CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

207844Orig1s000

STATISTICAL REVIEW(S)

STATISTICAL REVIEW AND EVALUATION

NDA #:	207844 (dated June 19, 2014)
Sponsor:	Amedra Pharmaceuticals LLC
Name of Drugs:	Albenza Chewable Tablets
Indication:	Treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, *Taenia solium* and treatment of cystic hydatid disease of the liver, lung, and peritoneum, caused by the larval form of the dog tapeworm, *Echinococcus granulosus*
Biometrics Division:	Division of Biometrics IV
Statistical Reviewer:	Cheryl Dixon, Ph.D.
Concurring Reviewer:	Karen Higgins, Sc.D.
Medical Division:	Division of Anti-Infective Products
Medical Reviewer:	Kimberly Martin, M.D.
Project Manager:	Gregory DiBernardo

Executive Summary:
This NDA is for a new formulation, Albenza (albendazole) Chewable Tablets, 200 mg. Albenza Tablets, 200 mg is currently approved under NDA 20666 for the treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, *Taenia solium*, and cystic hydatid disease of the liver, lung, and peritoneum caused by the larval form of the dog tapeworm, *Echinococcus granulosus*.

To support the approval of the new formulation for the same indications, four bioequivalence studies were conducted. The studies were randomized, open-label, balanced, two-treatment, three-period, three-sequence, single dose, reference replicated, cross-over studies in healthy male and female subjects under fed and fasted conditions. The objective of the studies was to assess the bioequivalence between the test product (Albenza Chewable Tablets, 200 mg) and the corresponding reference product (the current approved Albenza Tablets, 200 mg).

Conclusion and Recommendations
No new efficacy or safety studies in patients with either hydatid disease or neurocysticercosis have been conducted for the new formulation of Albenza Chewable Tablets. Therefore, there are no statistical comments regarding the safety and efficacy of Albenza Chewable Tablets. With this submission, the Applicant is putting the combined Albenza Tablets and Albenza Chewable Tablets label in Physician Labeling Rule (PLR)

format. The Adverse Reactions section of the combined label is based on the information included in the Albenza Tablets approved labeling. Due to the limited information available on the trials to support the initial approval of Albenza Tablets, no Clinical Studies section is proposed, per the Medical Division, for the combined label.

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/s/

CHERYL A DIXON
04/14/2015

KAREN M HIGGINS
04/14/2015
I concur.