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FILE MEMORANDUM

May 25, 1970

MCA-FDCC Committee - May 18, 1970

Mr. Sam D. Fine
FDA, Associate Commissioner for Compliance

Mr. Fine is counterpart of Mr. Dale Lindsay, Assoc. Comm. for Science. Present head of Bureau of Foods, Pesticides and Product Safety is Dr. V.O. Wodicka, an old classmate of Mr. Fine, recent obtained from Hunt-Wesson Co.

Mr. Fine indicated that all decisions of cyclamates were made by Mr. Finch. He indirectly inferred that cyclamate story was reason for ouster of Dr. Ley. With respect to deferrment of discard of present diet drink bottles, Mr. Fine pointed out that soft drink industry has a $100,000,000.00 investment in bottles and if they were forced to throw away present returnable bottle stock they would go to non-returnable bottles exclusively thereby adding to mounting disposable waste problem. Hence, cap and carton labeling of bottles is permitted until Oct. 1, 1972. One suit has already developed form use of sugar in diet drinks i.e. diabetic coma produced.

With respect to GRAS list, FDA has already granted brief contract with NAS-NRC for their view on what to do with the GRAS list. The Federal Register notice was to get information on all materials that were generally regarded as safe prior to 1958. Letters have been issued over a period of 30 years and FDA has no good idea of how many substances were covered or what they were. The sanctions remain, only the opinions are revoked. If FDA concludes that any GRAS material or any prior sanctioned material is deleterious they can ban its use by other provisions in the FD&C Act.

Mr. Fine cited the recent brominated vegetable oil case wherein Canadian data convinced FDA that something had to be done. FDA had meetings with FEMA and the Soft Drink Association who agreed to removal of the product from the GRAS list and from the soda water standard. There is now in preparation a petition requesting a tolerance level of 15 ppm of brominated vegetable oil in soda water based on Canadian data supplied to FDA.

In the case of saccharin, NAS was given all data available to FDA one month ago and opinion is expected in about one month. Long term feeding studies are underway. With respect to accusation by Dr. Richardson that FDA work

on saccharin in 1950 showed deleterious effects which were disregarded by his superiors Mr. Fine stated that FDA is undertaking careful investigation and would act on saccharin limitation if needed or do somethin about Dr. Richardson if accusation is unfounded.

In review of GRAS list and prior sanctions priority is on direct additives; there is no intent to look for trouble in the indirect additive field, Mr. Fine revealed that, after considerable search, it was found that original GRAS list was prepared by Mr. Checchi, now a consultant outside FDA.

Whereas prior FDA administrators have concentrated on drug regulation, it is anticipated that this one will concentrate on foods. Jim Grant, Deputy Commissioner of FDA is thinking in terms of nutritional labeling for foods, i.e. labeling for nutritional value rather than listing of ingredients.

In answer to question as to confidentiality of information on which food additive states opinions were based (disclosures were frequently very specific and of a proprietary nature) Mr. Fine disclaimed any knowledge of policy here and suggested the company write to FDA to get opinion direct from Mr. Rankin.

W. A. Knapp
Consultant - Toxicology