ACRP
ASSOCIATION OF CLINICAL RESEARCH PROFESSIONALS

MISSION:
ACRP promotes excellence in clinical research.

99 Canal Center Plaza
Suite 200
Alexandria, VA 22314
USA

T | 703.254.8100
F | 703.254.8101

office@acrpnet.org
www.acrpnet.org

February 9, 2015

Division of Documents Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

In reference to docket number: **FDA-2013-D-1275-0001**

The Association of Clinical Research Professionals (ACRP) is the primary resource for clinical research professionals in the pharmaceutical, biotechnology and medical device industries, and those in hospital, academic medical centers and physician office settings. ACRP was founded in 1976 to address the educational and networking needs of research nurses and others who supported the work of clinical investigations. Almost 40 years later, ACRP is a global association comprised of individuals dedicated to clinical research and development. Our mission is "ACRP promotes excellence in clinical research." The Academy of Physicians in Clinical Research (APCR) is an affiliate of ACRP and is the leading professional organization, exclusive to physicians, that supports and addresses these unique issues and challenges of all physicians involved in clinical research.

ACRP appreciates the opportunity to provide the FDA with our comments on the Considerations for Pediatric Studies for Drugs and Biological Products as this issue has a significant impact on our membership. The attached document provides detailed comments, suggestions, and recommendations on specific sections of the draft guidance.

We applaud the FDA's efforts on this important issue and hope that our feedback helps improve the final version of the document. Please let me know if you have any questions regarding our comments, or if we may otherwise serve as a resource on issues related to clinical research.

Sincerely,

Terri Hinkley, RN, BScN, MBA, CCRC
Interim Executive Director

FDA-2013-D-1275-0001: Considerations for Pediatric Studies for Drugs and Biological Products			
Page Number	**Text Line**	**Reference** *(if applicable)*	**Comments**
2	60-62		We would request that the agency consider something more substantial than an additional six months of exclusivity. It would seem appropriate to offer an additional 1 to 1.5 year exclusivity.
5/6	138-9, 157-8, 166-8, 179-80 202-3		The note that growth and developmental changes will change ADME/PK is not new, perhaps some examples here would help underscore the importance of this information and give the reader some guidance about how to control these changes across the variety of pediatric ages/changes.
9	296-298	21CFR50.53	The choice of a single dose of an **OTC** cough and cold product as an example is most curious, and not representative of clinical need, especially since such products are contra-indicated in children under 4. A better, more representative example is requested.
13	441-442		"However, extrapolation of data to very young pediatric patients, particularly neonates, is rarely credible." We find this statement to be very accurate. Does the Agency have a suggestion on how to extrapolate data for these age groups?
13	438-446		Extrapolation of data from adults or different age groups is very tricky at best. It would be helpful if more information or examples would be given about where this may be appropriate.
14	461-463		"…PK studies in the pediatric population should determine how the dosage regimen should be adjusted to achieve the same level of systemic exposure in adults as defined above." This statement is obvious but no suggestions are provided as to how to achieve this goal. This should be expanded.
16	532-533		An explanation as to why a pediatric formulation should be characterized in relation to the adult formulation is requested. The pediatric population is not just small adults, the same as the elderly are not just older adults. Dose adjustments are not made on weight alone.