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RESEARCH**

APPLICATION NUMBER:
50-755

PHARMACOLOGY REVIEW

REVIEW AND EVALUATION OF PHARMACOLOGY/TOXICOLOGY DATA
Division of Anti-infective Drug Products, HFD-520

NDA number: 50-755 (AZ)

KEY WORDS: Augmentin, amoxicillin, clavulanate

Reviewer Name: Kenneth Seethaler, R.Ph., Ph.D., D.A.B.T.

Date of submission: April 5, 2000

Review completion date: May 5, 2000

Review format: Label review

Scientific literature reviewed: Yes () No (x)

Information to sponsor: Yes () No (x)

Sponsor: SmithKline Beecham Pharmaceuticals
One Franklin Plaza
Philadelphia, PA 19101

Contact person: Cynthia D'Ambrosio, Ph.D.
Associate Director, U. S. Regulatory Affairs
Phone 215-751-3468

Drug: Augmentin ES 14:1 suspension

INTRODUCTION

Augmentin ES is a combination product consisting of the antibiotic amoxicillin and the beta-lactamase inhibitor clavulanate potassium in a 14:1 ratio for suspension. Tablet, and powder for suspension formulations of Augmentin have been approved previously by FDA. This submission is a response to a FDA "not approvable" action letter.

_____ it is believed that there are no preclinical safety concerns with Augmentin.

RECOMMENDATIONS

The "Carcinogenesis, Mutagenesis, Impairment of Fertility", "Teratogenic Effects", "Nursing Mothers", and "Overdosage" sections of this label have been reviewed. The comparisons between the animal doses, and the human dose are based on body surface area. The label is considered to be acceptable as written.

From the Pharmacology/Toxicology perspective, there is no objection to the approval of this NDA.

/S/

Kenneth Seethaler, R.Ph., Ph.D., D.A.B.T.
Pharmacologist/Toxicologist, HFD-520

cc: Original NDA 50-755
HFD-104
HFD-340
HFD-520
HFD-520/Pharm/K. Seethaler
HFD-520/MO/M.Makhene
HFD-520/Micro/A.Sheldon
HFD-520/Chem/A. Yu
HFD-520/CSO/J.Cintron
HFD-520/Biopharm/F.Pelsor
HFD-520/Biostat/D.Lin

Concurrence only:

HFD-520/R. Osterberg

/S/ 5/15/00

HFD-520/L. Gavrilovich

/S/ 5/15/00