August 16, 1971

Protocol Submitted by Union Carbide Corporation for a study of the effect of Carbaryl on reproduction in Monkeys.

Dr. O. G. Fitzhugh
Toxicological Advisor
Office of Pesticides Programs

I have studied the protocol and have asked Doctors Whitmore and Schmidt for their comments also. Dr. Schmidt has worked with the monkey colony at Ft. Detrick, and in addition he contacted other people in this area. The comments of these several persons are:

1. The number of monkeys to be used is in excess of that really needed for this type of study.

2. If this is to be a complete fertility study, then a certain number of males should also be treated. The procedure would be mating treated females to treated males, treated females to untreated males, and untreated females to treated males. It is suggested that two males and four females for each group would be an adequate number of monkeys to use.

3. This suggestion is merely one which the petitioners might want to consider. In the previous study with Carbaryl in dogs by the Woodard Laboratories in 1969, abnormalities such as umbilical hernia, cleft palate, and intussusception were noted. If the petitioner is looking for abnormalities then some offspring from each of the dose levels of Carbaryl should be held over until the F2 generation can be examined. This would involve feeding the monkeys until breeding age which is approximately three years.

4. It is our combined opinion that they would really need to feed only two levels plus a control. If they want to feed an additional level in order to make reasonably certain that they can find the no-effect level, we feel that 60 milligrams per kilo is a little high, but here again the petitioner may have good reasons for wanting this high a level. This is just offered as a suggestion, but not one which they need to abide by.

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cc: DBaker
PP No. 1008 ✓ Aldicarb
Reading File
GEWhitmore
RSchmidt

dtb:init:GEWhitmore
RSchmidt

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