



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

1955 '02 JUN 25 A9:37

JUN 20 2002

Robert G. Pinco
Heili Kim
Buchanan Ingersoll Professional Corporation
1776 K Street, N.W.
Suite 800
Washington, D.C. 20006-2365

RE: Docket No. 96N-0277

Dear Mr. Pinco and Mr. Kim:

This is in response to your letter dated May 21, 2002, addressed to Dockets Management Branch, and sent via facsimile to the attention of John D. Lipnicki on May 23, 2002. In your letter, on behalf of Merck KGaA and its United States affiliate EM Industries, Inc., you requested a 90-day extension of the 120-day period for submitting a "priority review" Time and Extent Application (TEA) based on a previously filed citizen petition.

Your letter referenced the final rule published in the FEDERAL REGISTER of January 23, 2002 (67 FR 3060) entitled "Additional criteria and procedures for classifying over-the-counter (OTC) drugs as generally recognized as safe and effective and not misbranded." In that rule, the agency said it would give priority review to any party converting an old citizen petition (for considering certain foreign conditions for OTC drug monographs) to the new TEA format if the TEA was submitted within 120 days after publication of the final rule (i.e., by May 23, 2002). You indicated that the age of the petition (December 17, 1980) and the location of the parent company (Germany) have complicated preparation of the TEA. In addition, you stated that the agency's letter about converting the petition to a TEA was not received until April 23, 2002.

We have reviewed your request and believe that a 90-day extension is appropriate. If the above referenced TEA is submitted by August 21, 2002, it will be given priority review.

If you have any questions, please contact Walter Ellenberg, Ph.D., Regulatory Health Project Manager, at 301-827-2222.

Sincerely yours,

Charles J. Ganley, MD

Director

Division of Over-the-Counter Drug Products

Office of Drug Evaluation V

Center for Drug Evaluation and Research

96N-0277

LET 1

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: JUN 20 2002

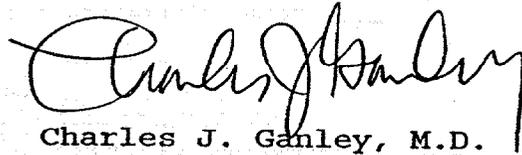
FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 96N-0277

TO: Dockets Management Branch, HFA-305

The attached material should be placed on public display under the above referenced Docket No.

This material should be cross-referenced to Comment No. _____


Charles J. Ganley, M.D.

Attachment