

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

203441Orig1s000

PROPRIETARY NAME REVIEW(S)

**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management**

Proprietary Name Review--Final

Date: November 19, 2012

Reviewer(s): Lissa C. Owens, PharmD
Division of Medication Error Prevention and Analysis

Team Leader: Lubna Merchant, M.S., PharmD
Division of Medication Error Prevention and Analysis

Drug Name(s) and Strength(s): Gattex (Teduglutide [rDNA origin]) for Injection
5 mg/vial

Application Type/Number: NDA 203441

Applicant/sponsor: NPS Pharmaceuticals

OSE RCM #: 2012-1866

*** This document contains proprietary and confidential information that should not be released to the public.***

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Gattex is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Gattex, acceptable in OSE Review RCM # 2011-4409 dated February 22, 2012.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review RCM # 2011-4409. We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. The searches of the databases yielded no new names, thought to look or sound similar to Gattex and represent a potential source of drug name confusion.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of November 6, 2012. The Office of Prescription Drug Promotion OPDP re-reviewed the proposed name on October 4, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Gattex, did not identify any vulnerabilities that would result in medication errors with any additional names. Thus, DMEPA has no objection to the proprietary name, Gattex, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Gastroenterology and Inborn Errors Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If you have further questions or need clarifications, please contact Franklin Stephenson, OSE project manager, at 301-796-3872.

4 REFERENCES

1. **OSE Reviews:** Siahpoushan, Manizheh., OSE RCM #2011-4409, Proprietary Name Review for Gattex (NDA 203441), February 22, 2012
2. **Drugs@FDA** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)
Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved [brand name](#), [generic drugs](#), [therapeutic biological products](#), [prescription](#) and [over-the-counter](#) human drugs and [discontinued drugs](#) and “[Chemical Type 6](#)” approvals.
3. **USAN Stems** (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page?>)
USAN Stems List contains all the recognized USAN stems.
4. **Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request**
Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

LISSA C OWENS
11/19/2012

LUBNA A MERCHANT
11/19/2012

**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management**

Proprietary Name Review—Final

Date: July 26, 2012

Reviewer(s): Teresa McMillan, PharmD
Division of Medication Error Prevention & Analysis

Team Leader Lubna Merchant, M.S., PharmD
Division of Medication Error Prevention & Analysis

Drug Name(s) and Strength(s): Gattex (Teduglutide [rDNA origin]) for Injection
5 mg/vial

Application Type/Number: NDA 203441

Applicant/sponsor: NPS Pharmaceuticals

OSE RCM #: 2012-474

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Gattex is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Gattex , acceptable in OSE Review #2011-4409 dated February 22, 2012.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review OSE Review #2011-4409. We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. The searches of the databases yielded no new names, thought to look or sound similar to Gattex and represent a potential source of drug name confusion.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of July 24, 2012. The Office of Prescription Drug Promotion OPDP re-reviewed the proposed name on July 5, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Gattex, did not identify any vulnerability that would result in medication errors with any additional name(s). Thus, DMEPA has no objection to the proprietary name, Gattex, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Gastroenterology and Inborn Errors Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If you have further questions or need clarifications, please contact Nitin Patel, OSE project manager, at 301-796-5412.

4 REFERENCES

1. OSE Reviews

OSE Review# 2011-4409; Proprietary Name Review of Gattex; Siahpoushan, M., February 22, 2012.

2. *Drugs@FDA* (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved [brand name](#), [generic drugs](#), [therapeutic biological products](#), [prescription](#) and [over-the-counter](#) human drugs and [discontinued drugs](#) and “[Chemical Type 6](#)” approvals.

3. *USAN Stems* (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page?>)

USAN Stems List contains all the recognized USAN stems.

4. *Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request*

Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

TERESA S MCMILLAN
07/26/2012

LUBNA A MERCHANT
07/27/2012

**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management**

Proprietary Name Review

Date: February 22, 2012

Reviewer: Manizheh Siahpoushan, PharmD, Safety Evaluator
Division of Medication Error Prevention and Analysis

Team Leader: Zachary Oleszczuk, PharmD
Division of Medication Error Prevention and Analysis

Deputy Director: Kellie Taylor, PharmD, MPH
Division of Medication Error Prevention and Analysis

Division Director: Carol Holquist, RPh
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Gattex (Teduglutide [rDNA origin]) for Injection
5 mg/vial

Application Type/Number: NDA 203441

Applicant: NPS Pharmaceuticals

OSE RCM #: 2011-4409

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Gattex, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 REGULATORY HISTORY

NPS Pharmaceuticals submitted a request for Proprietary Name Review of Gattex (Teduglutide [rDNA origin]) for Injection, for NDA 203441, on November 30, 2011. DMEPA reviewed the proposed proprietary name, Gattex in the IND phase (IND 058213) in OSE Review #2009-2001, dated March 19, 2010 and found the name acceptable.

1.2 PRODUCT INFORMATION

The following product information is provided in the November 30, 2011 proprietary name submission.

- Active Ingredient: Teduglutide
- Indication of Use: Treatment of adult patients with Short Bowel Syndrome (SBS) to improve intestinal absorption of fluid and nutrients.
- Route of administration: Subcutaneous
- Dosage form: Powder for Injection
- Strength: 5 mg per vial
- Dose and Frequency of Administration: 0.05 mg/kg administered once daily, subcutaneously to alternating sites between one fo the four quadrants of the abdomen, or into alternating thighs or alternating arms.
- How Supplied: Supplied in a sterile, single-use, 3 mL vial containing 5 mg of Gattex as a white lyophilized powder to be reconstituted with 0.5 mL Sterile Water for Injection supplied in disposable pre-filled syringes. Available in a 30-vial kit and a one-vial kit.

30-vial Kit:

- *Thirty single-use vials of drug
- *Thirty disposable prefilled syringes containing Sterile Water for Injection USP for reconstitution with 30 separate needles to attach to the syringes.
- *Thirty sterile disposable 1 mL syringes with needle for dosing
- *Sixty ^{(b) (4)} alcohol swabs

One-vial Kit:

- *One single-use vial of drug
- *One disposable prefilled syringe containing Sterile Water for Injection USP for reconstitution with a separate needle to attach to the syringes.

- *One sterile disposable 1 mL syringe with needle for dosing
- *One alcohol swab

- Storage: Prior to dispensing: Store at 2°C to 8°C (36°F to 46°F), Do not freeze. (b) (4) “Store at room temperature up to 25°C (77°F). Do not freeze.
- Container and Closure systems: The container closure system for teduglutide for injection is comprised of 3-mL, Type I glass tubing vials (b) (4) crimped aluminum seals fitted with (b) (4) (b) (4), flip-off buttons. The Sterile Water for Injection is supplied in prefilled, single-use, USP Type I glass syringes (b) (4). The Sterile Water for Injection, USP prefilled syringe is supplied (b) (4).

2 RESULTS

The following sections provide the information obtained and considered in the evaluation of the proposed proprietary name.

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Gastroenterology and Inborn Errors Products (DGIEP) concurred with the findings of OPDP’s promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects of the name were considered in the overall evaluation.

2.2.1 *United States Adopted Names (USAN) SEARCH*

On December 7, 2011 the United States Adopted Name (USAN) stem search, identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 *Components of the Proposed Proprietary Name*

The Applicant did not propose the intended meaning or the derivation of the proposed proprietary name.

This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 *FDA Name Simulation Studies*

Twenty-six practitioners participated in DMEPA’s prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Fifteen participants interpreted the name correctly as Gattex (11 participants from the inpatient and 4 participants from the outpatient prescription studies). Four

participants from the voice prescription studies omitted one of the two letter ‘t’s from the name (i.e. Gatex). Two participants from the outpatient prescription studies interpreted letter ‘G’ as letter string ‘Er’. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE, December 9, 2011 e-mail, the Division of Gastroenterology and Inborn Errors Products (DGIEP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Gattex. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Gattex, identified by the primary reviewer (PR) and the Expert Panel Discussion (EPD). Table 1 also includes the names identified by (b) (4) not identified by DMEPA and require further evaluation.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, and (b) (4))

Look Similar					
Name	Source	Name	Source	Name	Source
Adipex	(b) (4)	Gatimax	EPD	Satric	EPD
Algitex	(b) (4)	Gatol	EPD	SetonET	EPD
Antistax	(b) (4)	Gel-Kam	EPD	Sitrex PD	EPD
Antrex	(b) (4)	Gerimal	EPD	Solex	EPD
Atarax	(b) (4)	Gets-it	EPD	Gallium	EPD
Attenuvax	(b) (4)	Gildess Fe ***	PR	Galzin	EPD
Axert	(b) (4)	Gilenya	EPD	Gamunex	EPD
Catex	(b) (4)	Giltuss	EPD	Sotret	EPD
Catrix	EPD	Gleevec	(b) (4)	Subutex	EPD
Cetralax	EPD	Goflex	EPD	Sulla	EPD
Coldex A	EPD	Halotex	EPD	Sulten-10	EPD
Cotabax	EPD	Kantrex	(b) (4)	Sultrin	EPD

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Table 1 Continued: Collective List of Potentially Similar Names (DMEPA, EPD, and,

Look Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Crantex	EPD	Lasix	(b) (4)	Sutent	EPD
Dexamethasone	(b) (4)	(b) (4)	EPD	Testrex	(b) (4)
Entex	(b) (4)	Qutenza	EPD	Trudexa	(b) (4)
Ganite	EPD	Ranexa	(b) (4)	Zostex	(b) (4)
Ganitrising	(b) (4)	Salex	EPD	Zyprexa	(b) (4)
Gatifloxacin	(b) (4)	Salflex	EPD		
Sound Similar					
Capex	EPD	Chantix	EPD	Ganvex	EPD
Ketek	EPD				
Look and Sound Similar					
Gas-X	EPD	Gattex	EPD	Guiatex II SR and Guiatex II PE	EPD
Gatten	EPD	Gattexo	EPD	Guiatuss	EPD
Gatter	EPD	Guiadex DM and Guiadex PD	EPD		

Our analysis of the 65 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined 65 names will not pose a risk for confusion as described in Appendix D through E.

2.2.7 Communication of DMEPA’s Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Gastroenterology and Inborn Errors Products via e-mail on January 10, 2012. At that time we also requested additional information or concerns that could inform our review. As of February 22, 2012, the Division of Gastroenterology and Inborn Errors Products did not forward any additional concerns with the proposed proprietary name, Gattex.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

If you have further questions or need clarifications, please contact Nitin Patel, OSE project manager, at 301-796-5412.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Gattex, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your November 30, 2011 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review. Additionally, this proprietary name must be re-evaluated 90 days prior to the approval of the application. The conclusions upon re-review are subject to change.

4 REFERENCES

1. ***Micromedex Integrated Index*** (<http://csi.micromedex.com>)

Micromedex contains a variety of databases covering pharmacology, therapeutics, toxicology and diagnostics.

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion.

3. ***Drug Facts and Comparisons, online version, St. Louis, MO***
(<http://factsandcomparisons.com>)

Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products. This database also lists the orphan drugs.

4. ***FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]***

DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

5. ***Division of Medication Errors Prevention and Analysis proprietary name consultation requests***

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

6. ***Drugs@FDA*** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved brand name, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and "Chemical Type 6" approvals.

7. ***U.S. Patent and Trademark Office*** (<http://www.uspto.gov>)

USPTO provides information regarding patent and trademarks.

8. ***Clinical Pharmacology Online*** (www.clinicalpharmacology-ip.com)

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common,

combination, nutraceutical and nutritional products. It also provides a keyword search engine.

9. Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at (www.thomson-thomson.com)

The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

10. Natural Medicines Comprehensive Databases (www.naturaldatabase.com)

Natural Medicines contains up-to-date clinical data on the natural medicines, herbal medicines, and dietary supplements used in the western world.

11. Access Medicine (www.accessmedicine.com)

Access Medicine® from McGraw-Hill contains full-text information from approximately 60 titles; it includes tables and references. Among the titles are: Harrison's Principles of Internal Medicine, Basic & Clinical Pharmacology, and Goodman and Gilman's The Pharmacologic Basis of Therapeutics.

12. USAN Stems (<http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml>)

USAN Stems List contains all the recognized USAN stems.

13. Red Book Pharmacy's Fundamental Reference

Red Book contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.

14. Lexi-Comp (www.lexi.com)

Lexi-Comp is a web-based searchable version of the Drug Information Handbook.

15. Medical Abbreviations Book

Medical Abbreviations Book contains commonly used medical abbreviations and their definitions.

16. CVS/Pharmacy (www.CVS.com)

This database contains commonly used over the counter products not usually identified in other databases.

17. Walgreens (www.walgreens.com)

This database contains commonly used over the counter products not usually identified in other databases.

18. Rx List (www.rxlist.com)

RxList is an online medical resource dedicated to offering detailed and current pharmaceutical information on brand and generic drugs.

19. Dogpile (www.dogpile.com)

Dogpile is a [Metasearch](#) engine that searches multiple search engines including Google, Yahoo! and Bing, and returns the most relevant results to the search.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by OPDP. OPDP evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, we consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.). DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.¹

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name

¹ National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/about/MedErrors.html>. Last accessed 10/11/2007.

and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.²

The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples. DMEPA applies expertise gained from root-cause analysis of postmarketing medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g., "T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details).

² Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

Table 1. Criteria Used to Identify Drug Names that Look- or Sound-Similar to a Proposed Proprietary Name.

Type of Similarity	Considerations when Searching the Databases		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Lastly, DMEPA considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the

safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

DMEPA gathers CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the database and information searches to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend additional names, additional searches by the primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

3. FDA Prescription Simulation Studies

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically

scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

4. Comments from Other Review Disciplines

DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.³ When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product

³ Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

characteristics listed in Section 1.2 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, Expert Panel Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

“Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting? And Are there any components of the name that may function as a source of error beyond sound/look-alike”

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the question is no, the Safety Evaluator is not convinced that the names possess similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes to determine the likely *effect* of the drug name confusion, by asking:

“Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?”

The answer to this question is a central component of the Safety Evaluator’s overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

Moreover, DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Overall Risk Assessment:

- a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

The threshold set for objection to the proposed proprietary name may seem low to the Applicant/Sponsor. However, the safety concerns set forth in criteria a through e above are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names, confusing, or misleading names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the

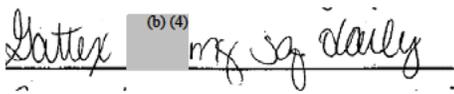
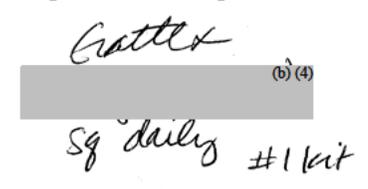
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Gattex	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'G'	'C', 'E', 'S', 'H', 'A', 'K', 'L', 'R', 'O', 'T', 'Z', 'Q', 'Cr'	'J'
Lower case 'g'	'q', 'j', 's'	'k', 'j'
Lower caes 'a'	'e', 'el', 'ci', 'cl', 'd', 'o', 'u'	Any vowel
Lower case 't'	'r', 'f', 'x', 'A'	'd'
Lower case 'e'	'a', 'i', 'l', 'o', 'u', 'p'	Any vowel
Lower case 'x'	'a', 'd', 'f', 'k', 'n', 'p', 'r', t', 'v', 'y', 'u'	'ks', 'kz', 's', 'z'

Appendix C: Prescription Simulation Samples and Results

Figure 1. Gattex Study (Conducted on 12/12/2011)

Handwritten Requisition Medication Order	Verbal Prescription
<p>Medication Order:</p> 	<p>Gattex (b)(4) sq daily # 1 kit</p>
<p>Outpatient Prescription:</p> 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

85 People Received Study

26 People Responded

Study Name: Gattex

Total	12	7	7	26
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
ERATTEX	0	0	2	2
GALTEX	1	0	0	1
GANTAX	0	1	0	1
GANTEX	0	2	0	2
GATEX	0	4	0	4
GATTEX	11	0	4	15
GATTLEX	0	0	1	1

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

Proprietary Name	Active Ingredient	Similarity to Gattex	Failure preventions
Adipex	Phentermine Hydrochloride	Look	Name lacks orthographic and/or phonetic similarity to Gattex.
Algitex	N/A (Could not identify this name as a drug product in any databases listed in Section 4, References.)	Look	Name lacks orthographic and/or phonetic similarity to Gattex.
Antistax	A nutritional supplement that contains natural Flaven (red vine leaf)	Look	Name lacks orthographic and/or phonetic similarity to Gattex.
Antrex	Calcium Folate	Look	Product is marketed in Turkey and Finland, not the United States.
Atarax	Hydroxyzine	Look	Name lacks orthographic and/or phonetic similarity to Gattex.
Attenuvax	Attenuvax	Look	Name lacks orthographic and/or phonetic similarity to Gattex.
Axert	Almotriptan Malate	Look	Name lacks orthographic and/or phonetic similarity to Gattex.
Catex	Ciprofloxacin	Look	Product is marketed in Spain, not the United States.
Cetraxal	Ciprofloxacin Hydrochloride Otic solution	Look	Name lacks orthographic and/or phonetic similarity to Gattex.
Chantix	Varenicline Tartrate	Sound	Name lacks orthographic and/or phonetic similarity to Gattex.
Gamunex	Immune Globulin	Look	Name lacks orthographic and/or phonetic similarity to Gattex.
Ganvex	N/A (Could not identify this name as a drug product in any databases listed in Section 4, References.)	Sound	Name lacks orthographic and/or phonetic similarity to Gattex.
Gantrisin	Sulfisoxazole Acetyl	Look	Name lacks orthographic and/or phonetic similarity to Gattex.

Proprietary Name	Active Ingredient	Similarity to Gattex	Failure preventions
Gatifloxacin	Established name for Tequin	Look	Name lacks orthographic and/or phonetic similarity to Gattex.
Gatimax	Gatifloxacin	Look	Product not marketed in the United States; available only in Indonesia.
Gatten	Scientific Name: Euonymus atropurpureus. Family: Celastraceae	Look and sound	Known as 'Wahoo'. Found in the Natural Medicine Database only. Only one Canadian Licensed product listed to contain Wahoo. No other information could be located in any other databases listed in the Reference Section (Section 4)
Gatter	Scientific Name: Euonymus atropurpureus. Family: Celastraceae	Look and sound	Known as 'Wahoo'. Found in the Natural Medicine Database only. Only one Canadian Licensed product listed to contain Wahoo. No other information could be located in any other databases listed in the Reference Section (Section 4)
Gattex	Teduglutide	Look and sound	Trademark by NPS Pharmaceuticals. Proprietary name under evaluation in this review.
Gattexo	Teduglutide	Look and sound	Same product as the proposed proprietary name, Gattex from the same Applicant, NPS Pharmaceuticals. Product is currently registered in Mexico and marked (b) (4) in the US.
Gerimal	Ergoloid Mesylate	Look	Name lacks orthographic and/or phonetic similarity to Gattex. Additionally, the Application was withdrawn FR effective 6/6/90.
Gleevec	Imatinib Mesylate	Look	Name lacks orthographic and/or phonetic similarity to Gattex.
Goflex	N/A	Look	International brand name for Nabumetone in several countries. Not marketed in the US under this name.
Halotex	Haloprogin topical (OTC)	Look	Name lacks orthographic and/or phonetic similarity to Gattex.
Kantrex	Kanamycin Sulfate	Look	Name lacks orthographic and/or phonetic similarity to Gattex. Additionally, Application was withdrawn FR effective 4/5/93.

Proprietary Name	Active Ingredient	Similarity to Gattex	Failure preventions
Lasix	Furosemide	Look	Name lacks orthographic and/or phonetic similarity to Gattex.
Ranexa	Ranolazine	Look	Name lacks orthographic and/or phonetic similarity to Gattex.
	(b) (4)	Look	NDA 20985, name found unacceptable in OSE #00-0016 due to vulnerability to confusion with the over the counter sunscreen product named (b) (4). The product was approved on 10/27/00 under the name, Carac.
Subutex	Buprenorphine Hydrochloride	Look	Name lacks orthographic and/or phonetic similarity to Gattex.
Testrex	Testosterone Propionate	Look	Product is marketed in Spain.
Trudexa	Adalimumab	Look	Product is marketed under the name, Humira in the US. It is available in Luxembourg and Netherlands
Zostex	Brivudine	Look	This product is available in Austria, Germany, and Turkey.
Zyprexa	Olanzapine	Look	Name lacks orthographic and/or phonetic similarity to Gattex.
Ketek	Telithromycin	Sound	Name lacks orthographic and/or phonetic similarity to Gattex.
Dexa-methasone	Established name for Decadron	Look	Name lacks orthographic and/or phonetic similarity to Gattex.
Gatol	N/A	Look	Name found in the CVS database, however no other information could be obtained about this product in any of the databases listed in Section 4, References.
Satric	Metronidazole	Look	Application withdrawn FR effective 1/6/1993.
Sulla	Sulfameter	Look	Application withdrawn FR effective 5/29/2002.
Sulten-10	Sulfacetamide Sodium	Look	Application withdrawn FR effective 2/2/2001.
Sultrin	Triple Sulfa	Look	Application withdrawn FR effective 6/16/2006.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

<p>Proposed name: Gattex (Teduglutide [rDNA origin]) For Injection</p>	<p>Strength: 5 mg per vial</p>	<p>Usual dose: 0.05 mg/kg subcutaneously once daily.</p>
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>
<p>1 Salex (Salicylic Acid) Cream, Lotion, and Shampoo 6%</p> <p>Usual Dose: Apply to the scalp after wetting the hair. Work into lather, leave on for several minutes, then rinse thoroughly. The shampoo may be used daily until the condition clears, then as needed to maintain remission. Apply a 6% topical preparation to the affected area at night; place under occlusion and wash off in the morning</p>	<p>Orthographic: Both names end with the letter string '-ex', share the letter 'a' in the second position, and an upstroke ('t' vs. 'l' in the third position. Additionally, letter 'G' may appear similar to letter 'S' when scripted.</p> <p>Overlap in the Frequency of Administration: Daily</p> <p>Strength: Single strength</p>	<p>Orthographic: Letter 't' in the fourth position of the name Gattex provides a different shape for this name and can help differentiate Gattex and Salex when scripted.</p> <p>Usual Dose: 0.05 mg/kg vs. one application</p>

<p>Proposed name: Gattex (Teduglutide [rDNA origin]) For Injection</p>	<p>Strength: 5 mg per vial</p>	<p>Usual dose: 0.05 mg/kg subcutaneously once daily.</p>
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>
<p>2</p> <p>Gilenya (Fingolimod) Capsule 0.5 mg</p> <p>Usual Dose: One capsule (or 0.5 mg) orally once daily.</p>	<p>Orthographic: Both names begin with letter 'G' and share an upstroke ('t' vs. 'l') in the third position. Additionally, letter 'a' and letter string '-ex' in Gattex may appear similar to letter 'i' and letter string '-en-' in Gilenya, respectively, when scripted.</p> <p>Frequency of Administration: Once daily</p> <p>Strength: Single strength</p>	<p>Orthographic: Letter 't' in the fourth position of the name, Gattex, and letter string '-ya' in the name, Gilenya provide a different shape and length for these names and can help differentiate Gattex and Gilenya when scripted.</p> <p>Usual Dose: 0.05 mg/kg vs. one capsule (or 0.5 mg)</p>

Proposed name: Gattex (Teduglutide [rDNA origin]) For Injection	Strength: 5 mg per vial	Usual dose: 0.05 mg/kg subcutaneously once daily.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
3	<div style="text-align: right;">(b) (4)</div>	

*** This document contains proprietary and confidential information that should not be released to the public.

Proposed name: Gattex (Teduglutide [rDNA origin]) For Injection	Strength: 5 mg per vial	Usual dose: 0.05 mg/kg subcutaneously once daily.	
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode	
4	<p>Qutenza (Capsaicin) Topical Patch 8%</p> <p>Usual Dose: Apply to affected joints 3 to 4 times daily; for best results use 3 to 4 times daily continuously.</p>	<p>Orthographic: Both names share letter 't' in the third position. Additionally, letter strings 'Ga-' and '-ex' in Gattex may appear similar to letter strings 'Qu-' and '-en' in Qutenza, respectively, when scripted.</p> <p>Strength: Single strength</p>	<p>Orthographic: Letter 't' in the fourth position of the name, Gattex and letter string '-za' in the name, Qutenza provide a different shape and length for these names which can help differentiate Gattex and Qutenza when scripted.</p> <p>Frequency of Administration: Once daily vs. 3 to 4 times daily.</p> <p>Usual Dose: 0.05 mg/kg vs. one application</p>
5	<p>Capex (Aluminum Acetate) Shampoo, 0.01%</p> <p>Usual Dose: Apply sparingly to the affected area two to four times per day, depending on the severity of the condition</p>	<p>Orthographic/Phonetic: Both names end with the letter string '-ex' and share letter 'a' in the second position. Additionally, letter 'G' in Gattex may appear similar to letter 'C' in Capex when scripted. Phonetically, both names consist of two syllables and end with the same sound 'ex'.</p> <p>Strength: Single strength</p>	<p>Orthographic/Phonetic: The two letters 't' in Gattex and letter 'p' in Capex provide a different shape for these two names which can help differentiate Gattex and Capex when scripted. Phonetically, the first syllables 'Ga' and 'Ca' sound different and can help differentiate the two names when spoken.</p> <p>Frequency of Administration: Once daily vs. 2 to 4 times daily</p> <p>Usual Dose: 0.05 mg/kg vs. one application</p>

<p>Proposed name: Gattex (Teduglutide [rDNA origin]) For Injection</p>	<p>Strength: 5 mg per vial</p>	<p>Usual dose: 0.05 mg/kg subcutaneously once daily.</p>
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>
<p>6</p> <p>Catrix Cream (Promotes accelerated wound and scar healing, a higher quality of granulation and vascularization of the tissue.</p> <p>Usual Dose: Apply daily as directed.</p>	<p>Orthographic: Both names consist of six letters, share the letter string '-at-' and end with letter 'x'. Additionally, letters 'G' and 'e' in Gattex may appear similar to letters 'C' and 'i' in Catrix, respectively, when scripted.</p> <p>Strength: Single strength</p> <p>Overlap in the Frequency of Administration: Daily</p>	<p>Orthographic: Letter 't' in the fourth position of the name, Gattex provides a different shape for this name which can help differentiate Gattex and Catrix when scripted.</p> <p>Usual Dose: 0.05 mg/kg vs. one application.</p> <p>Additionally, this name was found in the Redbook online database, however, the name shows as 'deactivated' in this database. Additionally, we do not have evidence from drug usage databases that shows this product is prescribed.</p>

Proposed name: Gattex (Teduglutide [rDNA origin]) For Injection	Strength: 5 mg per vial	Usual dose: 0.05 mg/kg subcutaneously once daily.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>7</p> <p>Coldex A (Chlorpheniramine Maleate, Phenylephrine HCL, and phenyltoloxamine Citrate) Tablet 4 mg/20 mg/40 mg</p> <p>Usual Dose: One tablet orally every 4 to 6 hours.</p>	<p>Orthographic: Both names consist of six letters, end with the letter string '-ex', and consist of two upstrokes in the third and fourth positions (2't's in Gattex vs. 'l' and 'd' in Coldex). Additionally, letter string 'Ga-' in Gattex may appear similar to letter string 'Co-' in Coldex A when scripted.</p> <p>Strength: Single strength</p>	<p>Frequency of Administration: Once daily vs. every 4 to 6 hours</p> <p>Usual Dose: 0.05 mg/kg vs. one tablet</p>
<p>8</p> <p>Cotab AX (Chlorpheniramine Maleate and Codeine Phosphate) Tablet, 4 mg/20 mg</p> <p>Usual Dose: One tablet orally twice daily.</p>	<p>Orthographic: If Cotab AX is scripted as one word (i.e. Cotabax), both names share letter 't' in the third position and end with letter 'x'. Additionally, letter strings 'Ga-' and '-te-' in Gattex may appear similar to letter strings 'Co-' and '-ba-' in Cotab AX, respectively, when scripted.</p> <p>Strength: Single strength</p>	<p>Orthographic: Letter 'a' in the fourth position of the name, Cotab AX provides a different shape and length for this name and can help differentiate Gattex and Cotab AX when scripted.</p> <p>Frequency of Administration: Once daily vs. twice daily.</p> <p>Usual Dose: 0.05 mg/kg vs. one tablet</p>

Proposed name: Gattex (Teduglutide [rDNA origin]) For Injection	Strength: 5 mg per vial	Usual dose: 0.05 mg/kg subcutaneously once daily.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>9 Crantex Guaifenesin and Phenylephrine Hydrochloride) Oral Solution 100 mg-7.5 mg/5 mL</p> <p>(Product is discontinued, however, generic equivalents are available)</p> <p>Usual Dose: 5 to 10 mL orally every 4 to 6 hours.</p>	<p>Orthographic: Both names end with the letter string '-tex'. Additionally, letter string 'Ga-' in Gattex may appear similar to the letter string 'Cra-' in Crantex when scripted</p> <p>Strength: Single strength</p> <p>Possible Numerical Overlap in the Usual Dose: A final calculated dose of 5 mg (for a 100 kg patient) in Gattex may be misinterpreted with 5 mL in Crantex.</p>	<p>Orthographic: Letter 't' in the third position of the name, Gattex provides a different shape for this name and can help differentiate Gattex and Crantex when scripted.</p> <p>Frequency of Administration: Once daily vs. every 4 to 6 hours.</p>

Proposed name: Gattex (Teduglutide [rDNA origin]) For Injection	Strength: 5 mg per vial	Usual dose: 0.05 mg/kg subcutaneously once daily.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>10 Gallium Injection (Gallium Citrate) 2 mCi/mL</p> <p>(A radio-pharmaceutical)</p> <p>Usual Dose: 2 to 5 mCi intravenously for diagnostic imaging.</p>	<p>Orthographic: Both names begin with the letter string 'Ga-' and consist of two upstrokes in the third and fourth positions ('t' vs. 'l'). Additionally, letter string '-ex' in Gattex may appear similar to the letter string '-iu-' in Gallium when scripted.</p> <p>Route of Administration: Parenteral</p> <p>Strength: Single strength</p> <p>Possible Numerical Overlap in the Usual Dose: A final calculated dose of 5 mg (for a 100 kg patient) in Gattex may be misinterpreted with 5 mCi in Gallium.</p>	<p>Orthographic: Extra letter 'm' in Gallium provides a longer length for this name which can help differentiate Gattex and Gallium when scripted.</p> <p>Frequency of Administration: Once daily vs. one time</p>

Proposed name: Gattex (Teduglutide [rDNA origin]) For Injection	Strength: 5 mg per vial	Usual dose: 0.05 mg/kg subcutaneously once daily.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>11 Galzin (Zinc Acetate) Capsule 25 mg, 50 mg</p> <p>Usual Dose: Adults: 25 to 50 mg orally of elemental zinc per day.</p> <p>Infants and Children: 0.5 to one mg elemental zinc/kg/day orally in divided doses given 1 to 3 times per day.</p>	<p>Orthographic: Both names consist of six letters, begin with the letter string 'Ga-', and share an upstroke in the third position ('t' vs. 'l'). Additionally, letter string '-ex' in Gattex may appear similar to letter string '-in' in Galzin when scripted.</p> <p>Overlap in the Frequency of Administration: Daily</p> <p>Partial Overlap in the Strength: 5 mg in Gattex may be misinterpreted as 50 mg in Galzin (if 5 is scripted with a trailing zero).</p> <p>Possible Overlap in the Usual Dose: 0.05 mg/kg in Gattex may be misinterpreted with 0.5 mg/kg in Galzin</p>	<p>Orthographic: Letter 't' in the fourth position of the name, Gattex and letter 'z' in the name, Galzin provide different shapes for these names and can help differentiate Gattex and Galzin when scripted.</p>

Proposed name: Gattex (Teduglutide [rDNA origin]) For Injection	Strength: 5 mg per vial	Usual dose: 0.05 mg/kg subcutaneously once daily.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>12 Ganite (Gallium Nitrate) Injection 25 mg/mL</p> <p>Usual Dose: 100 to 200 mg/m²/day intravenously over 24 hours for 5 consecutive days.</p>	<p>Orthographic/Phonetic: Both names consist of six letters and begin with the letter string ‘Ga-’.</p> <p>Phonetically, both names consist of two syllables and share the sound ‘Ga’ in the first syllable.</p> <p>Route of Administration: Parenteral</p> <p>Strength: Single strength</p>	<p>Orthographic/Phonetic: Letter ‘x’ at the end of the name, Gattex and letter ‘t’ in the third position of this name provide a different shape for this name and can help differentiate Gattex and Ganite when scripted. Phonetically, the second syllable of each name (‘ttex’ vs. ‘nite’) sounds different and can help differentiate the two names when spoken.</p> <p>Frequency of Administration: Once daily vs. over 24 hours for 5 consecutive days.</p> <p>Usual Dose: 0.05 mg/kg vs. 100 to 200 mg/m²/day</p>

Proposed name: Gattex (Teduglutide [rDNA origin]) For Injection	Strength: 5 mg per vial	Usual dose: 0.05 mg/kg subcutaneously once daily.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>13 Gas-X (Simethicone) Thin strip, 62.5 mg Extra Strength Tablets or Chewable Tablets, or Softgel, 125 mg Tablets or Chewable Tablets, 80 mg Infant Drops, 20 mg/0.3 mL</p> <p>Usual Dose: Adults and Adolescents: 40 to 125 mg PO four times per day after meals and at bedtime. Infants and Children less than 2 years of age: 20 mg 4 times per day after meals and at bedtime.</p>	<p>Orthographic/Phonetic: Both names begin with the letter string 'Ga-'. Phonetically, both names consist of 2 syllables and share the sound 'Ga' in the first and the sound 'ex' in the second syllable.</p> <p>Possible Numerical Overlap in the Usual Dose: A final calculated dose of 4 mg (for an 80 kg patient) may be misinterpreted as 40 mg (if 4 is scripted with a trailing zero) in Gas-X.</p>	<p>Orthographic: Letter 't' in the third and fourth positions of the name, Gattex provides a different shape for this name and can help differentiate Gattex and Gas-X when scripted. Phonetically, 'tt' in Gattex does not sound similar to 's' in Gas-X when spoken.</p> <p>Frequency of Administration: Once daily vs. 4 times per day or pm</p>

Proposed name: Gattex (Teduglutide [rDNA origin]) For Injection	Strength: 5 mg per vial	Usual dose: 0.05 mg/kg subcutaneously once daily.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>14</p> <p>Gel-Kam (Stannous Fluoride) Dental Gel, 0.4% Dental Rinse, 0.63%</p> <p>Usual Dose: Gel: Cover the bristles with gel. Brush thoroughly. Keep on teeth for 1 minute, then expectorate. Rinse: Pour the concentrated rinse to the 1/8 fluid ounce mark in the mixing vial, then add water to the 1 fl. oz. line and mix. Place one-half of the mixed solution into the mouth and vigorously swish for 1 minute, then expectorate</p>	<p>Orthographic: Both names consist of six letters, begin with letter ‘G’ and consist of two upstrokes in the 3rd and 4th positions (‘t’ in Gattex vs. ‘l’ and ‘k’ in Gel-Kam). Additionally, letters ‘a’ and ‘e’ in Gattex may appear similar to letters ‘e’ and ‘a’ in Gel-Kam, respectively, when scripted.</p> <p>Strength: Single Strength</p> <p>Overlap in the Frequency of Administration: Daily</p>	<p>Usual Dose: 0.05 mg/kg vs. Brush or rinse for 1 minute</p>
<p>15</p> <p>Gets-it Corn/Callus Remover (Salicylic Acid) Liquid, 12%</p> <p>Usual Dose: 12 to 40% salicylic acid plaster, pad, or disc may be applied to the affected area for 48 hours. When removed, the area should be soaked in water to facilitate removal of corn.</p>	<p>Orthographic: Both names consist of six letters, begin with letter ‘G’ and share the upstroke ‘t’ in the third position. Additionally, letter string ‘-ex’ and letter ‘a’ in Gattex may appear similar to letter string ‘-it’ and letter ‘e’ in Gets-it, respectively, when scripted.</p> <p>Strength: Single strength</p>	<p>Orthographic: Letter ‘t’ in the fourth position of the name, Gattex provides a different shape for this name which can help differentiate Gattex and Gets-it when scripted.</p> <p>Frequency of Administration: Once daily vs. for 48 hours</p> <p>Usual Dose: 0.05 mg/kg vs. one application</p>

Proposed name: Gattex (Teduglutide [rDNA origin]) For Injection	Strength: 5 mg per vial	Usual dose: 0.05 mg/kg subcutaneously once daily.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>16</p> <p>Gildess Fe (Ferrous Fumarate, Norethindrone Acetate, Ethinyl Estradiol) Tablet 1/20, 1.5/30</p> <p>Usual Dose: One tablet orally once daily.</p>	<p>Orthographic: Both names begin with letter 'G', consist of two upstrokes in the third and fourth positions ('t' in Gattex vs. 'l' and 'd' in Gildess Fe), and share letter 'e' in the fifth position. Additionally, letters 'a' and 'x' in Gattex may appear similar to letters 'i' and 's' in Gildess Fe, respectively, when scripted.</p> <p>Frequency of Administration: Once daily</p>	<p>Orthographic: If included, the modifier 'Fe' can help differentiate Gattex and Gildess Fe when scripted. Additionally, the second letter 's' in the name, Gildess provides a different shape for this name that can help differentiate Gattex and Gildess when scripted.</p> <p>Strength: 5 mg vs. 1/20 and 1.5/30</p> <p>Usual Dose: 0.05 mg/kg vs. one tablet</p>

Proposed name: Gattex (Teduglutide [rDNA origin]) For Injection	Strength: 5 mg per vial	Usual dose: 0.05 mg/kg subcutaneously once daily.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>17 Giltuss (Dextromethorphan Hydrobromide, Guaifenesin, Phenylephrine Hydrochloride) Oral Solution 15 mg-300 mg-10 mg/5 mL Giltuss HC Syrup 5 mg-300 mg-10 mg/5 mL Ped-C Solution 3 mg-50 mg-2.5 mg/mL Pediatric Solution 5 mg-50 mg-2.5 mg/mL TR Extended-Release Tablet 30 mg-600 mg-20 mg</p> <p>Usual Dose: Adults: 10 mL orally every 4 hours as needed (not to exceed 6 doses per day) Children 6 to 12 years: 5 mL orally every 4 hours as needed, Children 2 to 6 years: 2.5 mL orally every 4 hours as needed. Tablets: One tablet orally twice daily (not to exceed two doses in 24 hours)</p>	<p>Orthographic: Both names begin with letter 'G' and consist of two upstrokes in the third and fourth positions ('t' in Gattex vs. 'l' and 't' in Giltuss). Additionally, letter 'a' and letter string '-ex' in Gattex may appear similar to letter 'i' and letter string '-us-' in Giltuss, respectively, when scripted.</p> <p>Strength: Single strength</p> <p>Possible Numerical Overlap in the Usual Dose: A final calculated dose of 2.5 or 5 mg (for a 50 or 100 kg patient) in Gattex may be misinterpreted with 2.5 or 5 mL in Giltuss.</p>	<p>Orthographic: The second letter 's' in the name, Giltuss provides a different shape for this name that can help differentiate Gattex and Giltuss when scripted.</p> <p>Frequency of Administration: Once daily vs. every 4 hours as needed</p>

Proposed name: Gattex (Teduglutide [rDNA origin]) For Injection	Strength: 5 mg per vial	Usual dose: 0.05 mg/kg subcutaneously once daily.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>18</p> <p>Guiatex II SR (Guaifenesin, Pseudoephedrine Hydrochloride) Extended-release Tablets 600 mg-60 mg</p> <p>(Discontinued with no generic equivalents available)</p> <p>Guiatex PE (Guaifenesin, Phenylephrine Hydrochloride) Oral Syrup 200 mg-5 mg/5 mL</p> <p>(Discontinued, however, generic equivalents are available)</p> <p>Usual Dose: 5 to 10 mL orally every 4 to 6 hours as needed (Do not exceed 4 doses in 24 hours). Children: 2.5 to 5 mL orally every 4 to 6 hours as needed.</p>	<p>Orthographic/Phonetic: Both names begin with letter 'G' and end with the letter string '-tex'. Additionally, letter 'a' in Gattex may appear similar to letter 'u' in Guiatex when scripted. Phonetically, both names share the sound 'tex' in the last syllable and the letter 'G' in the first syllable when spoken.</p> <p>Strength: Single strength</p> <p>Possible Numerical Overlap in the Usual Dose: A final calculated dose of 2.5 or 5 mg (for a 50 or 100 kg patient) in Gattex may be misinterpreted with 2.5 or 5 mL in Guiatex PE.</p>	<p>Orthographic/Phonetic: Letter 't' in the third position of the name, Gattex and the letter string '-ia-' in the name Guiatex PE provide different shapes and length for these two names which can help differentiate Gattex and Guiatex PE when scripted. Phonetically, the sound 'Ga' is different than the sound 'Gu' in the first syllable. Additionally, the second syllable of Guiatex PE ('ia') can help differentiate the two names when spoken.</p> <p>Frequency of Administration: Once daily vs. every 4 to 6 hours as needed.</p>

Proposed name: Gattex (Teduglutide [rDNA origin]) For Injection	Strength: 5 mg per vial	Usual dose: 0.05 mg/kg subcutaneously once daily.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>19</p> <p>Guiadex DM (Dextromethorphan Hydrobromide and Potassium Guaiacolsulfonate) Solution 15 mg-300 mg/5 mL</p> <p>(Discontinued with no generic equivalents available)</p> <p>Guiadex PD (Guaiifenesin and Phenylephrine) Extended-release Tablet 600 mg-10 mg</p> <p>Usual Dose: One tablet orally every 12 hours (max 2 tablets/ 24 hours).</p>	<p>Orthographic/Phonetic: Both names begin with letter 'G' and end with the letter string '-ex'. Additionally, letters 'a' and 't' in Gattex may appear similar to letters 'u' and 'd' in Guiadex, respectively, when scripted. Phonetically, the sound 'tex' in the last syllable sounds similar to the sound 'dex'.</p> <p>Strength: Single strength</p>	<p>Orthographic/Phonetic: Letter 't' in the third position of the name, Gattex and the letter string '-ia-' in the name, Guiadex PD provide different shapes and length for these two names which can help differentiate Gattex and Guiatex PE when scripted. Phonetically, there are 2 syllables in Gattex vs. 3 syllables in Guiadex DM. Also, the sound 'Ga' is different than the sound 'Gu' in the first syllable. Additionally, the second syllable of Guiatex PE ('ia') can help differentiate the two names when spoken.</p> <p>Frequency of Administration: Once daily vs. every 4 to 6 hours as needed.</p> <p>Usual Dose: 0.05 mg/kg vs. one tablet</p>

Proposed name: Gattex (Teduglutide [rDNA origin]) For Injection	Strength: 5 mg per vial	Usual dose: 0.05 mg/kg subcutaneously once daily.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>20</p> <p>Guiatuss (Guaifenesin) Oral Syrup 100 mg/5 mL</p> <p>Usual Dose: 2.5 mL to 10 mL orally every 4 hours as needed (max 6 doses/24 hours).</p>	<p>Orthographic/Phonetic Both names begin with letter 'G'. Additionally, letter string '-tex' and letter 'a' in Gattex may appear similar to letters string '-tus-' and letter 'u' (in the second position) in Guiatuss, respectively, when scripted. Phonetically, the two names share the sound 'G' in the first syllable. Additionally, the last syllables ('tex' vs. 'tuss') may sound similar when spoken.</p> <p>Strength: Single strength</p> <p>Possible Numerical Overlap in the Usual Dose: A final calculated dose of 2.5 or 5 mg (for a 50 or 100 kg patient) in Gattex may be misinterpreted with 2.5 or 5 mL in Guiatuss.</p>	<p>Phonetic: Letter 't' in the third position of Gattex, and letter string '-ia-' and letter 's' in the eighth position of the name, Guiatuss provide different shapes and length for the two names and can help differentiate Gattex from Guiatuss when scripted. Phonetically, the sound 'ia' in the second syllable of the name Guiatuss provide a different sound for this name and can help differentiate Gattex and Guiatuss when spoken.</p> <p>Frequency of Administration: Once daily vs. every 4 hours as needed.</p>

Proposed name: Gattex (Teduglutide [rDNA origin]) For Injection	Strength: 5 mg per vial	Usual dose: 0.05 mg/kg subcutaneously once daily.	
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode	
21	<p>Salflex (Salsalate) Tablet 500 mg, 750 mg</p> <p>Usual Dose: 1 to 2 tablets orally 2 or 3 times per day.</p>	<p>Orthographic: Both names end with the letter string '-ex', share letter 'a' in the second position and consist of two upstrokes in the third and fourth positions ('t' in Gattex vs. 'l' and 'f' in Salflex). Additionally, letter 'G' may appear similar to letter 'S' when scripted.</p>	<p>Orthographic: Letter 'l' in the fifth position of the name, Salflex provides a different shape for this name which can help differentiate Gattex and Salflex when scripted.</p> <p>Strength: 5 mg vs. 500 mg and 750 mg</p> <p>Frequency of Administration: Once daily vs. 2 or 3 times daily.</p> <p>Usual Dose: 0.05 mg/kg vs. one to two (or 500 to 750 mg)</p>
22	<p>Sitrex PD (Guaifenesin and Phenylephrine Hydrochloride) Oral Solution 7.5 mg-75 mg/5 mL</p> <p>Usual Dose: 5 to 10 mL orally every 4 hours as needed (max 6 doses/24 hours).</p>	<p>Orthographic: Both names consist of six letters, end with the letter string '-ex', and share letter 't' in the third position. Additionally, letter string 'Ga-' in Gattex may appear similar to letter string 'Si-' in Sitrex PD when scripted.</p> <p>Strength: Single strength</p> <p>Possible Numerical Overlap in the Usual Dose: A final calculated dose of 5 mg (for a 50 kg patient) in Gattex may be misinterpreted with 5 mL in Sitrex PD.</p>	<p>Orthographic: Letter 't' in the fourth position of the name, Gattex provides a different shape for this name and can help differentiate Gattex and Sitrex PD when scripted.</p> <p>Frequency of Administration: Once daily vs</p>

Proposed name: Gattex (Teduglutide [rDNA origin]) For Injection	Strength: 5 mg per vial	Usual dose: 0.05 mg/kg subcutaneously once daily.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>23 Sotret (Isotretinoin) Capsule 10 mg, 20 mg, 30 mg, 40 mg</p> <p>Usual Dose: The recommended dosage range is 0.5 to 1 mg/kg/day given in two divided doses with food for 15 to 20 weeks.</p>	<p>Orthographic: Both names consist of six letters and share letter 't' in the third position. Additionally, letter strings 'Ga-' and '-ex' in Gattex may appear similar to letter strings 'So-' and 'et' in Sotret, respectively, when scripted.</p> <p>Possible Numerical Overlap in the Usual Dose: 0.05 mg/kg in Gattex may be misinterpreted as 0.5 mg/kg in Sotret.</p>	<p>Orthographic: Letter 't' in the fourth position of the name, Gattex provides a different shape for this name and can help differentiate Gattex and Sotret when scripted.</p> <p>Frequency of Administration: Once daily vs. two divided doses for 15 to 20 weeks.</p>
<p>24 SetonET (5 multi-item blister cards, 6 each Prenatal Multivitamin and Multimineral with Iron Tablet, and 6 each Omega-3 Fatty Acids 430 mg, Capsules)</p> <p>Usual Dose: One capsule/tablet orally once daily.</p>	<p>Orthographic: Both names share letter 't' in the third position. Additionally, letter strings 'Ga-' and '-ex' in Gattex may appear similar to letter strings 'Se-' and '-on' in SetonET, respectively, when scripted.</p> <p>Strength: Single strength</p> <p>Frequency of Administration: Once daily</p>	<p>Orthographic: Letter 't' in the fourth position of the name, Gattex and letter string 'ET' in SetonET provide different shapes and length for these names and can help differentiate Gattex and SetonET when scripted.</p> <p>Usual Dose: 0.05 mg/kg vs. one capsule/tablet</p>

<p>Proposed name: Gattex (Teduglutide [rDNA origin]) For Injection</p>	<p>Strength: 5 mg per vial</p>	<p>Usual dose: 0.05 mg/kg subcutaneously once daily.</p>
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>
<p>25 Sutent (Sunitinib Malate) Capsule 12.5 mg, 25 mg, 50 mg</p> <p>Usual Dose: 37.5 mg to 50 mg orally once daily on a schedule of four weeks on, 2 weeks off. Dose increase or reduction of 12.5 mg increments is recommended.</p>	<p>Orthographic: Both names consist of six letters and share letter 't' in the third position. Additionally, letter strings 'Ga-' and '-ex' in Gattex may appear similar to letter strings 'Su-' and '-en' in Sutent, respectively, when scripted.</p> <p>Frequency of Administration: Once daily</p> <p>Partial Overlap in the Strength: 5 mg in Gattex may be misinterpreted as 50 mg in Sutent (if 5 mg is scripted with a trailing zero).</p> <p>Possible Numerical Overlap in the Usual Dose: The final calculated dose in Gattex may be 5 mg (for a 100 kg patient) which can be misinterpreted as 50 mg in Sutent (if 5 mg is scripted with a trailing zero).</p>	<p>Orthographic: Letter 't' in the fourth position of the name, Gattex and letter 't' in the sixth position of the name, Sutent provide different shapes for these names and can help differentiate Gattex and Sutent when scripted.</p>

Proposed name: Gattex (Teduglutide [rDNA origin]) For Injection	Strength: 5 mg per vial	Usual dose: 0.05 mg/kg subcutaneously once daily.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>26 Entex (Guaifenesin and Phenylephrine Hydrochloride) Oral liquid 100 mg, 7.5 mg/5 mL</p> <p>(Discontinued product, however, generic equivalents are available)</p> <p>Usual Dose: 5 to 10 mL orally every 4 to 6 hours as needed (max 40 mL/day)</p>	<p>Orthographic: Both names end with letter string '-tex'. Additionally, letter 'G' in Gattex may appear similar to letter 'E' in Entex when scripted.</p> <p>Strength: Single strength</p> <p>Possible Numerical Overlap in the Usual Dose: A final calculated dose of 5 mg (for a 50 kg patient) in Gattex may be misinterpreted with 5 mL in Entex.</p>	<p>Orthographic: Letter 't' in the third position of the name, Gattex provides a different shape for this name and can help differentiate Gattex and Entex when scripted.</p> <p>Frequency of Administration: Once daily vs. every 4 to 6 hours.</p>

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/s/

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