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FOR FILES

R & D Dept.

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- Dr. I. W. Hughes (2) - Louisville
- Mr. R. M. Gibb - Montreal
- Mr. R. S. Wade (2) - Montreal
- Dr. F. Seehofer (2) - Hamburg
- Mr. R. G. Nicholls - Swiney
- Dr. C. I. Ayres - Southampton

Dear

REPORTS B44 and B45

Enclosed are copies of two reports prepared in GR & DC. These are being circulated in the "B" report series as they relate to earlier Biological Reports. The separation of internal reports from those prepared by the contracting laboratories was a number of advantages, particularly since it makes it possible to discuss the results in clear language rather than by reference to some sample code.

Report B44: A statistical analysis of the incidence of tumour-bearing animals in JANUS promotion study B30/31 - Report No. RD.1517 restricted.

This report gives details of the statistical analysis undertaken on the results of the promotion study of condensate from a number of PRT variants (Report B39 : November, 1976).

The conclusions which are given in the summary, and in more detail on pages 12 and 13, modify the position predicted from the provisional results in that:-

- (1) The base weight is now shown to have a significant effect on tumorigenic activity.
- (2) The effect of the solubles on tumorigenic activity, which was predicted as significant in the preliminary analysis, cannot be clearly established from the analysis of the results of the complete experiment. There is, however, some evidence to support the hypothesis that increasing levels of solubles increase the tumorigenic effect (page 10 para. 5).

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Report B45: A comparison of the tumorigenic activities
of JANUS condensates B0, B2 and B4 -
Report No. RL.1537 restricted

This report started as an attempt to compare the results of a number of separate early JANUS experiments. Subsequently, following the exclusion of cocoa from the list of additives submitted by the Hunter Committee, the objective was expanded to examining the effect of cocoa in more detail.

From examination of the early JANUS results, it is apparent that the decline in tumour response of the animals treated with carcinogens was probably due to a decrease, during storage, in the activity of the solutions and pure chemicals. Comparison of the tumorigenic activity of condensates in Experiments B0, B2 and B3 with those represented in Experiment B5 shows that the sensitivity of the animals was unchanged and thus adds strong support to this hypothesis. With this assumption the results of Experiments B0-B4 can be intercompared as set out in Tables 41, 42 and 47.

Further examination of the results from the typical American blended cigarettes (B2) with those from various flavoured cigarettes (B0 and B4), together with the re-analysis of the NCI results, leads to the conclusion that the use of cocoa does not increase the tumorigenicity of the smoke condensate. These conclusions have been put to the Secretariat of the Hunter Committee, with the request that they reconsider their attitude to the acceptability of cocoa as a tobacco additive.

Yours sincerely,



D. G. FELTON

Encs.

cc: Dr. S. J. Green
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