Development of Preventive HIV Vaccines for Use in Pediatric Populations

FDA is issuing guidance providing recommendations to sponsors regarding data to support the: 1) Initiation of pediatric studies of a preventive HIV vaccine under a United States (U.S.) investigational new drug application (IND); and 2) licensure of a preventive HIV vaccine for pediatric use. The guidance also provides recommendations to investigators and institutional review boards (IRBs) who are involved with these pediatric studies.

This guidance specifically addresses issues regarding development of a preventive HIV vaccine for use in healthy U.S. pediatric populations.

The guidance is available on the FDA web site at http://www.fda.gov/cber/gdlns/pedhiv.htm. Copies of this guidance are also available from the Office of Communication, Training and Manufacturers Assistance (HFM-40), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, or by calling 1-800-835-4709 or 301-827-1800.

Written comments on this guidance may be submitted at any time to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. You should identify all comments with the title of this guidance, *Development of Preventive HIV Vaccines for Use in Pediatric Populations*.

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