

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

202450Orig1s000

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: July 12, 2012

Reviewer: Carlos M Mena-Grillasca, RPh
Division of Medication Error Prevention and Analysis

Team Leader: Lubna Merchant, MS, PharmD
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Tudorza Pressair (Aclidinium Bromide) Inhalation Powder
400 mg per actuation

Application Type/Number: NDA 202450

Applicant/sponsor: Forest Laboratories, Inc.

OSE RCM #: 2012-1510

*** 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, Tudorza Pressair 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, Tudorza Pressair, acceptable in OSE Review RCM# 2011-4488 dated February 21, 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# 2011-4488. 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 Tudorza Pressair 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 9, 2012. The Office of Prescription Drug Promotion OPDP re-reviewed the proposed name on July 12, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

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

DMEPA considers this a final review; however, if approval of the NDA 202450 is delayed beyond 90 days from the date of this review, the Division of Pulmonary, Allergy, and Rheumatology 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 Nichelle Rashid, OSE project manager, at 301-796-3904.

4 REFERENCES

1. **Agustin, Reasol; OSE Review 2011-4488, Tudorza Pressair Proprietary Name Review; February 21, 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/

CARLOS M MENA-GRILLASCA
07/12/2012

LUBNA A MERCHANT
07/12/2012

**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 21, 2012

Reviewer(s): Reasol S. Agustin, PharmD, Safety Evaluator
Division of Medication Error Prevention and Analysis

Team Leader: Carlos Mena-Grillasca, RPh
Division of Medication Error Prevention and Analysis

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

Drug Name(s) and Strength(s): Tudorza Pressair (Aclidinium Bromide) Inhalation Powder,
400 mcg per actuation

Application Type/Number: NDA 202450

Applicant/Sponsor: Forest Laboratories, Inc

OSE RCM #: 2011-4488

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Tudorza Pressair, 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

This review corresponds to a request from Forest Laboratories, Inc., dated December 1, 2012, for an assessment of the proposed proprietary name, Tudorza Pressair, regarding potential name confusion with other proprietary or established drug names in the usual practice setting. The name, Tudorza Pressair, is the third proprietary name for Acclidinium Bromide Inhalation powder. The first proposed proprietary name for this product (IND 068653), (b) (4), was found unacceptable by DMEPA in OSE Review #2010-2738, dated June 16, 2011. The name was found unacceptable due to (b) (4)

(b) (4) The second proposed proprietary name for this product (NDA 202450), (b) (4) was found unacceptable by DMEPA in OSE Review #2011-3220, dated November 8, 2011. The name was found unacceptable due to (b) (4). The modifier “Pressair” was determined acceptable by the Office of Prescription Drug Promotion (OPDP) from a promotional perspective. However, the clinical reviewer expressed concern stating that *the term “Pressair has the potential to be interpreted as suggesting that the device itself imparts some therapeutic effect, i.e., one “presses” the device and receives “air.”* DMEPA communicated this concern to OPDP and OPDP maintained their position. DMEPA and clinical reviewer, after a teleconference, decided to defer to OPDP’s decision regarding the promotional perspective.

1.2 PRODUCT INFORMATION

The following product information is provided in the December 1, 2012 proprietary name submission.

- Active Ingredient: Acclidinium Bromide
- Indication of Use: Maintenance treatment of chronic obstructive pulmonary disease (COPD)
- Route of Administration: Oral inhalation
- Dosage Form: Dry powder for inhalation
- Strength: 400 mcg
- Dose and Frequency of Administration: One inhalation (400 mcg) twice daily
- How Supplied: Sealed labeled aluminum pouch and multi-dose dry powder inhaler
- Storage: Store at 25°C (77°F); excursions permitted from 15 to 30°C (59-86°F) [See USP Controlled Room Temperature]”
- Container and Closure Systems: Almirall inhaler is the primary container closure system and is non-refillable, breath-actuated, multi-dose and device-metered dry powder inhaler.
- Intended pronunciation: TU door za

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 Pulmonary, Allergy, and Rheumatology Products (DPARP) 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 January 11, 2012 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 in the proposed name submission that Tudorza was not derived from any one particular concept.

This proprietary name is comprised of a root name "Tudorza" and a modifier "Pressair". The modifier "Pressair" describes the inhalation device. The product can be potentially prescribed by name "Tudorza" or modifier "Pressair" because omission of the part of the proprietary name when it is comprised of more than one word (e.g., modifier) is cited in the literature¹. Thus, the root name "Tudorza" or the modifier, "Pressair" should not be error-prone when placed in isolation or used combined.

Although the modifier "Pressair" for this product is not necessary since there is no other formulation of Tudorza marketed, it is common practice to have a modifier for the device. Additionally, there are no other products with the name "Pressair" and this modifier was found acceptable from the safety and promotional perspectives in OSE RCM #2011-3220. Thus, we do not object to the use of this modifier.

2.2.3 FDA Name Simulation Studies

Thirty practitioners participated in DMEPA's prescription studies conducted on December 23, 2011. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Five out of 9 inpatient participants interpreted the proposed name, Tudorza Pressair, correctly. The most common misinterpretation occurred with participants misinterpreting the letter 'o' for 'a' in 'TudOrza' and 'a' for 'o' in TudorZA'. Three out of 9 voice participants interpreted the proposed name, Tudorza Pressair, correctly. The most common misinterpretation occurred with participants misinterpreting the letter 'z' for 's' in 'TudorZA'. Two out of 12 outpatient participants interpreted the proposed name, Tudorza Pressair, correctly. The most common misinterpretation occurred with participants misinterpreting the letter 'T' for 'L' and 'F' in 'Tudorza' and 'o' for 'e' in TudOrza'. 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 20, 2011 e-mail, the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) did not have any objections to the proposed name at the initial phase of the proprietary name review.

¹ Cohen, M.R. (2007). Medication Errors. Washington D.C.: American Pharmacists Association Publisher

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, Tudorza Pressair. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Tudorza Pressair identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines. Table 1 also includes the names identified from the FDA Prescription Simulation or by (b) (4), not identified by DMEPA and requires further evaluation.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, FDA Name Simulation Studies, and External Name Study if applicable)

Look Similar (Tudorza)					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Taclonex	FDA	Tubersol	FDA	Tolectin	FDA
Caturza	FDA	Today	FDA	Tolinase	FDA
Tyvaso	FDA	Trinalin	FDA	Fodosine	FDA
Jolessa	FDA	Zaditor	FDA	(b) (4)	FDA
Lodosyn	FDA	Teslac	FDA	Trilipix	FDA
Tribenzor	FDA	Tornalate	FDA	Tasmar	FDA
Tradjenta	FDA	Terbinex	FDA	Tetcaine	FDA
Tikosyn	FDA	Tobrex	FDA	Zyclara	Primary
Zydone	Primary	Zytopic	Primary	Zytiga	Primary
Tarka	External	Toradol	External		
Look Similar (Pressair)					
Premarin	FDA	Presamine	FDA	Pramine	FDA
Provera	FDA	Primacor	FDA	PreSun	FDA
Prestara	FDA	Precedex	FDA	PreCare	FDA
Prevnar	FDA	Precose	FDA		
Sound Similar (Tudorza)					
Tekturna Tekturna HCT	External				
Look and Sound Similar (Tudorza)					
Tudorza	FDA	Tarceva	FDA		
Look and Sound Similar (Pressair)					
Proair HFA	FDA				

Our analysis of the 46 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined all 46 names will not pose a risk for confusion as described in Appendices D and E. The following names, Premarin, Prevnar, PreCare, and ProAir HFA have been evaluated in OSE RCM #2011-3220, dated November 8, 2011. Since none of the product characteristics have been changed since our previous review, these names will not be included in Appendix E.

2.2.6 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Pulmonary, Allergy, and Rheumatology Products via e-mail on February 6, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Pulmonary, Allergy, and Rheumatology Products on February 6, 2012, they did not have any objections with the proposed proprietary name, Tudorza Pressair.

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 Nichelle Rashid, OSE project manager, at 301-796-3904.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Tudorza Pressair, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your December 1, 2011 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review.

Additionally, the proposed proprietary name must be re-reviewed 90 days prior to approval of the NDA. 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* (www.thomsonhc.com/home/dispatch)

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* (www.medilexicon.com)

Medical Abbreviations dictionary 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.²

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 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.

² National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.³

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).

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		
	Potential Causes of Drug Name Similarity	Attributes Examined to Identify Similar Drug Names	Potential Effects
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-	Phonetic	Identical prefix	<ul style="list-style-type: none"> Names may sound similar

³ Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

alike	similarity	Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	when pronounced and lead to drug name confusion in verbal communication
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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 Office of Prescription Drug Promotion (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.⁴ 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 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.

⁴ Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

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, Tudorza	Scripted may appear as	Spoken may be interpreted as
'T'	F, Z, J, L, C	D
lowercase 'u'	n, y, v, w, any vowel	Any vowel
lowercase 'd'	cl, ci	b, t
lowercase 'o'	a, c, e, u	Oh, any vowel
lowercase 'r'	s, n, e, v	l
lowercase 'z'	c, e, g, n, m, q, r, s, v	s, x
lowercase 'a'	el, ci, cl, d, o, u, any vowel	Any vowel
Letters in Name, Pressair	Scripted may appear as	Spoken may be interpreted as
'P'	B, D, N, R	'B'
lowercase 'r'	s, n, e, v	l
lowercase 'e'	a, c, i, l, o, u, p	Any vowel
lowercase 's'	G, 5, g, n	x, z
lowercase 's'	G, 5, g, n	x, z
lowercase 'a'	el, ci, cl, d, o, u, any vowel	Any vowel
lowercase 'i'	e	Any vowel
lowercase 'r'	s, n, e, v	

Appendix C: Prescription Simulation Samples and Results

Figure 1. Tudorza Pressair Study (Conducted on December 23, 2011)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Tudorza Pressair One puff BID</i></p>	<p>Tudorza Pressair</p> <p>Inhale one puff by mouth twice a day</p> <p>#1</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Tudorza Pressair 1 puff bid #1</i></p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

85 People Received Study
30 People Responded

INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
FUDERZA PRESSAIR	0	0	1	1
FUDORZA PRESSAIR	0	0	1	1
LUDENZA PRESSAIR	0	0	1	1
LUDERZA PRESSAIR	0	0	1	1
LUDONZA PRESSAIR	0	0	1	1
LUDORZA PRESSAIR	0	0	4	4
LUDOZA PRESSAIR	0	0	1	1
TODOORSY PRESSAIR	0	1	0	1
TUDARZA PRESSAIR	1	0	0	1
TUDARZO PRESSAIR	1	0	0	1
TUDORSA PRESAIR	0	1	0	1
TUDORSA PRESSAIR	0	1	0	1
TUDORZA	0	1	0	1
TUDORZA PRESAIR	1	0	0	1
TUDORZA PRESS AIR	0	1	0	1
TUDORZA PRESSAIR	5	3	2	10
TUDORZO PRESSAIR	1	0	0	1
TWODORSA PRESS AIR	0	1	0	1
TOTAL	9	9	12	30

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 Tudorza Pressair	Failure preventions
Today	Nonoxyl 9	Look	Lacks sufficient orthographic similarity to result in name confusion
Tradjenta	Linagliptin	Look	Lacks sufficient orthographic similarity to result in name confusion
Tasmar	Tolcapone	Look	Lacks sufficient orthographic similarity to result in name confusion
Tyvaso	Treprostinil	Look	Lacks sufficient orthographic similarity to result in name confusion
Tarka	Trandolapril and verapamil	Look	Lacks sufficient orthographic similarity to result in name confusion
Tarceva	Erlotinib	Look and Sound	Lacks sufficient orthographic and phonetic similarity to result in name confusion
Fodosine***	Forodesine Hydrochloride	Look	(b) (4)
Caturza	Pharmaceutical preparation for the treatment or prevention of gastrointestinal disorders	Look	Caturza could not be retrieved in other databases except Saegis and USPTO. Product characteristics are not available.
(b) (4)	Olmesartan medoxomil; Amlodipine besylate; Hydrochlorothiazide	Look	(b) (4) Product currently marketed as Tribenzor.
Trinalin	Azatadine Maleate; pseudoephedrine sulfate	Look	Application withdrawn FR effective dated April 4, 2005. Lacks sufficient orthographic and phonetic similarity to result in name confusion.
Teslac	Testolactone	Look	Application withdrawn FR effective dated August 20, 2010 and July 8, 2011. Generics are still available but preliminary usage data shows that the proprietary name, Teslac is no longer used in prescription writing.
Tornalate	Bitolterol Mesylate	Look	Application withdrawn with FR effective dated December 7, 2007. Preliminary usage data shows that the proprietary name, Tornalate is no longer used in prescription writing.

Proprietary Name	Active Ingredient	Similarity to Tudorza Pressair	Failure preventions
Tolectin Tolectin-600 Tolectin DS	Tolmentin	Look	Application withdrawn with FR effective dated July 8, 2011 Lacks sufficient orthographic and phonetic similarity to result in name confusion.
Tolinase	Tolazamide	Look	Application withdrawn with Pending FR notice dated August 13, 2008. Generics are still available but preliminary usage data shows that the proprietary name, Tolinase is no longer used in prescription writing.

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><u>Proposed name:</u> Tudorza Pressair (Acclidinium bromide) Dosage form and strength: Dry powder inhaler (400 mcg per actuation) Usual dose: One inhalation twice daily</p>		<p>Other failures to consider with this product: <i>How supplied: Dry powder inhaler containing 400 mcg of acclidinium bromide per actuation</i> <i>Available as single strength and may be omitted during prescription writing.</i></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; (name confusion)</p>
<p>Jolessa (Ethinyl estradiol 30 mcg and Levonorgestrel 0.15 mg) Dosage form and strength: Single strength combination (30 mcg/0.15 mg) and may be omitted Usual dose: One tablet by mouth daily or Take as directed</p>	<p>Orthographic similarity: The letter ‘T’ and ‘J’ and ‘orza’ and ‘essa’ appear orthographically similar when scripted. Both names contain an upstroke ‘d’ and ‘l’ in the third position. Strength: Both are available as single strengths and may be omitted from a prescription. Directions for use: Both can be written with “Use as directed.”</p>	<p>Orthographic difference: The letter ‘z’ in Tudorza can be written with a downstroke which is absent in Jolessa giving the names different shapes. Also, the letter string ‘ol’ in Jolessa appears orthographically similar to the letter ‘d’ in Tudorza giving Tudorza an additional letter ‘u’ between the first and third letter which helps differentiate the names. In addition, Tudorza Pressair contains a modifier and if scripted, the modifier would help further differentiate the names.</p>

<p><u>Proposed name:</u> Tudorza Pressair (Acclidinium bromide) Dosage form and strength: Dry powder inhaler (400 mcg per actuation) Usual dose: One inhalation twice daily</p>		<p>Other failures to consider with this product: <i>How supplied: Dry powder inhaler containing 400 mcg of acclidinium bromide per actuation</i> <i>Available as single strength and may be omitted during prescription writing.</i></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; (name confusion)</p>
<p>Lodosyn (Carbidopa) Dosage form and strength: Oral tablets: 25 mg Usual dose: One tablet by mouth 3 to 4 times daily. Given in conjunction with carbidopa and levodopa</p>	<p>Orthographic similarity: The letter strings ‘udor’ and ‘odos’ appear orthographically similar when scripted. Also, both names contain a downstroke ‘z’ and ‘y’ in the sixth position. Strength: Both are available as single strengths and may be omitted from a prescription.</p>	<p>Orthographic difference: Tudorza Pressair contains a modifier. If scripted, the modifier would help differentiate the names. Dose: Tudorza Pressair is dosed as ‘one inhalation’ vs. Lodosyn is dosed as ‘one tablet’ Concomitant therapy: Lodosyn is given in conjunction with carbidopa and levodopa.</p>
<p>Tubersol (Tuberculin PPD) Dosage form and strength: Intradermal solution: 5 unit/0.1 mL Usual dose: 0.1 mL intradermally</p>	<p>Orthographic similarity: Both names begin with the letter string ‘Tu’ and an upstroke in the third position. Strength: Both are available as single strengths and may be omitted from a prescription.</p>	<p>Orthographic difference: Tubersol contains an upstroke ‘l’ at the end of the name which is absent in Tudorza. Also, the letter ‘z’ in Tudorza can be written with a downstroke which is absent in Tubersol giving the names different shapes. Frequency: Tudorza Pressair is used twice daily vs. Tubersol is only given once.</p>

<p><u>Proposed name:</u> Tudorza Pressair (Acclidinium bromide) Dosage form and strength: Dry powder inhaler (400 mcg per actuation) Usual dose: One inhalation twice daily</p>		<p>Other failures to consider with this product: <i>How supplied: Dry powder inhaler containing 400 mcg of acclidinium bromide per actuation</i> <i>Available as single strength and may be omitted during prescription writing.</i></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; (name confusion)</p>
<p>Taclonex (Calcipotriene and Betamethasone) Dosage form and strength: Topical ointment and suspension 0.05% and 0.064% Usual dose: Ointment: Apply an adequate layer of ointment to the affected area(s) once daily for up to 4 weeks. The ointment should be rubbed in gently and completely. Suspension: Apply to affected areas on the scalp once daily for 2 weeks or until cleared. Treatment may be continued for up to 8 weeks.</p>	<p>Orthographic similarity: The letter string ‘Tudo’ and ‘Taclo’ appear orthographically similar when scripted. Strength: Both are available as single strengths and may be omitted from a prescription. Directions for use: Both can be written with “Use as directed.”</p>	<p>Orthographic difference: Taclonex contains a cross stroke ‘x’ which is absent in Tudorza. Also, the letter ‘z’ in Tudorza can be scripted with a downstroke giving the names different shapes. Dosage form: Taclonex is available in two dosage forms (ointment and suspension) and will need clarification for a complete prescription. Route of administration: Tudorza Pressair is an oral inhalation vs. Taclonex is a topical ointment or suspension.</p>
<p>Tikosyn (Dofetilide) Dosage form and strength: Oral capsule: 125 mcg, 250 mcg, 500 mcg Usual dose: One capsule (500 mcg) by mouth twice daily</p>	<p>Orthographic similarity: The letter string ‘Tu’ and ‘Ti’ appear orthographically similar when scripted. Both names contain an upstroke ‘d’ and ‘k’ in the third position and a downstroke ‘z’ and ‘y’ in the sixth position.</p>	<p>Strength: Single vs. multiple. Tudorza Pressair is available in single strength and may be omitted from a prescription vs. an order for Tikosyn will require strength as it is available in multiple strengths. There is no numerical overlap between the two strengths during prescription writing.</p>

<p><u>Proposed name:</u> Tudorza Pressair (Acclidinium bromide) Dosage form and strength: Dry powder inhaler (400 mcg per actuation) Usual dose: One inhalation twice daily</p>		<p>Other failures to consider with this product: <i>How supplied: Dry powder inhaler containing 400 mcg of acclidinium bromide per actuation</i> <i>Available as single strength and may be omitted during prescription writing.</i></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; (name confusion)</p>
<p>Tribenzor (Olmesartan medoxomil; Amlodipine besylate; Hydrochlorothiazide) Dosage form and strength: Oral Tablets: 20 mg/5 mg/12.5 mg; 40 mg/5 mg/12.5 mg; 40 mg/5 mg/25 mg; 40 mg/10 mg/12.5 mg; 40 mg/10 mg/25 mg Usual dose: One tablet by mouth daily</p>	<p>Orthographic similarity: The letter string ‘Tu’ and ‘Tri’ and ‘orza’ and ‘enzo’ appear orthographically similar when scripted. Both names contain an upstroke ‘d’ and ‘b’ in similar positions.</p>	<p>Orthographic difference: Tribenzor (9 letters) appear longer than Tudorza (7 letters) when scripted because of the letter ‘r’ at the end of Tribenzor which is absent in Tudorza. Strength: Single vs. multiple. Tudorza Pressair is available in single strength and may be omitted from a prescription vs. an order for Tribenzor will require strength as it is available in multiple strengths.</p>
<p>Tekturna (Aliskiren Fumarate) Dosage form and strength: Oral tablets: 150 mg, 300 mg Tekturna HCT (Aliskiren and Hydrochlorothiazide) Dosage form and strength: Oral tablets: 150 mg/12.5 mg, 150 mg/25 mg, 300 mg/12.5 mg, 300 mg/25 mg Usual dosage: One tablet by mouth daily.</p>	<p>Orthographic similarity: The letter string ‘Tu’ and ‘Te’ appear orthographically similar when scripted. Both names contain an upstroke in the third position.</p>	<p>Orthographic difference: Tekturna contains an additional upstroke ‘t’ which is absent in Tudorza. Also, the letter ‘z’ in Tudorza can be written with a down stroke giving the names different shapes. Strength: Single vs. multiple. Tudorza Pressair is available in single strength and may be omitted from a prescription vs. an order for Tekturna will require strength as it is available in multiple strengths. There is no numerical overlap between the two strengths during prescription writing.</p>

<p><u>Proposed name:</u> Tudorza Pressair (Acclidinium bromide) Dosage form and strength: Dry powder inhaler (400 mcg per actuation) Usual dose: One inhalation twice daily</p>		<p>Other failures to consider with this product: <i>How supplied: Dry powder inhaler containing 400 mcg of acclidinium bromide per actuation</i> <i>Available as single strength and may be omitted during prescription writing.</i></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; (name confusion)</p>
<p>Trilipix (Choline fenofibrate) Dosage form and strength: Delayed-release capsule: 45 mg, 135 mg Usual dose: One capsule by mouth daily</p>	<p>Orthographic similarity: The letter string ‘Tu’ and ‘Tri’ appear orthographically similar when scripted. Both names contain an upstroke ‘d’ and ‘l’ and downstroke ‘z’ and ‘p’ in similar positions.</p>	<p>Orthographic difference: Trilipix contains a crosstroke ‘x’ at the end of the name which is absent in Tudorza. Strength: Single vs. multiple. Tudorza Pressair is available in single strength and may be omitted from a prescription vs. an order for Trilipix will require strength as it is available in multiple strengths. There is no numerical overlap between the two strengths during prescription writing.</p>
<p>Zydone (Hydrocodone 5 mg and Acetaminophen 400 mg) Dosage form and strength: Single strength combination (5 mg/400mg) and may be omitted Usual dose: One or two tablets by mouth every 4 to 6 hours, up to 8 tablets per day.</p>	<p>Orthographic similarity: The letter ‘T’ and ‘Z’ and the letter string ‘dor’ and ‘don’ appear orthographically similar when scripted. Strength: Both are available as single strengths and may be omitted from a prescription.</p>	<p>Orthographic difference: Tudorza (7 letters) appear longer than Zydone (6 letters) when scripted. The letter ‘z’ in Tudorza can be written with a downstroke which is absent in Zydone and the ‘y’ in Zydone provides a downstroke in the second position which is absent in Tudorza giving the names different shapes. Frequency: Tudorza Pressair is used twice daily vs. Zydone is taken every 4 to 6 hours as needed. Drug schedule: Zydone is a Schedule III controlled substance which is monitored closely and will require dose and quantity for a complete outpatient prescription.</p>

<p><u>Proposed name:</u> Tudorza Pressair (Acclidinium bromide) Dosage form and strength: Dry powder inhaler (400 mcg per actuation) Usual dose: One inhalation twice daily</p>		<p>Other failures to consider with this product: <i>How supplied: Dry powder inhaler containing 400 mcg of acclidinium bromide per actuation</i> <i>Available as single strength and may be omitted during prescription writing.</i></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; (name confusion)</p>
<p>Zytopic (Triamcinolone) Dosage form and strength: Topical cream (kit): Single strength (1%) and may be omitted Usual dose: Apply thin film to affected areas 2-3 times/day</p>	<p>Orthographic similarity: The letter string ‘Tu’ and ‘Zy’ appear orthographically similar when scripted. Both names contain an upstroke in the ‘d’ and ‘t’ in the third position. Strength: Both are available as single strengths and may be omitted from a prescription.</p>	<p>Orthographic difference: Tudorza contains a downstroke ‘z’ in the sixth position vs. Zytopic contains a downstroke ‘y’ and ‘p’ in the second and fifth position giving the names different shapes. Route of administration: Tudorza Pressair is an oral inhalation vs. Zydone is a topical cream.</p>
<p>Zaditor (Ketotifen Fumarate) Dosage form and strength: Ophthalmic solution: 0.025% Usual dose: Instill 1 drop in the affected eye(s) every 8 to 12 hours</p>	<p>Orthographic similarity: the letter string ‘Tud’ and ‘Zad’ appear orthographically similar when scripted. Strength: Both are available as single strengths and may be omitted from a prescription.</p>	<p>Orthographic difference: Zaditor contains an upstroke ‘t’ in the fifth position which is absent in Tudorza and Tudorza contains a downstroke ‘z’ in the sixth position giving the names different shapes. Route of administration: Tudorza Pressair is an oral inhalation vs. Zaditor is an ophthalmic solution.</p>
<p>Zytiga (Abiraterone Acetate) Dosage form and strength: Oral tablet 250 mg. Usual dose: Four tablets (1,000 mg) once daily in combination with prednisone 5 mg twice daily</p>	<p>Orthographic similarity: The letter string ‘Tu’ and ‘Zy’ appear orthographically similar when scripted. Both names contain an upstroke ‘d’ and ‘t’ in the third position Strength: Both are available as single strengths and may be omitted from a prescription.</p>	<p>Orthographic difference: Tudorza contains two letters ‘or’ in between the upstroke ‘d’ and downstroke ‘z’ vs. Zytiga contains one letter ‘i’ in between the crosstroke ‘t’ and downstroke ‘g’ giving the names different shapes. Also, the ‘y’ in Zytiga provides a downstroke in the second position which is absent in Tudorza.</p>

<p><u>Proposed name:</u> Tudorza Pressair (Acclidinium bromide) Dosage form and strength: Dry powder inhaler (400 mcg per actuation) Usual dose: One inhalation twice daily</p>		<p>Other failures to consider with this product: <i>How supplied: Dry powder inhaler containing 400 mcg of acclidinium bromide per actuation</i> <i>Available as single strength and may be omitted during prescription writing.</i></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; (name confusion)</p>
<p>Tetcaine (Tetracaine HCL) Dosage form and strength: Ophthalmic Solution 0.5%. Usual dose: Cataract extraction: 1 or 2 drops every 5 to 10 minutes for 3 to 5 doses Foreign body/suture removal: 1 to 2 drops every 5 to 10 minutes for 1 to 3 installations</p>	<p>Orthographic similarity: The letter string “Tu’ and ‘Te’ appear orthographically similar when scripted. Both names contain an upstroke ‘d’ and ‘t’ in the third position. Strength: Both are available as single strengths and may be omitted from a prescription.</p>	<p>Orthographic difference: The letter ‘z’ in Tudorza can be scripted as a downstroke which is absent in Tetcaine giving the names different shapes. Setting of use: Tetcaine is commonly used during eye surgery procedures. Route of administration: Tudorza Pressair is an oral inhalation vs. Tetcaine in an ophthalmic solution.</p>
<p>Terbinex (Terbinafine-Hydroxypropyl Chitosan) Dosage form and strength: Combination kit (Oral tablets 250 mg & Eco-formula nail enhancer). Single strength and may be omitted Usual dose: Onychomycosis of the fingernail: One tablet once daily for 6 weeks Onychomycosis of the toenail: One tablet once daily for 12 weeks</p>	<p>Orthographic similarity: The letter string ‘Tu’ and ‘Te’ appear orthographically similar when scripted. Strength: Both are available as single strengths and may be omitted from a prescription.</p>	<p>Orthographic difference: Tudorza contains an upstroke in the third position which is absent in Terbinex. Also, the letter ‘z’ in Tudorza can be scripted as a downstroke and would help differentiate the two names. In addition, Terbinex contains an upstroke in the fourth position and a cross stroke ‘x’ in the last position giving the names different shapes. Length of use: Terbinex is either a six-week or twelve-week regimen vs. Tudorza Pressair is used as a maintenance medication.</p>

<p><u>Proposed name:</u> Tudorza Pressair (Acclidinium bromide) Dosage form and strength: Dry powder inhaler (400 mcg per actuation) Usual dose: One inhalation twice daily</p>		<p>Other failures to consider with this product: <i>How supplied: Dry powder inhaler containing 400 mcg of acclidinium bromide per actuation</i> <i>Available as single strength and may be omitted during prescription writing.</i></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; (name confusion)</p>
<p>Toradol (Ketorolac) Dosage form and strength: Oral tablet: 10 mg; Injection solution: 15 mg/mL, 30 mg/mL; 60 mg/2 mL; 300 mg/10 mL Usual dose: Single dose: 60 mg intramuscularly or 30 mg intravenously; Multiple dose: 30 mg intramuscularly or intravenously every 6 hours; no more than 5 days</p>	<p>Orthographic similarity: The letter string ‘Tu’ and ‘To’ appear orthographically similar when scripted</p>	<p>Orthographic difference: Tudorza contains an upstroke ‘d’ in the third position and a downstroke in the sixth position vs. Toradol contains two upstrokes in the fifth and last position, giving the names different shapes.</p> <p>Strength: Single vs. multiple. Tudorza is available in single strength and may be omitted from a prescription vs. an order for Toradol will require strength as it is available in multiple strengths. There is no numerical overlap between the two strengths during prescription writing.</p> <p>Dosage form and route of administration: Toradol is available in multiple dosage forms and route of administration (oral tablets and injection solution given intravenously or intramuscularly) therefore specific instructions are required in order to be a complete prescription.</p> <p>Length of use: Toradol is limited to no more than 5 days of use vs. Tudorza Pressair is used as a maintenance medication.</p> <p>Dose: Tudorza Pressair is dosed ‘one inhalation’ vs. Toradol is dosed as ‘xx’ mL or ‘one tablet’</p>

<p><u>Proposed name:</u> Tudorza Pressair (Acclidinium bromide) Dosage form and strength: Dry powder inhaler (400 mcg per actuation) Usual dose: One inhalation twice daily</p>		<p>Other failures to consider with this product: <i>How supplied: Dry powder inhaler containing 400 mcg of acclidinium bromide per actuation</i> <i>Available as single strength and may be omitted during prescription writing.</i></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; (name confusion)</p>
<p>Tobrex (Tobramycin Sulfate) Dosage form and strength: Ophthalmic solution and ointment: 0.3%. Usual dose: Mild to moderate infections: Instill 1 or 2 drops into the affected eye(s) every 4 hours; Severe infections: Instill 2 drops into the eye(s) hourly until improvement Ointment: Mild to moderate infections: Apply a half-inch ribbon into the affected eye(s) 2 or 3 times a day; Severe infections: Instill a half-inch ribbon into the affected eye(s) every 3 to 4 hours until improvement</p>	<p>Orthographic similarity: The letter string ‘Tu’ and ‘To’ appear orthographically similar when scripted. Both names contain an upstroke ‘d’ and ‘b’ in the third position. Strength: Both are available as single strengths and may be omitted from a prescription.</p>	<p>Orthographic difference: Tudorza (7 letters) appear longer than Tobrex (6 letters) when scripted. Also, the letter ‘z’ in Tudorza can be written with a downstroke which is absent in Tobrex and Tobrex contains a crosstroke ‘x’ in the last position which is absent in Tudorza giving the names different shapes. Dosage form: Tobrex is available in two dosage forms (solution and ointment) which need to be specified during prescription writing. Route of administration: Tudorza Pressair is an oral inhalation vs. Tobrex is an ophthalmic solution and ointment.</p>

<p><u>Proposed name:</u> Tudorza Pressair (Acclidinium bromide) Dosage form and strength: Dry powder inhaler (400 mcg per actuation) Usual dose: One inhalation twice daily</p>		<p>Other failures to consider with this product: <i>How supplied: Dry powder inhaler containing 400 mcg of acclidinium bromide per actuation</i> <i>Available as single strength and may be omitted during prescription writing.</i></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; (name confusion)</p>
<p>Zyclara (Imiquimod) Dosage form and strength: Topical Cream: 3.75%. Usual dose: Actinic keratoses: Treatment consists of 2 cycles (14 days each) separated by 1 rest period (14 days) with no treatment. Apply up to 2 packets once daily at bedtime to affected area on either face or balding scalp (but not both concurrently); apply no more than 2 packets at each application and no more than 56 packets per 2 cycles of treatment. Leave on skin for 8 hours. Remove with mild soap and water.</p>	<p>Orthographic similarity: The letter string ‘Tudor’ and ‘Zyclar’ appear orthographically similar when scripted. Strength: Both are available as single strengths and may be omitted from a prescription.</p>	<p>Orthographic difference: The letter ‘z’ in Tudorza can be written with a downstroke which is absent in Zyclara and the ‘y’ in Zyclara provides a downstroke in the second position which is absent in Tudorza giving the names different shapes. Length of use: Zyclara is used in two cycles (14 days each) with a rest period (14 days) in between vs. Tudorza Pressair is used continuously. Route of administration: Tudorza Pressair is an oral inhalation vs. Zyclara is a topical cream.</p>
<p>Provera (Medroxyprogesterone Acetate) Dosage form and strength: Oral Tablets: 2.5 mg, 5 mg, 10 mg Usual dose: Abnormal uterine bleeding: 5 mg or 10 mg daily for 5 to 10 days, beginning day 16 or 21 of the menstrual cycle; Endometrial hyperplasia: 5 mg or 10 mg daily for 12 to 14 consecutive days per month, beginning day 1 or 16 of the cycle</p>	<p>Orthographic similarity to Pressair: The letter string ‘Pre’ and ‘Pro’ appear orthographically similar when scripted.</p>	<p>Strength: Single vs. multiple. Tudorza Pressair is available in single strength and may be omitted from a prescription vs. an order for Provera will require strength as it is available in multiple strengths. There is no numerical overlap between the two strengths during prescription writing. Dosing regimen: Tudorza Pressair is used continuously vs. Provera is used intermittently depending on diagnosis and menstrual cycle.</p>

<p><u>Proposed name:</u> Tudorza Pressair (Acclidinium bromide) Dosage form and strength: Dry powder inhaler (400 mcg per actuation) Usual dose: One inhalation twice daily</p>		<p>Other failures to consider with this product: <i>How supplied: Dry powder inhaler containing 400 mcg of acclidinium bromide per actuation</i> <i>Available as single strength and may be omitted during prescription writing.</i></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; (name confusion)</p>
<p>Prestara (Fluasterone) Dosage form and strength: Oral tablet 25 mg Usual dose: Adjunct support of andropause: Two tablets by mouth twice daily; Treatment of impotence: Two tablets by mouth once daily</p>	<p>Orthographic similarity to Pressair: Both names begin with the letter string ‘Pres’ Strength: Both are available as single strengths and may be omitted from a prescription.</p>	<p>Orthographic difference to Pressair: Prestara contains an upstroke ‘t’ which is absent in Pressair giving the names different shapes.</p>
<p>Precose (Acarbose) Dosage form and strength: Oral tablet: 25 mg, 50 mg, 100 mg Usual dose: Initial: 25 mg by mouth 3 times daily; Maximum dose: 60 kg or less: 50 mg 3 times daily; More than 60 kg: 100 mg 3 times daily</p>	<p>Orthographic similarity to Pressair: Both names begin with the letter string ‘Pre’</p>	<p>Orthographic difference to Pressair: Although the letter string ‘ssair’ and ‘cose’ have similar shapes, they appear orthographically different when scripted. Strength: Single vs. multiple. Tudorza Pressair is available in single strength and may be omitted from a prescription vs. an order for Precose will require strength as it is available in multiple strengths. There is no numerical overlap between the two strengths during prescription writing.</p>

<p><u>Proposed name:</u> Tudorza Pressair (Acclidinium bromide) Dosage form and strength: Dry powder inhaler (400 mcg per actuation) Usual dose: One inhalation twice daily</p>		<p>Other failures to consider with this product: <i>How supplied: Dry powder inhaler containing 400 mcg of acclidinium bromide per actuation</i> <i>Available as single strength and may be omitted during prescription writing.</i></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; (name confusion)</p>
<p>Presamine (Imipramine Hydrochloride) Dosage form and strength: Oral tablets 10 mg, 25 mg, 50 mg Usual dose: Depression: Hospitalized patients: 100 mg to 200 mg per day in divided doses; Outpatient: 50 mg to 150 mg per day</p>	<p>Orthographic similarity to Pressair: Both names begin with the letter string ‘Pres’</p>	<p>Orthographic difference to Pressair: Pressair (8 letters) appear shorter than Presamine (9 letters) when scripted. Although the letter string ‘sair’ and ‘amine’ have similar shapes, they appear orthographically different when scripted. Strength: Single vs. multiple. Tudorza Pressair is available in single strength and may be omitted from a prescription vs. an order for Presamine will require strength as it is available in multiple strengths. There is no numerical overlap between the two strengths during prescription writing.</p>
<p>Pramine (Imipramine Hydrochloride) Dosage form and strength: Oral tablets 10 mg, 25 mg, 50 mg Usual dose: Depression: Hospitalized patients: 100 to 200 mg per day in divided doses; Outpatient: 50 to 150 mg per day</p>	<p>Orthographic similarity to Pressair: The letter string ‘Pre’ and ‘Pra’ appear orthographically similar when scripted</p>	<p>Orthographic difference to Pressair: Although the letter string ‘sair’ and ‘mine’ have similar shapes, they appear orthographically different when scripted. Strength: Single vs. multiple. Tudorza Pressair is available in single strength and may be omitted from a prescription vs. an order for Pramine will require strength as it is available in multiple strengths. There is no numerical overlap between the two strengths during prescription writing.</p>

<p><u>Proposed name:</u> Tudorza Pressair (Acclidinium bromide) Dosage form and strength: Dry powder inhaler (400 mcg per actuation) Usual dose: One inhalation twice daily</p>		<p>Other failures to consider with this product: <i>How supplied: Dry powder inhaler containing 400 mcg of acclidinium bromide per actuation</i> <i>Available as single strength and may be omitted during prescription writing.</i></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; (name confusion)</p>
<p>PreSun Active; PreSun Ultra; PreSun Moisturizing Sunscreen with Keri; PreSun for Kids Spray Mist (Sunscreen) Dosage form and strength: Gel: Octyl methoxycinnamate, oxybenzone, octyl salicylate, SD alcohol 40 69%; Lotion: Avobenzone 3%, octyl methoxycinnamate 7.5%, octyl salicylate 5%, oxybenzone 3%; Gel: Avobenzone 3%, octyl methoxycinnamate 7.5%, octyl salicylate 5%, oxybenzone 6% Usual dose: Apply liberally to all exposed areas (2 mg/cm² is recommended) at least 30 minutes prior to sun exposure</p>	<p>Orthographic similarity to Pressair: Both names begin with the letter string 'Pres'</p>	<p>Orthographic difference to Pressair: Pressair (8 letters) appear longer than PreSun (6 letters) when scripted. Presun is available in multiple formulations and will require the use of the modifier for complete prescription. Dosage form: PreSun is available in two dosage forms (gel and lotion) and will need clarification for a complete prescription.</p>

<p><u>Proposed name:</u> Tudorza Pressair (Acclidinium bromide) Dosage form and strength: Dry powder inhaler (400 mcg per actuation) Usual dose: One inhalation twice daily</p>		<p>Other failures to consider with this product: <i>How supplied: Dry powder inhaler containing 400 mcg of acclidinium bromide per actuation</i> <i>Available as single strength and may be omitted during prescription writing.</i></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; (name confusion)</p>
<p>Precedex (Dexmedetomidine HCl) Dosage form and strength: Intravenous solution 100 mcg/mL Usual dose: ICU sedation: 0.2 to 0.7 mcg/kg/h Procedural sedation: Initiate at 0.6 mcg/kg/h and titrate to achieve desired clinical effect, with doses ranging from 0.2 to 1 mcg/kg/h. For awake fiberoptic intubation patients, 0.7 mcg/kg/h is recommended until the endotracheal tube is secured</p>	<p>Orthographic similarity to Pressair: Both names begin with the letter string ‘Pre’ Strength: Both are available as single strengths and may be omitted from a prescription.</p>	<p>Orthographic difference to Pressair: Precedex contain an upstroke ‘d’ which is absent in Pressair giving the names different shapes. Dose: Tudorza Pressair is dosed as ‘one inhalation’ vs. Precedex is dosed as ‘xx mcg or xx mL’ Route of administration: Tudorza Pressair is an oral inhalation vs. Precedex is s solution given intravenously.</p>
<p>Primacor (Milrinone Lactate; Milrinone in Dextrose) Dosage form and strength: Intravenous solution 1 mg/mL; Intravenous solution 200 mcg/mL in 5% Dextrose Usual dose: 0.375 mcg/kg/min to 0.75 mcg/kg/min as continuous IV infusion</p>	<p>Orthographic similarity to Pressair: The letter string ‘Pressa’ and ‘Prima’ appear orthographically similar when scripted</p>	<p>Strength: Single vs. multiple. Tudorza Pressair is available in single strength and may be omitted from a prescription vs. an order for Primacor will require strength as it is available in multiple strengths. There is no numerical overlap between the two strengths during prescription writing. Dose: Tudorza Pressair is dosed as ‘one inhalation’ vs. Primacor is weight-based and dosed as ‘xx mcg or xx mg or xx mL.’ There is no overlap in dose. Route of administration: Tudorza Pressair is an oral inhalation vs. Primacor is a solution given intravenously.</p>

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**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: November 8, 2011

Reviewer(s): Yelena Maslov, Pharm.D., Safety Evaluator
Division of Medication Error Prevention and Analysis

Team Leader Zachary Oleszczuk, Pharm.D., Team Leader
Division of Medication Error Prevention and Analysis

Division Director Carol Holquist, R.Ph., Director
Division of Medication Error Prevention and Analysis

Drug Name and Strength: (b) (4) (Aclidinium Bromide) Inhalation Powder,
400 mcg per Actuation

Application Type/Number: NDA 202450

Applicant/Sponsor: Forest Laboratories, Inc.

OSE RCM #: 2011-3220

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