

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

**APPLICATION NUMBER: 21-081**

**ENVIRONMENTAL ASSESSMENT AND/OR FONSI**      **ASSESS**

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

Date: 10<sup>th</sup> Feb-2000  
From: Komanduri Pardha  
Subject: Environmental Assessment  
TO: File for NDA 21-081

The sponsor claimed a categorical exclusion under 62 FR 145, section 25.31 (b) in view of the low amounts of HOE901 entering the environment (lower than 1ppb). (page 149, vol.11). I have incorporated in my chemistry review that this claim deemed satisfactory.

*ISI*  
Komanduri Pardha  
Review Chemist, HFD-510

*ISI* 2-10-00  
Duu Gong Wu, Ph.D.  
Team leader (chemistry), HFD-510

Cc:

NDA 21-081  
HFD-510/Division Files

APPEARS THIS WAY  
ON ORIGINAL