

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

20-987/S-007

ENVIRONMENTAL ASSESSMENT

May 21, 2001

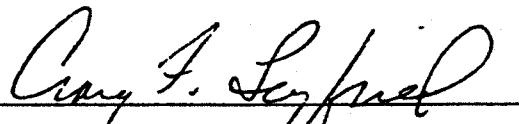
Environmental Assessment

Statement of Compliance

Wyeth-Ayerst Pharmaceuticals states that preparation of an Environmental Assessment (EA) for the proposed action, a supplement to the New Drug Application (No. 20-987) for the use of pantoprazole tablets for treatment of Zollinger-Ellison syndrome (ZES), is categorically excluded according to 21CFR §25.31(b).

The aforementioned regulation states that a categorical exclusion is permitted 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 increases the use of the active moiety, but the estimated concentration of the substance at the point of entry into the aquatic environment will be below one part per billion." The Expected Introduction Concentration (EIC) of pantoprazole is below one part per billion.

To the best knowledge of Wyeth-Ayerst Pharmaceuticals, no "extraordinary circumstances" exist associated with the proposed action as defined in 21CFR §25.15(d).



Craig F. Seyfried

Senior Director

Environmental Health & Safety

Wyeth-Ayerst Pharmaceuticals