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General Clinical Pharmacology Considerations for Pediatric Studies for Drugs and Biological Products Guidance for Industry DRAFT GUIDANCE This guidance document is being distributed for comment purposes only. Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register. For questions regarding this draft document, contact (CDER) Gilbert J. Burckart at 301-796-2065. U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER). December 2014 Clinical Pharmacology



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