

EXHIBIT 44

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015884

2 YR RAT

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TO : M Rose
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TWO YEAR CHRONIC ORAL TOXICITY OF PARAQUAT IN ALBINO RATS
INDUSTRIAL BIOTEST LABORATORIES REPORT.

I have examined this report in order to see whether it conforms to modern regulatory test requirements. My comments are:

- a) Only 30 animals/sex/group were used. Modern requirements demand at least 50 and preferably 75 or 100 animals/group.
- b) The number of animals examined histologically is remarkably small (control group 1, 22 out of 60; control group 2, 26 out of 60; test group 3, 23 out of 60). This compounds the point a) made above.
- c) There was a high mortality in the experiment and this is not taken into account in reporting the tumour incidencies. It could be argued that the mortality was so high that it invalidates the study as a carcinogenicity study.
- d) From table 4 it appears that only 13 tumours were diagnosed in 300 animals. By modern standards a tumour incidence of about 4% would be considered ludicrous as most rat studies have final tumour incidencies in the 30 - 70% range. It could be deduced from this that the method of identifying and reporting tumours was inadequate.
- e) On page 6 it is mentioned that almost all deaths were ascribed to respiratory illness. In the light of the fact that paraquat is a pulmonary toxin one would have expected a more detailed analysis of this aspect of the experiment.
- f) There is nothing in the haematological data to suggest that paraquat produced any effect on the haemopoietic system. Therefore it might be necessary to re-examine this effect in a further study.

My overall impression is that the Biotest report, which was prepared in 1964, will not meet up to modern requirements and nor would it withstand critical scrutiny.

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