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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

002404

1/18/83

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: VITAVAX TECHNICAL
Caswell # 165A, Company Product
Number 400-81

DATE: November 18, 1982

TO: H. Jacoby PM 21, Registration Division (TS-764)

cc: W. Burnam, W. Butler and R. Cyberly
Toxicology Branch (TS-767) *16/11/83*

Request

Review long term-Chronic Data . Carboxin effects on Mice. Study submitted in support of the Carboxin Registration Standard.

Conclusion

The submitted study is acceptable and classified as Core minimum data. The product is negative for oncogenicity up to the 2,500 ppm dose level (Highest dose level produce high mortality Data Review

Study Title: Lifetime Carcinogenicity Study in mice.

International Research and Development Corporation.

August 20, 1982

Accession Numbers 848261-846262 and 846263.

Product: VITAVAX

Subject: Charles River CD-1 mice

Dose Levels Used: 50; 2,500; and 5000 ppm incorporated in the diet.

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Number of mice per dose level: 50 male and 50 female per dose level plus 75 males and 75 females control (diet).

Observations: Daily for signs of Toxicity, mortality, palpable masses, behavior and any other pertinent findings.

Body weight and food consumption: Weekly for the first 14 weeks. Every 2 weeks for the next 12 weeks. Every 4 weeks to the termination.

Test diets: Prepared by blending and submitted for analysis at various intervals of 0-7 days and three months.

Serology: Hematology as CBC from 5 mice/sex/group at the 3, 6, 12 and 18 months.

Pathology: At the 19 months all animals were sacrificed and necropsied.

Tissue was collected from every organ (Complete). Microscopic examinations were performed in all tissues, organs, and any other entities as needed (Complete).

Results

Mortality: At the 5000 ppm level the mortality observed was greater than the controls. Hematology: Unremarkable. Histology at 2500 and 5000 ppm dose level, hypertrophy of centrilobular hepatocytes.

The NOEL = 50 ppm for mortality

Due to the lethality of the material, no tumors were observed at 5000 ppm (animals died before the possibility of tumor formation occurs). The product as tested is not oncogenic up to the 2,500 ppm dose level. At the highest dose level the mortality was greater than the controls, thus, oncogenicity can not be assessed.

Core Classification : Core Minimum

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