UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 10 1987

MEMORANDUM

SUBJECT: FMC 54800 (BIFENTHRIN)

TO: Mr. George LaRocca PM 15
Registration Division (TS-767C)

FROM: Byron T. Backus, Toxicologist
Toxicology Branch (TS-769C)

THROUGH: Marcia van Gemert Ph.D.
Section Head, Review Section III
Toxicology Branch (TS-769C)

and

Theodore M. Farber, Ph.D.
Branch Chief
Toxicology Branch (TS-769C)

EPA Reg. No. 279-3055
EPA I.D. Nos. 188065, 188487

Project Nos. 7-0434, 7-0455

Tox. Chem. 463F

Action Requested:

Review of tumor incidence data in a control group of mice in a recently conducted study by FMC Corporation, as well as a response from FMC Corporation to several Toxicology Branch reviews (including the mouse oncogenicity study) on Bifenthrin.

Background:

The FMC Corporation previously submitted a mouse oncogenicity study on the subject chemical (reviewed 08/08/86). In this study there were what appeared to be dose-related increased incidence trends for the following tumor types: leiomyosarcomas of the urinary bladder (males only); combined hepatocellular adenocarcinomas adenomas of the liver (males only) and combined bronchiolar alveolar adenomas and adenocarcinomas of the lung (females). For the leiomyosarcomas of the urinary bladder in males, there was a statistically significant elevation in tumor incidence at the highest dose level (600 ppm). For the combined adenocarcinomas and adenomas of

the liver in males the time-to-tumor tests were reported as showing a significant dose-relationship ($p = 0.022$), although the tumor incidence was not significantly elevated at the high dose level (7/49 vs. a control level of 2/49).

For the combined incidence of bronchiolar alveolar adenocarcinomas and adenomas in the females, a number of exposed groups (50, 200 and 600 ppm, but not 500 ppm) had significantly elevated incidences relative to controls, but there was no dose-related trend.

Conclusions and Recommendations:

1. With the reporting of an incidence of 18/50 combined bronchiolar alveolar adenocarcinomas and carcinomas in female controls of a second study (as compared with 14/50 in controls of the Bifenthrin study) the registrant's position that these tumors were not caused by administration of the Bifenthrin is considerably strengthened (18/50 and 23/48 - the latter being the combined incidence of these tumors in highest dose females in the Bifenthrin study - are not significantly different, with $p = 0.32$ by Yates' corrected Chi square by our calculations).

2. The registrant's responses to previous reviews (including the mouse oncogenicity and rat oncogenicity studies), as well as the additional control data, will be included in the material presented to the Peer Review Committee. This presentation is tentatively scheduled for April.

3. Although the cover letter of December 15, 1986 from the FMC Corporation states that there is a response to the toxicology review of a rat multi-generation reproduction study (FMC study no. A83-977) this was not included in the copy received by the Toxicology Branch.

172