



APR 19 2002

COPY 8157/02 MAY -1 A10

Robert G. Pinco  
Counsel to European-American  
Phytomedicines Coalition  
1776 K St., N.W.  
Washington, D.C. 20006

Re: Docket No. 95P-0145  
Comment No. CP1

Dear Mr. Pinco:

This letter concerns your citizen petition (CP) dated May 26, 1995. The petition is filed under Docket No. 95P-0145 in the Dockets Management Branch.

Since your petition was submitted, the agency has informed you and other interested parties that it was developing a process by which drugs without any marketing experience in the United States could become eligible for consideration in the agency's over-the-counter (OTC) drug review. We are pleased to inform you that the process is now being implemented.

This process is described in a final rule entitled "Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded," which was published in the Federal Register of January 23, 2002 (67 FR 3060). A copy is enclosed for your information. This final rule is effective on February 22, 2002.

The final rule requires the submission of a Time and Extent Application (TEA) (see § 330.14(c)) to request consideration under the OTC drug review. The required information and format for a TEA are set out in the final rule (see § 330.14(c)). Three copies of the TEA are to be submitted to the Central Document Room (see § 330.14(d)).

If you wish to pursue inclusion in the OTC drug monograph system of an OTC drug product or active ingredient that was the subject of your CP, please submit a TEA in the required format. We do not intend to take further action on your CP.

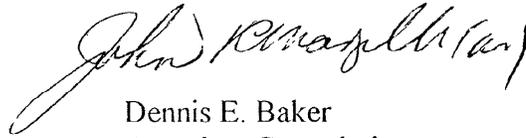
As stated in comment 20 of the final rule that established the TEA process, the agency will give priority to TEA's associated with pending CP's if those CP's are converted to TEA's that are submitted within 120 days after publication of that final rule.

95P-0145

LET 3

We look forward to reviewing your TEA upon submission.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Dennis E. Baker". The signature is written in a cursive style with a large, sweeping initial "D".

Dennis E. Baker  
Associate Commissioner  
for Regulatory Affairs

Enclosure

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:

4.26.02

FROM:

Director  
Division of OTC Drug Products, HFD-560

SUBJECT:

Material for Docket No. 95P-0145

TO:

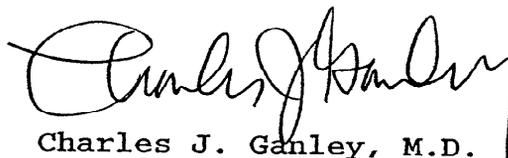
Dockets Management Branch, HFA-305



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



This material should be cross-referenced to Comment No. CP1

  
Charles J. Ganley, M.D.

Attachment