genzyme

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Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Subject: **Docket No. 00N-0074**
Interim Rule: Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products

19 July, 2001

Dear Sir/Madam:

Thank you for the opportunity to comment on the "Interim Rule: Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products" published in the Federal Register on April 24, 2001. Below is Genzyme's comment for your consideration.

21 CFR Part 50 §50.55 (g) states that "(w)hen the IRB determines that assent is required, it must also determine whether and how assent must be documented." We request that FDA define a minimum standard for documentation of assent similar to that of informed consent. If an IRB determines that pediatric assent is warranted for a trial, but decides that documentation of the assent is unnecessary, how will Sponsors, much less FDA, determine that assent has actually occurred? A minimal standard will assist us in our monitoring and other quality assurance efforts, and will facilitate increased consistency across clinical sites.

Genzyme appreciates the opportunity to comment on the "Interim Rule: Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products." Please contact me at (617) 374-7275 or Juliette Shih at (617) 761-8929 should you have any questions regarding this letter.

Cordially,

Robert E. Yocher
Vice President
Regulatory Affairs

C7

00N-0074

From: JULIETTE ELAN SHIH (617)761-8929
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