

**Drug Name:** (b) (4) (Spinosad)  
**Indication:** Head lice  
**NDA:** 22-408

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## NDA Statistical Report Review

**NDA#:** 22-408  
**Applicant:** ParaPRO  
**Drug Name:** (b) (4)  
**Indication:** Head lice  
**Documents Reviewed:** Appendix 2 (Statistical Report)  
**Medical Officer:** Patricia Brown, M.D., DDDP  
**Statistical Reviewer:** Carin Kim, Ph.D., DBIII

The sponsor's statistical analysis (Appendix 2) in this Complete Response submission is the same as that presented as the "statistical report" (SDN 15, dated April 19, 2010), and was the subject of statistical review dated May 19, 2010. Please refer to our previous statistical review for comments.

Carin Kim, Ph.D  
Mathematical Statistician, DBIII

Mohamed Alosh, Ph.D.  
Statistics Team Lead, DBIII

cc

Orig. NDA 22-408

DDDP/Walker

DDDP/Diglisic

DDDP/Brown

DDDP/Williams

OBIO/Patrician

DBIII/Wilson

DBIII/Alosh

DBIII/Kim

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22408	ORIG-1	PARAPRO PHARMACEUTICA LS LLC	SPINOSAD

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/s/

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CARIN J KIM  
08/25/2010

MOHAMED A ALOSH  
08/25/2010