CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-055

PHARMACOLOGY REVIEW

Division of Anti-Infective and Ophthalmology Products

Memorandum to the file for NDA 22-055
Date: February 2, 2007
From: Maryam Rafie-Kolpin, Ph.D.
To: Maureen Dillon-Parker
Through: Terry Peters, DVM

Sponsor: Glaxo SmithKline Pharmaceuticals

Drug: Altabax™ (Retapamulin) ointment, 1%

Drug Class: SB-275833 is a new semi-synthetic antibiotic class called pleuromutilins. According to the sponsor this class of antibiotics inhibits prokaryotic protein synthesis through interaction with the 50S ribosomal subunit.

Indication: Treatment of primary impetigo

Route of Administration: Topical

Altabax™ (retapamulin) is a semi-synthetic derivative of pleuromutilin, isolated through fermentation from *Clitopilus passeckerianus* that is being developed for the topical treatment of uncomplicated skin and skin-structure infections. Pleuromutilins inhibit bacterial protein synthesis at the elongation phase. The sponsor submitted a NDA application [redacted] in November 2005. This NDA was found to be approvable. Because the formulation of retapamulin proposed for NDA# 22-055 is identical to that of [redacted] no new nonclinical studies were included in this submission. The nonclinical studies were reviewed under [redacted], where retapamulin appeared safe for topical administration at the proposed dose. Therefore, retapamulin is approvable from a pharmacology/toxicology perspective.

Signatures:

Reviewer Signature _____

Team Leader Signature_____ Concurrence Yes ___ No ___

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/s/

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