CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

203441Orig1s000

STATISTICAL REVIEW(S)

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Sciences
Office of Biostatistics

STATISTICAL REVIEW AND EVALUATION

CLINICAL STUDIES

NDA/BLA #:	NDA 203-441
Supplement #:	
Drug Name:	GATTEX® (teduglutide) 0.05 mg/kg/day powder for subcutaneous injection
Indication(s):	The treatment of adult patients with Short Bowel Syndrome (SBS)
Applicant:	NPS Pharmaceuticals, Inc.
Date(s):	Stamp Date: November 30, 2011 PDUFA Goal date: December 30, 2012
Review Priority:	Standard with Major Amendment (13 month review cycle)
Biometrics Division:	Division of Biometrics III
Statistical Reviewer:	Behrang Vali M.S.
Concurring Reviewers:	Mike Welch Ph.D.
Medical Division:	Division of Gastroenterology and Inborn Errors Products
Clinical Team:	MO: John Troiani, M.D. MOTL and CDTL: Ruyi He, M.D.
Project Manager:	Matthew C. Scherer M.B.A.

Keywords: NDA review, Clinical Studies

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