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APPLICATION NUMBER:

205931Orig1s000

PHARMACOLOGY REVIEW(S)

Memo to the Division File

NDA 205931, Submitted 9/25/13

Doxycycline

From: Wendelyn Schmidt, Pharmacology/Toxicology Supervisor, DAIP

Date: November 19, 2013

Background:

The sponsor, Aqua Pharma, would like to license doxycycline hyclate tablets at 75, and 150 mg. No new pharmacology/toxicology data was submitted to this NDA. The labeling for the relevant pharmacology/toxicology sections are identical to previously approved labels. The excipient profile is within levels previously approved for compounds administered by the oral route.

Recommendation:

There are no pharmacology/toxicology issues with the approval of this compound.

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/s/

WENDELYN J SCHMIDT
01/13/2014