

US EPA ARCHIVE DOCUMENT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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DATE: March 18, 1981

SUBJECT: Oryzalin, 2-year rat studies on, tables of skin and thyroid tumor incidence
(dated 2/25/81) from Eli Lilly Co., defects in and request for new ones.

FROM: M. L. Quaife, Ph.D., TB/HED ; 16, 3/18/81
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623A

TO: Mr. Robert Taylor, PM
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THRU: Mr. William Burnam, Acting Chief *C. J. Chanson*
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PP No. 6F1859

Eli Lilly & Company
Indianapolis, Indiana

EPA (ltr. of 2/4/81, R. J. Taylor, EPA - Eli Lilly, Item 2, p. 1) asked for tables of incidence of each skin and thyroid tumor at various (each of four) time intervals - specified by month and day of the study - for each of the two 2-year rat studies on oryzalin.

The tables supplied by Eli Lilly in response are internally inconsistent - and therefore unusable for toxicologic evaluation - for the following reason:

The tables purport to provide tumor incidence figures for each of five consecutive (separate) time segments of the study, as well as the total incidence - in a column headed, "Term," which is described in the tables as referring to (study date) "0 thru term."

Therefore, the "Term" column should list a numerical value which is the sum of the numerical values for each of the corresponding (five) separate time segments.

In fact it does not do this, as casual inspection will show.

Thus, the tables are meaningless and of no value for further evaluation of these rat studies as to oncogenic potential of oryzalin shown.

Petitioner is requested to send new, correct tables to replace these tables.