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

SEP 21 1987

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MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Subject: Benefin 1471-71 (Record Number 201457): Review of the Interim Report of Gross Pathology Findings in A Two-Year Oncogenic Mouse Study with Benefin Caswell Number 130

From: John H.S. Chen, D.V.M. 9/14/87
Review Section I
Toxicology Branch
Hazard Evaluation Division (TS-769C)

To: Robert J. Taylor, Product Manager (25)
Herbicide-Fungicide Branch
Registration Division (TS-767C)

Thru: Robert B. Jaeger, Section Head 9/16/87
Review Section I
Toxicology Branch
Hazard Evaluation Division (TS-769C) 9/14/87

Petitioner:

Eli Lilly and Company
Greenfield, Indiana 46140

Action Requested:

Review of the interim report of gross pathology findings in a two-year oncogenic mouse study with Benefin (EL-110, Compound 54521). Lilly Research Laboratories Studies MO2785, MO2885 and MO 2985. August 7, 1987.

Recommendation:

Toxicology Branch acknowledges receipt of information from Eli Lilly and Company pertaining to preliminary evidence of adverse effects in a two-year oncogenic mouse (B6C3F1) study with Benefin recently terminated. The final tabulated report of this study is scheduled to be submitted in January 1989. An increased incidence of gross liver nodules was reported for high dose (dietary concentration of 0.15%) females in this interim report. No classification of these noted liver nodules (i.e. malignant and/or benign) was provided by the registrant at this time. Toxicology Branch will await the complete report for a full evaluation. In the interim, any additional new use of Benefin should be carefully weighed against the potential adverse effect demonstrated in mice.

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