have any further questions.

Sincerely yours,

Debbie Lumpkins
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