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May 21, 2002

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Rm. 1061 (HFA-305)
Rockville, MD 20852

Re: Docket No. 96N-0277, "Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded" -- Request for an Extension of the 120 days to Submit a Time and Extent Application Based on a Previously Filed Citizen Petition for Priority Review

Dear Sir or Madam:

On behalf of Merck KGaA and its U.S. affiliate EM Industries, Inc. (hereinafter Merck), we respectfully request a 90-day extension of the 120 days to submit a Time and Extent Application ("TEA") based on a previously filed citizen petition for priority review. Merck expects to submit a TEA for its product; however, an additional 90-days would allow for sufficient time to compile the necessary information for complete review of the TEA.

Background

On December 17, 1980, Merck filed a citizen petition (Docket No. 78N-0038) to reopen the rulemaking for Over-the-Counter ("OTC") sunscreen drug products to include additional information on its Eusolex 6300® (3-(4'-methylbenzylidene-D,L-camphor) product. Subsequent supplements to that petition were filed with the Food and Drug Administration ("FDA") on August 15, 1985, and May 11, 1999 providing additional data and support. Until we received recent notification on April 23, 2002, the citizen petition was pending before the Agency.

Rulemaking regarding the "Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded" began with the publication of an advance notice of proposed rulemaking (ANPRM) in the Federal Register of October 3, 1996. Merck submitted comments to that ANPRM on December 19, 1996 providing the Agency with substantive comments on foreign data and interim marketing. On December 20, 1999, FDA published a proposed rule concerning which Merck submitted comments on March 22, 2000.

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In the Federal Register of January 23, 2002, the FDA published the final rule, which provided, among other things, that those petitioners that had pending citizen petitions convert their petition into TEAs and resubmit the data within 120 days of the date of publication for priority review. By a letter dated April 19, 2002, the FDA notified Merck of the publication of the final rule, the opportunity to file a TEA, and that the Agency does "not intend to take further action" on the citizen petition. Merck received that letter on April 23, 2002.

Request For an Extension of Time to Submit a TEA for Priority Review

Since we have become aware of the opportunity to submit a TEA for priority review, we have worked diligently to gather the appropriate information. However, due to the extensive lapse of time since the filing of the citizen petition in December 1980, compiling anew the data originally submitted in the citizen petition and supplementing that information with data and other relevant information generated over the last 20 years has been difficult. In addition, much of the relevant information regarding the material time and extent of marketing of the Eusolex 6300 product resides with the parent company, Merck KGaA, in Germany. Obtaining the necessary information and dealing with language barriers has complicated the preparation of the TEA.

FDA May Not Refuse to Review a Properly Filed Citizen Petition

If the FDA is not willing to consider extending the 120 days for submitting a TEA for priority review, we request FDA to evaluate Eusolex 6300 based on the information previously filed with the Agency. Considering that the final rule merely requires a format change of the previously submitted information, and "a petitioner should be able to readily convert their petition to a TEA and submit it to the agency to begin the review process,"¹ the FDA is now exalting form over substance. Sufficient information was provided to FDA in the December 17, 1980 citizen petition and subsequently updated in the supplements to that petition on August 15, 1985 and May 11, 1999. FDA can reasonably conclude from the data already provided that Eusolex 6300 meets the definition of marketing "to a material extent" and "for a material time" and is eligible for evaluation of general recognition of safety and effectiveness in accordance with FDA's OTC drug monograph regulations.

Other Options that May be Pursued by Merck

Alternatively, without the grant of the extension of time for filing a TEA for priority review, we would deem that denial of additional time coupled with FDA's letter of April 19, 2002, to be a final administrative action on Merck's citizen petition filed on December 17,

¹ January 23, 2002, Federal Register, Vol. 67, p. 3060 at 3067. (67 FR 3060 at 3067).

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1980, and reviewable by the courts. Accordingly, we would take the necessary steps to appeal the Agency's determination and seek relief through the judicial system.

In addition, the FDA should be cognizant that the publication of the recent final rule may undermine its earlier decision to exclude the sunscreen ingredient in Eusolex 6300 (i.e., (3-(4'-methylbenzylidene-D,L-camphor))) from Category I. The sole reason for FDA's earlier decision regarding classification of the sunscreen ingredient into Category II was the product's lack of U.S. marketing experience. As reflected in the final rule, marketing experience outside the U.S. must now be considered and that would seem to require recategorization of Eusolex 6300 into Category I.

Conclusion

Merck has waited patiently for the FDA to rule on its 20 year old petition. With the publication of the final rule, Merck has the opportunity to gain meaningful relief to a decades-old request. The grant of the additional 90 days would provide the necessary time to submit a complete and sufficient TEA that complies with the requirements of the newly promulgated regulations. In light of the information provided, we respectfully request the FDA for a 90-day extension of the 120 days to submit a TEA based on a previously filed citizen petition for priority review.

Please contact us if additional information is required.

Sincerely,



Robert G. Pinco
Heili Kim

Enclosure

cc: Dr. Ina Höfgen-Müller, Merck KGaA
John D. Lipnicki, Food and Drug Administration.

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