

Draft Guidance for Industry on Exploratory Investigational New Drugs Studies

[Docket No. 2005D-0122]

The Regulatory Affairs Branch, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute, NIH appreciates the opportunity to submit comments concerning the Federal Register Notice of April 14, 2005, Docket No. 2005D-0122. Please find below our comments:

- Lines 36 and 188 indicate that the duration of dosing in an exploratory IND study should be limited (e.g., 7 days). Certain agents may not affect their target within this 7-day time frame, particularly at the low doses prescribed by this guidance. It may be necessary to dose for longer periods. Therefore, we suggest that the 7 day time frame be presented as a benchmark. Moreover, the guidance should indicate that a flexible approach to duration of dosing will be adopted, as long as data are provided that support a more extended duration.
- Regarding the preclinical toxicology testing strategy presented in the Attachment (line 447): It should be clearly noted in the guidance that this paradigm is only one example and that other paradigms can be utilized (e.g., for oncology products).
- This document does not apply to human cell or tissue products, blood and blood proteins, vaccines, or to products regulated as devices (see footnote 2). We recognize that this is appropriate, as these products differ in their requirements from CDER products. However, it would be extremely useful to investigators if a similar document was drafted that pertains specifically to therapeutic cancer vaccines, cellular, and gene transfer products (i.e., Office of Cellular, Tissue and Gene Therapies products). Many of these products (e.g., peptides) are relatively non-toxic and would greatly benefit from screening under an exploratory IND.
- We agree with the option to either withdraw/inactivate an exploratory IND when the exploratory phase is complete or to supplement the exploratory IND with the appropriate complement of preclinical data in order to convert it to a traditional IND (see line 175).