CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-221

ENVIRONMENTAL ASSESSMENT

REQUEST FOR EXCLUSION FROM REQUIREMENT FOR ENVIRONMENTAL ASSESSMENT

Pursuant to 21 CFR § 25.15 (d) and § 25.31 (a), Akorn, Inc. hereby claims a categorical exclusion from the requirement of an Environmental Assessment.

Under 21 CFR § 25.31 (a), a categorical exclusion exists for:

> Action on an NDA, abbreviated application, application for marketing approval of a biologic product, or a supplement to such applications, or action on an OTC monograph, if the action does not increase the use of the active moiety.

Akorn, Inc. is requesting FDA to take action by approving its application for New Drug Application for Akten ™ (lidocaine hydrochloride) Ophthalmic Gel, 3.5%. Akorn is unaware of any other data that would establish that its product might be toxic to organisms in the environment at expected levels of exposure.

Akorn, Inc. also certifies that, to the best of its knowledge and in its opinion, it is in compliance with all federal, state, and local environmental protection requirements.

On the basis of the foregoing, Akorn, Inc. submits that the criteria set forth in 21 CFR § 25.31 (a) are met and, therefore requests that it be categorically excluded from the requirement to submit an Environmental Assessment.

S. Boddapati

Sam Boddapati, Ph.D.
Vice President, Regulatory Affairs

6/29/07

Date