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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: The Rejection of Two Toxicology Studies in Conjunction with the Toxicology Branch Review of "Part 3 - Toxicology of BAYTHROID, Supplement No. 2 to original brochure dated September 15, 1983, Brochure No. 1434, December 31, 1985."

EPA No. 3125-GLE
Record No. 168966

Project No. 1356
Tox. Chem. No. 266E

TO: George LaRocca (PM Team #15)
Registration Division (TS-767c)

FROM: John E. Whalan, D.A.B.T., Toxicologist
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John E Whalan 7-16-86

THRU: Edwin R. Budd, Section Head
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Budd 7/17/86

for WBB 7/17/86

The following studies are invalid in their present form and must be revised before they will be reviewed:

1. "FCR 1272 (c.n.: cyfluthrin) STUDY FOR SUBCHRONIC INHALATIVE TOXICITY TO THE RAT FOR 13 WEEKS (exposure 63 x 6 hours)," [Bayer AG Institute of Toxicology; Report No. 12436; February 1, 1984; Accession No. 261771].

2. "4-fluoro-3-phenoxybenzaldehyde (FPBA) SALMONELLA/MICROSOME TEST TO EVALUATE FOR POTENTIAL POINT MUTATION. [Bayer AG Institute of Toxicology; Report No. 13429; April 22, 1985; Accession No. 261771].

These reports were lacking signatures of the performing scientists and Quality Assurance Officers. In a Doherty/Budd memorandum (PP 4F-3046/FAP 4H5427 and EPA Reg. No. 3125-GLR, 2-15-85), the failure of the Registrant to submit signed reports was cited along with the warning that studies would be classified Invalid unless signed reports were submitted. A memorandum from John Whalan (EPA No. 3125-GLR, May 8, 1986), reaffirmed this policy by stating that future studies would not be accepted without signatures. Accordingly, these reports will not be reviewed by the Toxicology Branch until they receive verifying signatures.

Also lacking from the Inhalation Toxicology report was a summary of the histopathology data. There was also scant description of the inhalation chamber and aerosol generator, and no mention of animal placement in the chamber. These are serious omissions found during a cursory inspection - there may be other deficiencies as well.

The histopathology summary must include the number of each tissue type examined per group, lesion severities, a key defining the severities, and the incidence of each lesion. An example that may be followed is attached. The pathology tables should be in English. Tables with abbreviations of German terminology require many hours to decode and reconstruct before any meaningful data can be extracted from them. All future submissions must be readily interpretable, and the histopathology tables must include all the characteristics mentioned above. As with the lack of signatures, the lack of readily interpretable pathology data has been a persistent deficiency in the past and will be used as criteria to invalidate future studies.

The Registrant is encouraged to review these and all future studies for readability and suitability, and request revisions from the performing laboratories as needed prior to submission to the EPA.

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