

H.W. Dwyer

March 20, 1987

J. D. Ong

Activities Report - February 1987
Health & Environmental Services Division

1. The annual urine cytology program for 1987 has begun with mailing cards and letters to 106 eligible retired or former employees who had exposure to beta-naphthalamine. The program is designed to provide early diagnosis of cancer of the urinary bladder.
2. At the request of the Vinyl Institute, R. K. Hinderer has provided an update of Medical Committee activities. All of the primate studies with HCl and PVC have been completed. Initial combustion toxicity evaluations with PVC have found a more toxic response with rodents than primates. These studies will be continued until the end of this year.
3. We are continuing to assist the FPD in obtaining pesticide clearances for Promac in a number of countries in Europe and the Far East. We are now gathering information on potential consultants for guidance and liaison activities with the respective countries/agencies.
4. The EPA Pesticide Establishment Report for Promac and No Foul have been submitted to EPA. No 1986 production was shown for either pesticide. For No Foul, BFG is now considered an applicator, not a producer. Our custom mixer is now considered the producer for EPA pesticide purposes.
5. Alza Laboratories wants to use the sodium salt of Carbopol 934-P in a time release cattle bolus application. We will make the C-934-P salt at the Avon Lake pilot plant initially. Alza plans to perform a Good Manufacturing Practice (GMP) inspection at Avon Lake March 11, 1987. In preparation for Alza's inspection, W. C. Bachtel made a similar inspection February 26. He made a number of recommendations to bring the pilot operations into compliance with GMP.

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6. On February 19 and 20, Walter Lang and W. C. Bachtel met with Monsanto and the EPA concerning the use of Carbopol 1342 as an inert pesticide ingredient. EPA's policy of approving inert pesticide ingredients has been changed very recently. EPA now requires an extensive minimum chemical and biological data set for all inerts. Exemptions to the required data are possible. Based on our discussions, we believe we can show that Carbopol-1342 is essentially similar to other acrylates now cleared, and thus obtain an exemption from further testing. It will be at least four to five months before we will obtain any response from EPA after our initial petition is submitted. If no exemption is granted, the cost to develop the additional toxicity data required would be prohibitive for this application.

Lever Brothers is interested in the use of Carbopol-934-P in a toothpaste formulation. We have authorized the FDA to refer to the Drug Masterfile on Carbopol-934-P for Lever Brothers' application.



Richard A. Guyton

cc: Leigh Carter

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