

Subject: FR Notice Comments - 72FR23832: Draft Five-Year Plan
Date: Wednesday, May 23, 2007 1:26 PM

Below is the result of your feedback form. It was submitted by
() on Wednesday, May 23, 2007 at 13:26:50

Comment_date: May 23, 2007

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Comments: In my opinion, validation of alternate methods by comparison with in vivo animal results is not only a waste of time and resources, but also misleading. The general consensus is that animal models leave much to be desired as predictors of human responses, but until several years ago there was nothing else available. But now there is. For non-invasive methods, such as skin irritation, humans can be used. Although invasive or unsafe methods cannot be performed in humans, there is, usually, epidemiologic data for comparison. To my delight, I recently found out that there is one method of which validation was based on human data. But to my chagrin, I think it is still the first one. Let us realize that comparison of in vitro results to animals is a step to the wrong direction for validation of alternate methods.

Respectfully
