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APPLICATION NUMBER:

207844Orig1s000

PHARMACOLOGY REVIEW(S)

Memo to the Division File

NDA 207844, supporting document #001, submit date June 19, 2014

Albenza (albendazole) chewable tablets, 200 mg

From: Wendelyn Schmidt, Pharmacology/Toxicology Supervisor, DAIP

To: Gregory DiBernardo, Project Manager

Date: May 18, 2015

Background:

The sponsor, Amedra Pharmaceuticals, has submitted a NDA for a new formulation of albendazole. No new non-clinical data was included in support of this submission. No substantive changes were made in the package insert label for Albenza.

Recommendations: There are no pharmacology/toxicology objections to the approval of this NDA. There are no substantive changes to the label from pharmacology/toxicology.

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/s/

WENDELYN J SCHMIDT
05/18/2015

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