

## Memorandum

Date

December 7, 1993

From

Additives Evaluation Branch #1 (HFS-226)

Subject

FlavrSavr<sup>an</sup> tomato: significance of pending DHEE question

To

L.S. Kahl, Ph.D., Biotechnology Policy Branch (HFS-206)

Through:

D.G. Hattan, Ph.D. Deputy Director \_\_\_\_ \\_\_\_

Division of Health Effects Evaluation (HFS-225)

FMF 526

Calgene

Davis, CA 95616

OPA is considering the possibility of stating, in the overall evaluation document, that FDA did not rely on Calgene's animal feeding studies in reaching its decision. This decision would be based on Pathology's stated inability to conclude whether or not there is a treatment related effect in rats consuming FlavrSavr tomatoes for 28 days. Pathology concludes that the responses which Calgene provided were insufficient to answer the questions that were posed, which is to say that unresolved questions still remain. Until these questions are answered, Pathology will be unable to conclude whether or not there is a treatment related effect in rats consuming FlavrSavr tomatoes for 28 days. Whether to continue to pursue answers to these unresolved questions is a matter of time/money/personnel and the most effective use thereof.

Concerning the one remaining question posed by DHEE, it is doubtful that an explanation of the non-random distribution of gavage injury in the second rat study would help resolve the question of whether or not there was a treatment-related effect in the feeding studies. DHEE's question reflects more on good laboratory practice than on toxic potential of the test ingredient; there appears to be no question that all of the lesion descriptions were consistent with gavage injury. In agreement with Pathology, we can state that the responses which Calgene provided were insufficient to answer the question that we posed. However, there is no reason to proceed with attempts to resolve the remaining DHEE question if, when the question is answered, the studies still cannot be used to unequivocally document the presence or absence of a treatment-related effect from consumption of FlavrSavr tomatoes.

Carl B. Johnson, Ph.D.

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