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*APPLICATION NUMBER:*

**022555Orig1s000**

**PHARMACOLOGY REVIEW(S)**

## **Supervisory Pharmacologist Memo**

**NDA: 22-555**

**Drug: Hexaminolevulinate hydrochloride (Cysview)**

**Sponsor: Photocure ASA**

**Submission Date: March 31, 2010**

### **Recommendation for the approval of NDA 22-555 (Cysview)**

From preclinical Pharmacology and Toxicology perspective, NDA 22-555 can be approved. The present submission is in response to the agency's Complete Response letter of December 30, 2009. Nonclinical deficiencies were not identified in the agency's Complete Response letter.

Dr. Yanli Ouyang original review recommended approval with labeling changes. I concur with the recommendations.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
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NDA-22555	ORIG-1	PHOTOCURE ASA	HEXVIX

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/s/

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ADEBAYO A LANIYONU  
05/17/2010