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RESEARCH**

APPLICATION NUMBER:
20-280/S-031

PHARMACOLOGY REVIEW

Pharmacia & Upjohn
7000 Portage Road
Kalamazoo, MI 49001-0199

Submission: 30 Jun, 3 Jul 2000

Pharmacology Review of NDA Supplement
Supplement to NDA 20-280 S-031

DRUG: GENOTROPIN (somatotropin [rDNA origin] for injection)

CATEGORY: Growth hormone.

INDICATION: This submission provides a clinical data supplement to support an additional label claim for use of GENOTROPIN in the treatment of growth failure in children born small for gestational age (SGA).

PHARMACOLOGY COMMENTS: No preclinical data were submitted under supplement S-031 and none is deemed to be needed. Thus, no pharmacology review is necessary for this supplement. There were no labeling changes made to the previously approved preclinical sections of the label.

Generally, a dose of 0.48 mg/kg body weight/week (divided into 6 or 7 subcutaneous injections) is recommended. This dose is twice the approved dose (up to 0.24 mg/kg body weight/week) recommended for Growth Hormone Deficient (GHD) and Prader-Willi Syndrome (PWS) patients. According to the Medical Officer, Dr. Saul Malozowski, this dose should pose no problem. Doses higher and lower have been tried and the chosen dose of 0.48 mg/kg body weight/week appears to be more physiological.

RECOMMENDATION: AP

/S/
David H. Hertig
Pharmacologist

cc: NDA 20-280 Orig
HFD-510 Division File
HFD-510 JEIHage
HFD-510 DHertig
HFD-510 CKing
Recommendation: AP

/S/
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