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January 13, 2006

Division of Dockets Management
Food and Drug Admininistration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir/Madam:

Request for Advisory Opinion

The undersigned submits this request for an advisory opinion of the Commissioner of Food and Drugs with respect to genetic toxicology testing: the Ames Assay, Mouse Lymphoma Assay and the Micronucleus Assay.

A. Issues involved

FDA regulation (21 CFR Part 58, 105 (says, something to the effect that, any study lasting more than 4 weeks (the duration of a study) has to have the test and control articles retained (archived).

One interpretation is that the definition of study duration is from study initiation (when the test article is logged in) to study completion (perhaps when the report is sent out). After asking this question to Dr. Rod Allnutt before Christmas, he indicated that the term "study duration" could mean "test article exposure duration", and therefore would exclude short term tests like the Ames (and other short term genetox assays). We would appreciate an "official" clarification of the term "study duration". Specifically, must samples of test articles and controls for these short term tests be retained/archived?"

As Dr. Allnutt opined, it probably was not the intent of the crafters of that regulation to include short term genetox assays. How should we proceed? We would be most appreciative of your response.

B. Statement of facts and law

21 CFR Part 58.105 (d) states that, "For studies of more than 4 weeks' duration, reserve samples from each batch of test and control articles shall be retained for the period of time provided by Sec. 58.195.

The undersigned certifies that, to the best of my knowledge and belief, this request includes all data, information, and views relevant to the matter, whether favorable or unfavorable to the position of the undersigned, which is the subject of the request.

Carol R. Tometsko
President and CEO