

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

205919Orig1s000

ENVIRONMENTAL ASSESSMENT

MEMORANDUM

Submission: NDA 205 919

Through: Ali Al Hakim, Ph.D., Branch Chief, DNDQA 1, Branch 2

From: Danuta Gromek-Woods, Ph.D., CMC Reviewer

Date: 25-Apr-2014

Subject: Environmental Assessment

Applicant requested categorical exclusion from environmental assessment as per 21 CFR 25.31(a) and provided the following justification: “Purinethol 50mg tablet (and equivalent generic tablets) is currently used in the treatment of acute lymphatic leukemia in the US. It is anticipated that the proposed indication for Purixan oral suspension will replace the use of the current 50mg tablet formulation in children, and thus there will be no increase in the use of the active moiety, 6-mercaptopurine”.

Therefore, the claim for categorical exclusion from Environmental Assessment is acceptable.

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/s/

DANUTA E GROMEK-WOODS
04/25/2014

ALI H AL HAKIM
04/25/2014