

US EPA ARCHIVE DOCUMENT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

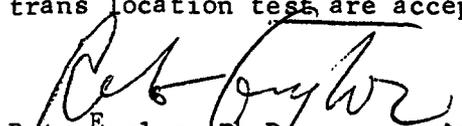
SUBJECT: Protocol Review for Teratology and Mutagenicity Studies DATE: July 29, 1976
Registration Number 34292-1

FROM: Toxicology Branch

TO: PM # 31

1. The protocol for the teratogenicity study appears to be adequate, with respect to number of animals, dose levels, and parameters studied. A final rationale for the choice of dose level will be required, the highest dose should if possible show some minimal effects on either mothers or fetuses.

2. The male dominant lethal mutagenicity study is not acceptable primarily because of its lack of sensitivity. The registrant must be referred to the Guidelines. The Ames test as a non-mammalian test is acceptable,; to fulfill the requirements for the test in a mammalian system the in vivo cytogenetics (bone marrow) and the mouse heritable xx trans location test are acceptable.


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