ACRP
ASSOCIATION OF CLINICAL
RESEARCH PROFESSIONALS

MISSION:
ACRP promotes excellence
in clinical research.

January 16, 2015

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

In reference to docket number: **FDA-2014-D-1461-0001**

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ACRP appreciates having the opportunity to review the FDA's Rare Pediatric Disease Priority Review Vouchers draft guidance. The Regulatory Affairs Committee of ACRP has reviewed the draft and offers its support. We are pleased to see the FDA's interpretation with regard to collection of data on adults with the rare pediatric disease, ensuring appropriate use of the vouchers and development of treatments to benefit pediatric populations, but not excluding adults from trial participation and potentially developing data for subsequent marketing approvals for the adult populations.

We applaud the FDA's efforts on this important issue and look forward to the final published guidance. Please let me know if ACRP may otherwise serve as a resource on issues related to clinical research.

Sincerely,

James D. Thomasell, CPA
Executive Director