

June 3, 2005

Richard Pazdur, MD  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Office of Oncology Drug Products

*Via email*

**Comment on DRAFT Guidance for Industry Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics**

Dear Dr. Pazdur,

The draft guidance is a helpful clarification of a complex topic. We applaud FDA's effort in this area, especially the emphasis on clinically relevant endpoints. We offer the following comments:

1. The sciences of biomarkers and imaging are moving forward rapidly, and we predict that NCI's grant investments in these areas will accelerate the pace of practical progress. In order to take advantage of this evolving body of knowledge, we urge FDA to work with sponsors and NCI (especially cooperative group trials where possible) to incorporate correlative science in their trials which will help to understand and use these tools most appropriately. For example, FDA could encourage collaborative efforts to:
  - a. Standardize accurate imaging evaluations
  - b. Improve development of accurate and reproducible assays
2. We fully support the summary and conclusion section, where sponsors are urged to work with FDA prior to submission of protocols intended to support BLA or NDA filings. This "pre-work" will support quicker development of solid protocols. At the same time, we have concerns about FDA's ability to get all of the work done, given current resource constraints. If the oncology division needs additional resources in order to deal with the workload, we urge FDA to make its case not only to Congress but also to the advocacy community, so that we can support efforts to increase resources.
3. One area where we would like to see additional clarification is in the level of evidence required for accelerated approval of therapies. Based on events of the past few years – the Iressa approval and subsequent ODAC examination of accelerated approval – we believe that accelerated approval has sometimes been granted for marginal or ineffective drugs. We believe that this draft guidance is setting standards which set the approval bar appropriately higher. At the same time, we feel that a simple

statement – that accelerated approval will be reserved for drugs which have a clear clinical benefit – would clarify this point.

In closing, we urge FDA to plan regular reviews of this and subsequent endpoint guidances, so that new endpoints can be identified, discussed and evaluated on a rolling, ongoing basis. Science is moving very quickly these days, and our infrastructures need to be pliable in order to take advantage of new findings as quickly as possible.

Thank you,

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