----- Original Message -----
From: Alicia L Carriquiry [alicia@iastate.edu]
Sent: 04/18/2007 01:04 PM
To: Paul Lewis; david.bellinger@childrens.harvard.edu; chambers@cvm.msstate.edu; Fisher@Fordham.edu; kannan.krishnan@umontreal.ca; mlebowit@u.arizona.edu; Lu-Ann Kleibacker; Neil Stiber
Subject: Comments on EMD-003.3 and WPC-001

>Hello everyone: Since I will be in and out of the conference via phone >today (there tomorrow) I wanted to share my comments on >EMD-003.3 and WPC-001 so that you have them in case I am not there.

EMD-003: I really have nothing to add to Mike Lebowitz's comments. He covered all the bases and I agree with everything he said.

The only comment for the Board and for EPA is that, as a Board, we MUST provide better guidelines for sample selection, both in terms of the populations from which samples need to be drawn and in terms of sample size. The "community of friends, colleagues and neighbors" that we have seen over and over from this particular registrant should be banned now, so that the next protocol does not include the same sub-standard sampling approach. Sample sizes justified on the basis of "10 is more than 6 and few enough to give good results" should also be deemed to be unacceptable. I would like for the Board to think about establishing criteria for sample size justification that are similar to those employed by NIH, FDA and others and that are based on scientic considerations. Perhaps those of us with more of a statistical background could consider drafting a sample size set of guidelines for consideration by the board.

WPC-001: I have similar comments regarding this protocol. More specifically:
* In the dosimetry phase, it may well be the case that the variability within person and between person in the doses applied is large enough to make the grand mean not really representative of what individuals in the population will apply. Should this be the case, it seems that rather than limiting the repellency portion of the study to a single dose which might not accurately represent the wide range of doses likely to be used in the "real world", registrants might consider computing repellency for a range of possible doses so that the public knows that the advertised control time for the product can vary depending on dose.

* In the repellency phase, the sample size is again very poorly justified.

* Still in the repellency phase, there is no discussion of how the mean protection time will be computed if some of the subjects experience no landings with intent to bite before the study concludes. In the presence of censoring the naive sample mean is biased, and a Kaplan_Meir type of approach will give a better estimate.

No other major comments. I will join the meeting at approximately 1:20 pm (in about 20 minutes) and will be in it until 2:00 pm. Then I will join again at 3:45 pm.

Best,

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