RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL

To inform prescribers and patients about the risks of possible acceleration of neoplastic growth and enhancement of colon polyp growth, gastrointestinal obstruction, and biliary and pancreatic disorders associated with GATTEX.

II. REMS ELEMENTS

A. Communication Plan

NPS will implement a communication plan to support implementation of the REMS. The communication plan materials will comprise:

1. A Dear Healthcare Professional letter to gastroenterologists, colorectal and gastrointestinal tract surgeons. In order to facilitate prescriber training and education, this initial letter will be distributed within 60 days of approval of GATTEX or at the time of product launch, whichever is sooner. The letter will be sent again at 12 and 24 months after product approval. NPS will also identify and send the DHCP letter to all other GATTEX prescribers within 60 days of the date of initial prescription, and again at 12 and 24 months after their initial prescription. This letter will be distributed via direct mail or electronic delivery and will be accessible via the GATTEX REMS website (www.GATTEXREMS.com). A copy of the Full Prescribing Information and a Medication Guide will be included in the Dear Healthcare Professional letter.

2. A Dear Professional Society letter to the leadership of the professional organizations listed below requesting that the letter be provided to the members of these professional organizations. The Dear Professional Society letter will be disseminated via direct mail or electronic delivery within 60 days of approval of GATTEX or at the time of product launch, whichever is sooner. The letter will be sent again at 12 and 24 months...
after product approval. A copy of the Full Prescribing Information and a Medication Guide will be included in the Dear Professional Society letter.

  i. American Society for Parenteral and Enteral Nutrition
  ii. American Gastroenterological Association
  iii. American College of Gastroenterology
  iv. Society for Surgery of the Alimentary Tract
  v. American Society of Colon and Rectal Surgery
  vi. American Board of Physician Nutrition Specialists (ABPNS)

The Dear Healthcare Professional letter and the Dear Professional Society letter are part of the REMS and are appended.

The Dear Healthcare Professional letter and the Dear Professional Society letter will be provided to MedWatch at the same time they are provided to the healthcare professionals and the professional society leadership.

B. **Elements To Assure Safe Use**

1. Healthcare providers who prescribe GATTEX will receive training.

   a. NPS Pharmaceuticals, Inc. will ensure that training is made available to healthcare providers who prescribe GATTEX. Training will consist of the Prescriber Education Slide Deck.

   b. NPS Pharmaceuticals, Inc. will ensure that retraining is made available to prescribers who have not written a prescription for Gattex within 12 months of completing REMS training.

   c. Each prescriber will be provided with the **Prescriber Education Slide Deck** which will include the following information:

      i. The risks of possible acceleration of neoplastic growth and enhancement of colon polyp growth associated with GATTEX.

      ii. The serious risk of gastrointestinal obstruction associated with GATTEX.

      iii. The serious risk of biliary and pancreatic disorders associated with GATTEX.

      iv. The recommended screening colonoscopy, follow-up colonoscopy, and monitoring laboratory tests

   d. NPS will ensure that the Prescriber Education Slide Deck will be available in hard copy and on the GATTEX REMS website.

NPS will ensure that prescribers can report that they have completed the Prescriber Education Slide Deck.
e. NPS will maintain a list of healthcare providers (HCPs) who have completed the Prescriber Education Slide Deck.

f. In order to facilitate patient and/or caregiver education about GATTEX, NPS will ensure that the What You Need to Know About Gattex Treatment: A Patient and Caregiver Counseling Guide will be available for prescribers to use to counsel patients considering GATTEX therapy about the possible acceleration of neoplastic growth and enhancement of colon polyp growth, gastrointestinal obstruction, and biliary and pancreatic disorders associated with GATTEX, as well as the recommended screening colonoscopy, follow-up colonoscopy and monitoring laboratory tests.

g. NPS will ensure that all educational materials listed in or appended to the GATTEX REMS will be available through the GATTEX REMS website, www.GATTEXREMS.com.

h. The following materials are part of the GATTEX REMS and are appended:
   - Prescriber Education Slide Deck
   - What You Need to Know About Gattex Treatment: A Patient and Caregiver Counseling Guide
   - GATTEX REMS Website Screenshots

These materials will also be available by calling NPS Pharmaceuticals, Inc. at 1-855-5GATTEX or 1-855-542-8839.

C. Timetable for Submission of Assessments

NPS will submit REMS assessments to FDA at 12 months from the date of initial approval of the REMS and annually thereafter. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. NPS will submit each assessment so that it is received by the FDA on or before the due date.