

US EPA ARCHIVE DOCUMENT

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

MEMORANDUM JUL 26 1982 ~~JUL 23 1982~~

TO: Jay Ellenberger
Registration Division (TS-767)

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

THRU: Orville E. Paynter, Chief
Toxicology Branch
Hazard Evaluation Division (TS-769)

WdB

SUBJECT: Upgrading of the Validation Status of IBT No. 8580-09771;
17-Day Cataractogenic Study of Prowl in White Leghorn
Chickens
CASWELL#454BB

Registrant: American Cyanamid Co.
Agricultural Research Division
P.O. Box 400
Princeton, New Jersey 08540

Background Information:

This study was validated on March 21, 1980 and classified as Supplementary Data. The major deficiency cited was a lack of confirmation that hens received the required amounts of test compound. The validation stated that the deficiency "... can be resolved by the registrant by duplicating the diet procedures outlined by IBT... If this problem is resolved, reclassification to the "valid" category is possible".

The registrant has now submitted additional information regarding diet preparation and analysis.

Recommendation:

It is recommended that this study be upgraded to valid status.

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Discussion:

The recently submitted data replicated diet preparation procedures indicated by IBT in the original raw data. The results of the recent study indicate that original diets were probably fortified to the required levels (1,000 and 3,000 ppm), were homogeneous, and were stable over the 17-day course of the study.

Other deficiencies noted in the original validation are considered by this reviewer to be minor and not to impact upon the study validity. It is therefore recommended that this study be upgraded to valid status.

Review of Data:

This study was reviewed in the memo of March 23, 1979 from John Doherty of Toxicology Branch. The results of this validation do not require a rereview of the study.

 JDC 7/23/82
Gary J. Burin, Toxicologist
Toxicology Branch
Hazard Evaluation Division (TS-769)

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