



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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June 5, 2000

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: International Conference on Harmonisation; E11: Clinical Investigation of Medicinal Products in the Pediatric Population, Docket Number 00D-1223, 65 Federal Register 19777, April 12, 2000

Dear Sir/Madam:

We are forwarding these written comments on the draft guidance for ICH E11: Clinical Investigation of Medicinal Products in the Pediatric Population to be placed on the docket. These comments were sent to us by our European colleagues.

Sincerely,

A handwritten signature in cursive script that reads "Rosemary Roberts".

Rosemary Roberts, M.D.
Medical Officer
Center for Drug Evaluation and Research ODE IV

cc: File

00D-1223

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