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New FDA guidance documents inform pediatric labeling, study conduct

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Seven pediatric-oriented guidance documents that cover a broad range of topics have been published by the Food and Drug Administration (FDA) in the last year.

Guidance documents inform sponsors, institutional review boards, clinical investigators and the public of the FDA's thinking about a specific topic. These documents address numerous regulatory issues, including clinical trial design, human subject protections, safety evaluation and product quality standards.

Guidance documents should be viewed as recommendations, except where specific regulatory or statutory requirements are cited.

Following is a summary of the documents.

Attention Deficit Hyperactivity Disorder: Developing Stimulant Drugs for Treatment(https://www.fda.gov/media/124334/download) provides general recommendations to sponsors developing stimulant drugs to treat attention-deficit/hyperactivity disorder in pediatric and adult patients.

Pediatric Information Incorporated Into Human Prescription Drug and Biological Product Labeling (https://www.fda.gov/media/84949/download) is intended to assist companies in determining the appropriate placement and content of pediatric information within prescription drug and biological product labeling so information is easily and consistently accessible to clinicians and consumers.

Pediatric HIV Infection: Drug Product Development for Treatment (https://www.fda.gov/media/113319/download) provides general recommendations on the development of antiretroviral drug products for the treatment of HIV infection in pediatric patients from birth to 18 years. The guidance also addresses the appropriate timing of pediatric studies and pediatric formulation development.

Considerations for the Inclusion of Adolescent Patients in Adult Oncology Clinical Trials (https://www.fda.gov/media/113499/download) and *Cancer Clinical Trial Eligibility Criteria: Minimum Age for Pediatric Patients* (https://www.fda.gov/media/121318/download) provide recommendations on including adolescents in adult oncology trials when appropriate and considerations for including pediatric patients as young as 2 years in adult cancer clinical trials. Ethical considerations as well as early and late phase trial considerations are discussed.

Atopic Dermatitis: Timing of Pediatric Studies During Development of Systemic Drugs (https://www.fda.gov/media/117570/download) addresses the FDA's thinking about the relevant age groups to study and how early in drug development applicants should include pediatric patients in studies of systemic drugs for atopic dermatitis.

E11(R1) Addendum: Clinical Investigation of Medicinal Products in the Pediatric Population (https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm530012.pdf) supplements the original International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use E11 Guidance: *Clinical Investigation of Medicinal Products in the Pediatric Population*. It is intended to complement and provide clarification and regulatory perspective on topics in pediatric drug development.

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