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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
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**SUBJECT: DOCKET NO. 00D-1336  
DRAFT GUIDANCE FOR INDUSTRY: PEDIATRIC ONCOLOGY  
STUDIES IN RESPONSE TO A WRITTEN REQUEST; AVAILABILITY**

Dear Sir or Madam:

Thank you for providing us the opportunity to comment on the Draft Guidance for Industry on Pediatric Oncology Studies in Response to a Written Request. Overall this is a clearly written document that will help in providing direction to our pediatric oncology Clinical Research activities. Our comments are outlined below:

## Comment 1

Page 2, Under III. WHAT IS SPECIAL ABOUT STUDYING..., Paragraph 2, Sentences 2 and 3:

We believe that the statements, "As a result, it is usually impossible to rely on the pharmacokinetic and safety data gathered from studies of a cancer drug in adults to guide the use of that drug in children. Therefore, it is imperative to evaluate the effectiveness and safety of new cancer drugs in pediatric populations," are too strong.

We would suggest replacing the words "impossible" and "imperative" with "difficult" and "important", respectively.

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## **Comment 2**

Page 2, Under III. WHAT IS SPECIAL ABOUT STUDYING..., Paragraph 4, Sentence 2:

We believe that the second half of the statement, "If appropriate, a specific disease may be targeted; otherwise, several studies in a variety of tumor types, such as brain tumors, solid tumors, or hematologic tumors should be planned", is too broad. This position would potentially lead to an overwhelming number of probe studies in all possible indications/tumor types. At best this would detract from Research efforts aimed at the more likely pediatric indications targets/leads, and at worse, discourage the entire pediatric effort for a development product. We would suggest that the investigational plan be discussed up front with the Agency and usually be focused on investigating the tumor type(s) which are the subject of the adult indication(s) being sought, taking into consideration the clinical and biological differences that may exist between adult and pediatric patients.

We would suggest the wording be revised to read: "If appropriate, a specific disease may be targeted; otherwise, studies in one or more tumor types, such as brain tumors, solid tumors, or hematologic tumors may be planned."

## **Comment 3**

Page 3, Under III. WHAT IS SPECIAL ABOUT STUDYING..., Paragraph 1, Sentence 1:

The current sentence reads as follows: "When planning pediatric protocols, applicants should discuss protocol designs with a pediatric cooperative study group." Discussing protocol designs with a pediatric cooperative study group should not be mandatory, but rather an FDA recommendation as stated earlier in the guidance.

We would suggest revising the sentence to read, "When planning pediatric protocols, applicants may wish to discuss protocol designs with a pediatric cooperative study group."

## **Comment 4**

Page 3, under IV. WHAT WILL A TYPICAL WRITTEN REQUEST ASK FOR?, First Paragraph of sub-section A., last sentence:

Minor comment: it would improve readability if the 21 CFR part were to be added and not leave only the subparts (subpart H, E and E).

**Comment 5**

Page 5, under V. WHAT WILL TYPICAL PROTOCOL LOOK LIKE?, Paragraph 4, the statement "Phase 2 studies should be considered for a range of potential indications based on consultation with pediatric oncologists." does not seem to belong in this section. It is also very broad and again puts the cooperative groups between the companies and FDA.

We would suggest to remove this sentence or modify it as follows: "Phase 2 studies should be considered for a range of potential indications based on consultation with the FDA and/or pediatric oncologists."

Schering appreciates the opportunity to provide comments on this draft guidance.

Respectfully submitted,



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