

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 20-740/S008/S013

ENVIRONMENTAL ASSESSMENT AND/OR FONSI

ENVIRONMENTAL

Date: May 10, 1999

Name of Applicant/Petitioner: Bayer Corporation
Pharmaceutical Division

Address: 400 Morgan Lane
West Haven, CT 06516

The submission of an environmental assessment for the proposed action to distribute Baycol 0.8 mg tablets is not required.

As per revised regulations in 21 CFR section 25.31(c), as published in the Federal Register on 4/01/98, the submission of an environmental assessment is not required when the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion.

As calculated by the formula in CDER's document, "Guidance for Industry for the Submission of an Environmental Assessment in Human Drug Application and Supplements," the concentration of Baycol entering the aquatic environment from the sale of all Baycol products,

Since the manufacture and distribution of Baycol tablets fits the requirements of the revised 21 CFR 25.31(c) categorical exclusion, an environmental assessment is not being submitted.

/S/

Signature of Responsible Official
Gary Toczyłowski
Director of Health, Environment
and Safety