CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

19-676/S-016

Clinical Pharmacology and Biopharmaceutics Review

CLINICAL PHARMACOLOGY & BIOPHARMACEUTICS REVIEW

NDA 19-676 / SE2-016	**SUBMISSION DATE:**	**11-JUN-99**
BRAND NAME:	**Nutropin**	
GENERIC NAME:	**Somatropin (rDNA origin) for injection**	
REVIEWER:	**Robert M. Shore, Pharm.D.**	
SPONSOR:	**Genentech, Inc., South San Francisco, CA**	
TYPE OF SUBMISSION:	**Labeling for Pubertal dosing**	

SUBMISSION:

This submission contains an interim report for study M0380G, 'A phase 3, randomized multicenter study of Nutropin® [somatropin (rDNA origin) for injection] treatment at two dosage levels in pubertal children with growth hormone deficiency.' The sponsor is proposing a new dosage regimen of 0.7 mg/kg/wk divided into daily SC injections for pubertal children, which is about double the currently recommended maximum pediatric dose of 0.3 mg/kg/wk divided into daily SC injections. The proposed labeling changes are in the 'Efficacy Studies' and 'Dosage' sections only. The data collected in the study were clinical endpoints, including final height, growth rate, and IGF-1 levels; no pharmacokinetic data for growth hormone had been collected in the study. Therefore, a formal review of this submission by The Office of Clinical Pharmacology and Biopharmaceutics is not necessary.

Robert M. Shore, Pharm.D. /S/ 21-JUL-99
Division of Pharmaceutical Evaluation II
Office of Clinical Pharmacology and Biopharmaceutics

Hae-Young Ahn, Ph.D., Team Leader /S/ 9/21/99

CC: NDA 19-676/SE2-016 (orig., 1 copy), HFD-510(Malozowski, Perlstein, King, Sahlroot), HFD-870(Ahn, ChenME), CDR (MurphyB)

code: NR