Vical
10390 Pacific Center Court, San Diego, CA 92121-4340
858•646•1100, FAX 858•646•1150
www vical com

July 31, 2003

Docket No. 03D-0112
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Attention: Jefferey Shuren
Associate Commissioner for Policy

Re: Comments on Draft Guidance for Industry in 68FR24486 (May 7, 2003)

Dear Associate Commissioner Shuren:

We at Vical Incorporated commend FDA for taking steps toward providing a formal process by which Sponsors may recommend independent consultants to participate in the review of protocols for clinical studies intended to serve as the primary basis of claims of efficacy.

We submit the following comments on the level 1 draft guidance, for consideration in the next level draft.

Comment to Section III: Scope of the Guidance

The scope of the draft guidance is limited to review of pivotal clinical protocols. However, there are important reasons to allow Sponsors to request and obtain from FDA agreement to include an independent consultant's review of any protocol that is intended to serve as a primary basis for a claim, including a protocol that is intended to be a primary demonstration of a claim for safety, efficacy, potency or comparability. This expanded scope is important where a number of biotechnology products present new and challenging approaches to development issues in which independent consultants may provide the special expertise needed to resolve an issue.

Comment to Section V: Independent Consultant Limited to One Protocol Review

Sponsors should be allowed to request participation of an independent consultant in protocol review more than once in the development of a product. Appropriate use of such an independent consultant can be expected at such milestones as a Pre-IND meeting, an End-of Phase 1 or End-of-Phase 2 meeting, or a Pre-BLA/NDA meeting. Section VIII clearly sets the expectation that FDA may deny a request to utilize an independent consultant if FDA believes the consultant would not serve a useful purpose; Section VIII thus protects FDA against abuse of the opportunity to request the participation of an independent consultant. Therefore, allowing Sponsors to request participation of an independent

consultant in protocol review more than once in the development of a product could facilitate resolution of complex issues while presenting little risk of abuse of the opportunity.

Comment to Section IV: Extension of PDUFA Meeting Management Goals

The draft guidance states as a matter of fact that the time to schedule and hold a formal PDUFA meeting will be extended an additional 60 days when there is a request for an independent consultant's participation in a protocol review.

It is clear that FDA needs time to select and screen a previously unscreened consultant, just as there is a clear need for the consultant to review previously unreviewed scientific issues. However, it seems likely that some sponsors will recommend well known consultants who may be already established as free of conflicting interests. In such cases, the time to screen the recommended consultant should be reduced. Therefore, if the sponsor has planned ahead and recommended an independent consultant already known to the FDA, FDA should avoid imposing again a 60 day screen period. In such cases FDA should allow the screening of potential independent consultants to occur on a parallel track with handling of a PDUFA meeting request. This approach will reduce some risk for both FDA and sponsors.

Thank you in advance for considering our comments.

Steven A. Kradjian
Executive Director
Regulatory Affairs
Vical Inc.
10390 Pacific Center Court
San Diego, CA 92121
(858)646-1117
sakradjian@vical.com