

**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)

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