CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-222

CORRESPONDENCE

3. The modified criteria proposed by TAP would not provide the Division with any greater confidence in the data than the modified Winnipeg analyses already conducted by the Medical Officer.

4. The Division stated that although time consuming, the requested data for the baseline pre-exacerbation dyspnea levels from clinic charts will still be necessary to meet the request for reanalysis cited in the approvable letter dated October 27, 2000. The Sponsor stated that this data may not exist. If data regarding pre-treatment dyspnea did exist, according to the Sponsor, the reanalysis could be performed. It is the Division's position that removing those patients without pre-exacerbation dyspnea from the reanalysis would unacceptably inflate the Type I error. The Sponsor stated that it will reconsider its proposal.

[redacted]

Agreements

1. The Sponsor agreed to reconsider its proposal for a reanalysis of AECB

[redacted]

Minutes Prepared By:

Cdr. R. Grant Hills
Regulatory Health Project Manager

HFD-520/K. HILLS

MAY 24 2000

NDA 21-222

TAP Pharmaceutical Products, Inc.
Attention: Ms. Donna K. Helms
Associate Director, Regulatory Affairs
2355 Waukegan Road
Deerfield IL 60015

Dear Ms. Helms:

Please refer to your New Drug Application (NDA) submitted December 29, 1999, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SPECTRACEF™ (cefditoren pivoxil), 200mg Tablets.

We acknowledge the omission of data from two principal investigators from the NDA's original analyses. We ask that you now provide efficacy and safety analyses with these data included, in order to complete our review of the NDA. Specifically, we would ask that you generate, by indication, efficacy analyses for the intent-to-treat, modified-intent-to-treat, clinically evaluable and microbiologically evaluable populations, as well as safety analyses by study, and integrated summaries of efficacy and safety.

If you have any questions, please contact Mr. R. Grant Hills, Regulatory Project Manager, at (301) 827-2125.

Sincerely yours,

/S/

Gary K. Chikami, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-222

[redacted]

TAP Pharmaceutical Products, Inc.
Attention: Alan Kreuger, M.S.
Senior Product Manager, Regulatory Affairs
675 North Field Drive
Lake Forest, IL 60045

Dear Mr. Kreuger:

Reference is made to your correspondence dated May 30, 2000, requesting FDA issue a Written Request under Section 505A of the Food, Drug, and Cosmetic Act for:

- NDA 21-222 for SPECTRACEF™ (cefditoren pivoxil) Tablets

[redacted]

We have reviewed your proposed pediatric study request and are unable to issue a Written Request based on your submission. The proposed studies do not provide a significant potential health benefit to the pediatric population, since many alternatives exist for treatment of otitis media and streptococcal pharyngitis in this population. Higher rates of diarrhea seen in adults and potential adverse effects from carnitine loss are potential safety concerns for pediatric patients that should be better characterized before a written request can be issued.

If you have any questions, call CDR Grant Hills, Regulatory Project Manager, at 301-827-2125.

Sincerely yours,

Janice M. Soreth, M.D.
Acting Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research