CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-105

PHARMACOLOGY REVIEW

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

NDA number: 21-105 (000) SEP 28 1999

KEY WORDS: Zotrim, phenazopyridine, sulfamethoxazole, trimethoprim

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

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Submission format: Literature reviews (Paper NDA)

Scientific literature reviewed: Yes (x) No ( )

Information to sponsor: Yes (x) No ( )

Sponsor: Able Laboratories, Inc./DynaGen, Inc.
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Vice-President, Clinical and Regulatory Affairs
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INTRODUCTION

This NDA seeks approval to market a blister-card package, containing three drugs already approved by the USFDA for use in the United States. The three drugs are phenazopyridine (Pyridium), sulfamethoxazole (Gantanol), and trimethoprim (Trimpex). Combinations of phenazopyridine and sulfamethoxazole [redacted] and combinations of sulfamethoxazole and trimethoprim (e.g. Bactrim) have also been approved for marketing in this country.

The package will contain two types of tablets: one of phenazopyridine (200 mg), and one consisting of a combination of sulfamethoxazole (800 mg) and trimethoprim (160 mg). There will be a total of 26 tablets in the package: six tablets of phenazopyridine, and 20 tablets of the sulfamethoxazole/trimethoprim combination. The treatment regimen for phenazopyridine will

be TID for two days, while the regimen for the sulfamethoxazole/trimethoprim combination will be BID for ten days.

This product will be intended for use in the treatment of uncomplicated urinary tract infections.

No experimental data was submitted in this NDA. The sponsor seeks approval for this convenience/compliance combination product, based on efficacy and safety data published in the scientific literature.

RECOMMENDATIONS

Since these three drugs and combinations thereof, have been approved already, it seems reasonable, from the Pharmacology/Toxicology perspective, to also approve this blister-pack combination.

The sponsor's proposed labeling has been taken from the Physicians Desk Reference for Pyridium and Bactrim, but the labeling is not in the latest format. For example, doses are expressed as mg/kg, different pregnancy categories (B and C) are used in different places, and the effects on nursing mothers are given for only one drug (phenazopyridine) and not the others.

It is recommended that the **PRECAUTIONS** section of the label be revised to correct these shortcomings.

/S/

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cc: Original NDA 21-105
HFD-104
HFD-340
HFD-520
HFD-520/Pharm/K. Seethaler
HFD-520/MO/H.Hamilton
HFD-520/Micro/H.Silver
HFD-520/Chem/B.Shetty
HFD-520/CSO/B.Duval-Miller
[redacted]
HFD-520/Biostat/D.Lin

Concurrence only:

HFD-520/R. Osterberg /S/ 9/28/99

HFD-520/L. Gavrilovich /S/ 9/29/99