



Han Xu, M.D.
Senior Researcher,
Pharm1 Medicine Technology INC.
No: A-1 Fuxing Road
Haidian District
Beijing 100038
P.R. China

MAR 3 2004

Dear Dr. Xu:

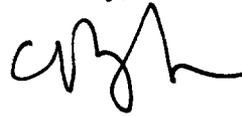
This letter concerns your undated Time and Extent Application (TEA) for Sea Buckthorn Granule. This TEA, received on October 30, 2003, requests that FDA add the botanical drug substance Sea Buckthorn Granule to an unspecified OTC drug monograph for the treatment of neurasthenia. Your TEA requests that FDA consider Sea Buckthorn Granule eligible for inclusion in the OTC drug monograph system based on anecdotal references to the use of this traditional Chinese medicine for over 1,000 years.

We have reviewed your TEA for Sea Buckthorn Granule and determined that the condition is ineligible for inclusion in the OTC drug monograph system. This determination is based on lack of adequate information provided in your TEA. Dr. Michael Koenig of this Division contacted you via e-mail on November 12, 2003, and advised you that FDA needs additional information required by 21 CFR 330.14(c). Dr. Koenig indicated that we would issue a letter of refusal if the requested information was not submitted by January 11, 2004. As of this date, we have not received the requested information. As described in the e-mail from Dr. Koenig, your TEA lacks the required information outlined in the following sections of 21 CFR 330.14(c):

- (1) Applicable OTC drug monograph
 - (1) Basic information - pharmacologic class(es), OTC strength(s) and dosage form(s) etc.
 - (1)(ii) Detailed description of the botanical drug substance
- (2) List of all countries in which the condition has been marketed
 - (2)(i) How the condition has been marketed
 - (2)(ii) The cumulative total number of dosage units sold
 - (2)(iii) A description of population demographics
 - (2)(v) A description of the system(s) for identifying adverse drug experiences
- (3) Copies of labeling translated into English
- (5) A list of all countries where the condition is marketed only as a prescription drug, if any
- (6) A list of all countries where the condition has been withdrawn from marketing, if any

If you have any questions regarding this letter, please call Ms. Laura Shay, Regulatory Health Project Manager, at 301-827-2222 or send her an e-mail at ShayL@cder.fda.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'CRosebraugh', written in a cursive style.

Curtis Rosebraugh, M.D., MPH
Deputy Director,
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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: MAR 3 2004

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