

COMMENTS ON MEETING MINUTES (11/16/98)

The Meeting Minutes have a few items that should be clarified for Merial. For instance the second paragraph refers to the term "CRP certified" as being a requirement before marketing the pipettes for dogs more than 88 pounds. This term should be replaced by the phrase "CRP testing per 16 CFR 1700.20 is complete for the seniors and children, the CRP data, a 3/5 inch disc of the data electronically, an amendment form, and the CRP certification " must be submitted and found acceptable by the Agency as a requirement before marketing the pipettes for dogs more than 88 pounds. The second paragraph mentions self certification of the CRP 6 pipette packages, which is correct, but Merial should be reminded that **any CRP self certification is contingent on the review and acceptability of the 3 pipette packages**. If the number of pipettes in a blister change each variation should be tested (e.g. a one pipette package should be tested even if the 3 pipette size was tested). CRP self certification may be allowed contingent on the review and acceptability of the 3 pipette packages.

A change in pipette color would not necessitate retesting as the blister and not the pipette is the CRP. However any change in blister color or design would necessitate retesting. The use of a box to contain the blister with the pipettes is mentioned. Merial should be advised that in accordance with 16 CFR 1700.20(a)(1): the children should be given the blister removed from the box (outer package); and the seniors may be given the blister either in or out of the box since directions for opening the blister are in both locations. I would recommend that the seniors be given the blister in the box and the time required to remove the blister from the box is not counted in the times allowed for attempting to open the blister.

Merial should be reminded **in writing** that the September 1, 1999 and May 1, 1999 dates allow the Agency a two month turnaround time for reviewing their submissions. In reality their **Deadlines are July 1, 1999 and March 1, 1999 for CRP test data and electronic data on disc to be in and acceptable to front end processing** for Frontline Top Spot products in pipettes and trigger sprayers respectively. Merial should also be reminded that this extension effectively gives them **10-14 months** (from May 1, 1998 to March or July 1, 1999) to get into CRP and a **second extension is highly improbable**. Furthermore, their own preliminary CRP test data demonstrates that **CRP is available, which is technically feasible, practicable, and appropriate as defined in 40 CFR 157.21, although it may not be their package of choice**. They should be reminded that CRP compliance does not have any provisions for their package of choice, but merely that CRP is available, which is technically feasible, practicable, and appropriate as defined in 40 CFR 157.21.