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27 July, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

PHARMACIA

RE: Docket No. 00N-0074
Interim Rule: *Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products*

Dear Sir or Madam:

Pharmacia appreciates the opportunity to review the interim rule, "***Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products***." In this regard, the following are our comments and requests for clarification.

General
In general, FDA has done a reasonably good job with a difficult task. The document provides a good review of the background history leading up to the Interim Rule and clearly states the needs and objectives. The document points out the complexity of the task in trying to work within the framework of many regulatory documents from different agencies. This Interim Rule does not provide much clarity to this complexity, in fact, it will be even more difficult for sponsors to sift through yet another regulatory document. The FDA has attempted to adopt and apply safeguards from the HHS subpart D; however, in doing so, they have introduced another level of complexity.

II. A.
The FDA has modified definitions from HHS subpart D for the Interim Rule. In the Pediatric Final Rule, the FDA referred to both the HHS subpart D and the AAP guidelines for providing safeguards for conducting clinical trials in children, yet in this Interim Rule, the only reference is made to the HHS subpart D. This may introduce some confusion as to which to follow. By modifying definitions, there are now several legal/regulatory documents that are all using slightly different definitions and terms. This will create challenges as sponsors meet the requirements under one document, but due to slightly modified terms and definitions fail to meet requirements under another document.

II. C.
There needs to be a clearer definition of "Greater than Minimal Risk". This term is vague in this section and the definition is open to

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interpretation. In the second paragraph, the FDA does specify the type of procedure that might fall into this category, but these are only examples.

II. D.
The FDA discusses study design that might "mitigate risks," including exit strategies, DMCs, and study amendments. These may be appropriate measures for an IRB for a clinical trial conducted by that institution, but it may not be appropriate action for an IRB involved in a sponsored global clinical trial where a DMC is part of the protocol and amendments are generated by the responsible sponsor.

PHARMACIA

Again, thank you for the opportunity to comment. Should any clarification of our input be required, please don't hesitate to contact Jenny Peters at (616)-833-8141.

Sincerely,

Pharmacia Corporation

Jenny L. Peters
Director
Global Regulatory Policy & Intelligence

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