

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
202020Orig1s000

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: June 28, 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): Rayos (Prednisone) Delayed-release Tablets
1 mg, 2 mg, 5 mg

Application Type/Number: NDA 202020

Applicant/sponsor: Horizon Pharmaceuticals, Inc

OSE RCM #: 2012-1413

*** 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, Rayos 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, Rayos, acceptable in OSE Review #2011-4489 dated March 1, 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 #2011-4489. We note that none of the proposed product characteristics were altered. We also evaluated the previously identified names of concern in OSE Review #2011-4489 and considered any lessons learned from recent post-marketing experience, which may alter our previous conclusion regarding the acceptability of the proposed proprietary name. We reevaluated a previously identified name “Ragus” (multivitamin w/iron) as a possible source of confusion for the proposed name Rayos. This name was reevaluated in light of a recent error reported by ISMP, which describes confusion between Prenexa (multivitamin) and Ranexa (ranolazine) where a written prescription for Ranexa 500 mg was dispensed instead of Prenexa.¹ A root cause of the error could be attributed to Ranexa having a fixed usual starting dose instead of a variation of starting doses, which would have prompted the pharmacist to contact the prescriber for clarification of the dose.

Thus, we re-evaluated “Ragus” from our previous review as a potential source of drug name confusion. Additionally, a search of the databases yielded no new names, thought to look or sound similar to Rayos and represent a potential source of drug name confusion. Failure mode and effects analysis was applied to determine if the proposed proprietary name, Rayos could potentially be confused with Ragus and lead to medication errors. This analysis determined that the name similarity between Rayos and Ragus was unlikely to result in medication error for the reasons presented in Appendix A.

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 June 25, 2012. The Office of Prescription Drug Promotion (OPDP) re-reviewed the proposed name on June 28, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

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

¹ “Ranexa and Prenexa too similar.” ISMP Medication Safety Alert! Community/Ambulatory Care Edition. Volume 11, Issue 3. March 2012.

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 Pulmonary, Allergy, and Rheumatology Products (DPAAP) 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. OSE Reviews

OSE Review# 2011-4489; Proprietary Name Review of Rayos; Agustin, R., March 1, 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.

Appendix A: FMEA Table

<p>Proposed name: Rayos (Prednisone)</p> <p>Dosage form(s): Delayed-Release Tablets</p> <p>Strength(s): 1 mg, 2 mg, 5 mg</p> <p>Usual dose: 5 mg or 1 tablet once daily at bedtime, approximately 10:00 pm. Patients currently on immediate release prednisone, prednisolone or methylprednisolone should be switched at an equivalent dose. The dose should be tapered to the lowest effective dose after satisfactory response has been achieved (e.g., 2 mg or 1 mg).</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: In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Ragus (Multivitamin with Iron)</p> <p>Dosage form: Oral tablets</p> <p>Usual dose: Take one tablet by mouth daily</p>	<p>Orthographic similarity: Both names begin with ‘Ra’ and the letter string ‘yos’ and ‘gus’ appear orthographically similar when scripted.</p> <p>Route of administration: Both are tablets taken orally.</p> <p>Frequency: Both are taken once daily.</p>	<p>Strength and Usual Dose: A prescription for Rayos will require a strength because it is available in multiple strengths (1 mg, 2 mg, and 5 mg) vs. Ragus is single strength and thus the strength does not need to be verified. There is no numerical overlap between the strengths.</p> <p>Additionally, the usual dose of Rayos may vary and is not fixed. Thus if a strength is omitted from a prescription, it would require verification.</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: March 01, 2012

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

Team Leader Yelena Maslov, Acting Team Leader
Division of Medication Error Prevention and Analysis

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

Drug Name(s) and Strength(s): Rayos (Prednisone Delayed release) Tablets,
1 mg, 2 mg, 5 mg

Application Type/Number: NDA 202020

Applicant/Sponsor: Horizon Pharmaceuticals, Inc

OSE RCM #: 2011-4489

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Rayos, 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

The Applicant submitted a request for an assessment of the proposed proprietary name, Rayos regarding potential name confusion with other proprietary names in IND 072569, dated February 18, 2011. DMEPA found the proprietary name Rayos acceptable from a safety and promotional perspective but recommended the addition of a modifier to reflect the dosage form, delayed extended release. This was communicated to the Applicant via a teleconference call and the Applicant withdrew the application for review of the proposed proprietary name, Rayos, dated August 12, 2011. Subsequently, the Applicant submitted an original New Drug Application for NP01 (prednisone, modified release), dated September 29, 2011 and in this submission they requested a review for the proposed proprietary name review for (b) (4). DMEPA found the proprietary name Rayos acceptable but recommended to drop the modifier “(b) (4)” because it is not an acceptable modifier (b) (4). This was communicated to the Applicant via a teleconference call, dated December 1, 2011. The Applicant withdrew the application for review of the proposed proprietary name, (b) (4) dated December 2, 2011. Subsequently, the Applicant submitted a request to review the proposed proprietary name Rayos, dated December 8, 2011.

1.2 PRODUCT INFORMATION

The following product information is provided in the October 29, 2011 proprietary name submission.

- Active Ingredient: Prednisone
- Indication of Use: Treatment of active Rheumatoid Arthritis in adult patients
- Route of Administration: Oral
- Dosage Form: Delayed-release tablets
- Strength: 1 mg, 2 mg, 5 mg
- Dose and Frequency: Initial dose: 5 mg once daily at bedtime, approximately 10:00 pm. Patients currently on immediate release prednisone, prednisolone or methylprednisolone should be switched at an equivalent dose. The dose should be tapered to the lowest effective dose after satisfactory response has been achieved (e.g., 2 mg or 1 mg).
- How Supplied: 30-count bottles, 100-count bottles, and 7-tablet professional use (not for sale)
- Storage: Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F). [See USP Controlled Room Temperature]

- Container and Closure Systems: Bottles are round and constructed of high-density polyethylene (HDPE) and fitted with (b) (4) tamper-evident screw caps. The screw caps used for the 30-tablet 35-mL and for the 100-tablet 75-mL bottle configurations are child-resistant.
- Intended pronunciation: ray-Os

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 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 safety evaluation.

2.2.1 United States Adopted Names (USAN) SEARCH

On February 9, 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 stated that the proposed name, Rayos, has no particular derivation or intent.

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

Thirty-nine practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Sixteen of the 17 inpatient participants responded correctly and one misinterpretation occurred with a participant misinterpreting the letter 's' for 'r' in 'RayoS'. Three out of the 11 voice participants responded correctly and the most common misinterpretation occurred with participants misinterpreting the letter 'a' for 'e' in 'RAYos' and omitting the letter 'y' in 'RaYos.' Seven out of 11 outpatient participants responded correctly to Rayos and the most common misinterpretation occurred with participants misinterpreting the letter 's' for 'r' in 'RayoS' and 'y' for 'z' in 'RaYos.' See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 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, Rayos. Table 1 lists the names with

orthographic, phonetic, or spelling similarity to the proposed proprietary name, Rayos 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 Med-ERRS 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					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
PEG-20M	FDA	Raxar	FDA	Neupro	FDA
Naqua	FDA	Rayor	FDA	Konyne	FDA
Ray-Tec	FDA	Resporal	FDA	Baycol	FDA
Bayer	FDA	Baros	FDA	Repan	FDA
Respa-BR	FDA	Revex	FDA	Prozac	FDA
Kuvan	FDA	Requa	FDA	Reglan	FDA
Ryna-12	FDA	Rowasa	FDA	Rosac	FDA
Regonol	FDA	Rythmol	FDA	Reyataz	FDA
ReoPro	FDA	Proquin XR	FDA	Depen	FDA
Daypro	FDA	Riopan	FDA	Ragus	FDA
Preque	FDA	Relpax	FDA	Reluri	FDA
Prazosin	FDA	Requip	FDA	Rezira	FDA
Reznare	FDA	Rogaine	FDA	Rozex	FDA
Sound Similar					
V-ray	FDA				
Look and Sound Similar					
Re-Azo	FDA	Beyaz	FDA	Vanos	FDA

Our analysis of the 44 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined all 44 names will not pose a risk for confusion as described in Appendices D and E.

2.2.6 Communication of DMEPA’s Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Division of Pulmonary, Allergy, and Rheumatology (DPARP) Products via e-mail on February 9, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail

correspondence from the Division of Division of Pulmonary, Allergy, and Rheumatology Products on February 16, 2011, they are in acceptance of the proposed proprietary name, Rayos. However, DPARP added that “Rayos” is the Spanish term for lightning or ray of light (b) (4)

, the proposed proprietary name may be considered promotional. DMEPA communicated the Division’s comment to the Office of Prescription Drug Promotion (OPDP) via email on February 16, 2012. OPDP responded via e-mail on February 24, 2012 and their decision remains unchanged; OPDP has no objection to the proposed proprietary name, Rayos, from a promotional perspective. DMEPA forwarded that information to the Division on February 24, 2012. DPARP did not forward any additional comments to DMEPA.

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, Rayos, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your December 8, 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.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 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

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

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

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		
	<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	<ul style="list-style-type: none"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

		Overlapping product characteristics	
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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.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 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:

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

“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.

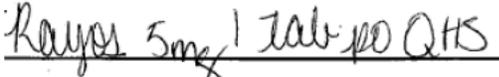
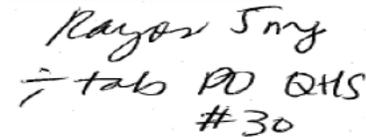
Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors 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, Rayos	Scripted may appear as	Spoken may be interpreted as
'R'	B, Pr, K, N	Wr, L
lowercase 'a'	el, ci, cl, d, o, u, any vowel	Any vowel
lowercase 'y'	f, p, u, v, x, Z	e, i, u
lowercase 'o'	a, c, e, u	Oh, any vowel
lowercase 's'	G, 5, g, n	x, z

Appendix C: Prescription Simulation Samples and Results

Figure 1. Rayos Study (Conducted on December 12, 2011)

Handwritten Requisition Medication Order	Verbal Prescription
<p>Medication Order:</p> 	<p>Rayos 5 mg Take one tablet by mouth at bedtime #30</p>
<p>Outpatient Prescription:</p> 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

85 People Received Study
39 People Responded

Study Name: Rayos

INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
RAOS	0	3	0	3
RAYOR	1	0	1	2
RAYOS	16	3	7	26
RAYOSE	0	2	0	2
RAZOS	0	0	3	3
REYOS	0	3	0	3
TOTAL	17	11	11	39

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 Rayos	Failure preventions
Neupro	Rotigotine	Look	The pair has sufficient orthographic differences.
PEG-20M	Polyethylene Glycol	Look	The pair has sufficient orthographic differences.
Regonol	Pyridostigmine	Look	The pair has sufficient orthographic differences.
Rythmol	Propafenone	Look	The pair has sufficient orthographic differences.
Ray-Tec	Factor IX Recombinant	Look	Ray-Tec could not be retrieved from any other pharmaceutical databases except Redbook.
Vray	Tipranavir	Sound	The pair has sufficient phonetic differences.
Naqua	Trichlormethiazide	Look	Application withdrawn FR effective dated April 4, 2005. Discontinued product with no available generics.
Raxar	Grepafloxacin HCl	Look	Application withdrawn FR effective dated June 14, 2007. Manufacturer voluntary recall due to severe cardiovascular events.
Rayor	Dihydroergotamine	Look	Rayor is an international brand name for Dihydroergotamine. Country of origin is Taiwan.
Konyne	Factor IX Recombinant	Look	Konyne could not be retrieved from any other pharmaceutical databases except Rx List and Dogpile.
Resporal	Pseudoephedrine sulfate and Dexbrompheniramine Maleate	Look	Application withdrawn FR effective dated August 27, 1992. Generics are available but
Baycol	Cerivastatin Sodium	Look	Application withdrawn Pending FR Notice dated October 2, 2004. Discontinued product with no available generics.

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: Rayos (Delayed-release Prednisone)</p>	<p>Dosage form and strength: Oral Tablets: 1 mg, 2 mg, 5 mg</p>	<p>Usual dose: One tablet by mouth at bedtime, approximately 10 pm.</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>Bayer PM (Aspirin and Diphenhydramine) Dosage form and strength: Oral tablets: 500 mg/38.3 mg Usual dose: Take 2 tablets by mouth at bedtime Bayer Aspirin Dosage form and strength: Oral tablets and delayed-release tablets: 325 mg Bayer Aspirin Enteric Coated Low Dose Dosage form and strength: Oral delayed-release tablets: 81 mg Bayer Childrens Aspirin Dosage form and strength: Oral chewable tablets: 81 mg Bayer Low Strength Dosage form and strength: Oral delayed-release tablets: 81 mg Usual dose: Acute myocardial infarction: 160 mg to 325 mg now. Analgesic and antipyretic: 324 mg to 1000 mg every 4 to 6 hours as needed. Stroke and angina: One tablet by mouth daily</p>	<p>Orthographic similarity: ‘R’ and ‘B’ and ‘o’ and ‘e’ appear orthographically similar when scripted. Also, both names contain the letter string ‘ay.’ Dosage form and route of administration: Both are tablets taken orally</p>	<p>Orthographic difference: Bayer is available in multiple formulations and will require the use of the modifier. Preliminary use data demonstrates that Bayer is not used when prescribing these products but is commonly prescribed as Bayer Aspirin, Bayer Child Aspirin, Bayer Enteric, and Bayer Aspirin Max. Strength: Rayos and Bayer are available in multiple strengths and will require a strength for a complete prescription. There is no numerical overlap between the strengths.</p>

<p><u>Proposed name:</u> Rayos (Delayed-release Prednisone)</p>	<p><u>Dosage form and strength:</u> Oral Tablets: 1 mg, 2 mg, 5 mg</p>	<p><u>Usual dose:</u> One tablet by mouth at bedtime, approximately 10 pm.</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>Respa-BR (Brompheniramine) Dosage form and strength: Oral tablets: 11 mg Usual dose: Take one tablet by mouth twice daily</p>	<p>Orthographic similarity: Both names begin with ‘R’ and the letter string ‘ayos’ and ‘espa’ appear orthographically similar when scripted. Dosage form and route of administration: Both are tablets taken orally</p>	<p>Strength: Multiple vs. single. An order for Rayos will require strength as it is available in multiple strengths vs. Respa-BR is available in single strength and may be omitted. There is no numerical overlap between the strengths. Frequency: Daily at bedtime vs. Twice daily</p>
<p>Revex (Nalmefene) Dosage form and strength: Injection solution 0.1 mg/mL; 1 mg/mL Usual dose: Intravenous: 0.5 mg per 70 kg; Intramuscular or subcutaneous: single dose of one mg should be effective within 5 to 15 minutes following administration</p>	<p>Orthographic similarity: Both names begin with ‘R’ and the letter string ‘ayo’ and ‘eve’ appear orthographically similar when scripted Strength: Both have multiple strengths and there is numerical overlap between the strengths during prescription writing (1 and 0.1 vs. 1).</p>	<p>Dosage form and route of administration: Oral tablets vs. Injection solution given intravenously, intramuscularly and subcutaneously Dose: One tablet vs. ‘xx’ mL or ‘xx’ mg Frequency: Daily at bedtime vs. once</p>
<p>Kuvan (Sapropterin) Dosage form and strength: Oral tablets: 100 mg Usual dose: 5 to 20 mg/kg once daily (400 mg to 1600 mg based on average body weight of 80 kg). Tablets should be dissolved in 120 to 240 mL of water or apple juice and taken within 15 minutes of dissolution.</p>	<p>Orthographic similarity: ‘R’ and ‘K’ and the letter string ‘uvan’ and ‘ayos’ appear orthographically similar when scripted. Dosage form and route of administration: Both are oral tablets. Frequency: Both are taken once daily. Rayos is recommended to be taken at bedtime.</p>	<p>Strength: Multiple vs. single. An order for Rayos will require strength as it is available in multiple strengths vs. Kuvan is available in single strength and may be omitted. There is no numerical overlap between the strengths.</p>

<p><u>Proposed name:</u> Rayos (Delayed-release Prednisone)</p>	<p><u>Dosage form and strength:</u> Oral Tablets: 1 mg, 2 mg, 5 mg</p>	<p><u>Usual dose:</u> One tablet by mouth at bedtime, approximately 10 pm.</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>Prozac (Fluoxetine) Dosage form and strength: Oral capsules: 10 mg, 20 mg, 40 mg Usual dose: Take one capsule by mouth every morning.</p>	<p>Orthographic similarity: ‘R’ and ‘P’ appear orthographically similar when scripted. Both names contain a downstroke ‘z’ and ‘y’ Strength: Both have multiple strengths and there is numerical overlap between the strengths during prescription writing (<i>1 mg vs. 10 mg, 2 mg vs. 20 mg</i>). Dosage form and route of administration: Both are oral dosage forms Frequency: Both are taken once daily. Rayos is recommended to be taken at bedtime.</p>	<p>Orthographic difference: Prozac contains an additional letter ‘r’ between ‘P’ and ‘oz’ which is absent in Rayos.</p>
<p>Requa (Activated charcoal) Dosage form and strength: Oral tablets: 250 mg Usual dose: 25 gm to 100 gm (100 to 400 tablets) as a single dose</p>	<p>Orthographic similarity: Both names begin with ‘R’ and contain a downstroke ‘y’ and ‘q’ in the third position. Dosage form and route of administration: Both are tablets taken orally.</p>	<p>Strength: Multiple vs. single. An order for Rayos will require strength as it is available in multiple strengths vs. Requa is available in single strength and may be omitted. There is no numerical overlap between the strengths. Frequency: Daily at bedtime vs. one-time</p>

<p><u>Proposed name:</u> Rayos (Delayed-release Prednisone)</p>	<p><u>Dosage form and strength:</u> Oral Tablets: 1 mg, 2 mg, 5 mg</p>	<p><u>Usual dose:</u> One tablet by mouth at bedtime, approximately 10 pm.</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>Repan (Acetaminophen 325 mg, Caffeine 40 mg, Butalbital 50 mg) Dosage form and strength: Oral tablets: 325 mg/40 mg/50 mg Usual dose: Take one to two tablets by mouth every 4 hours</p>	<p>Orthographic similarity: Both names begin with ‘R’ and contain a downstroke ‘y’ and ‘p’ in the third position. Dosage form and route of administration: Both are tablets taken orally.</p>	<p>Strength: Multiple vs. single. An order for Rayos will require strength as it is available in multiple strengths vs. Repan is available in single strength and may be omitted. Frequency: Daily at bedtime vs. every 4 hours</p>
<p>Beyaz (Ethinyl Estradiol and Drospirinone) Dosage form and strength: Oral tablets: 3 mg/0.02 mg Usual dose: Take one tablet by mouth daily</p>	<p>Orthographic similarity: ‘R’ and ‘B’ and the letter string ‘ayo’ and ‘eya’ appear orthographically similar when scripted. Phonetic similarity: Both names contain two syllables. The enunciation of the first and last syllable ‘Ray and Bey’ and ‘az and os’ sound similar when spoken.</p>	<p>Strength: Multiple vs. single. An order for Rayos will require strength as it is available in multiple strengths vs. Beyaz is available in single strength and may be omitted. There is no numerical overlap between the strengths.</p>

<p><u>Proposed name:</u> Rayos (Delayed-release Prednisone)</p>	<p><u>Dosage form and strength:</u> Oral Tablets: 1 mg, 2 mg, 5 mg</p>	<p><u>Usual dose:</u> One tablet by mouth at bedtime, approximately 10 pm.</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>Reglan (Metoclopramide) Tablets, Oral solution, and Injection solution</p> <p>Dosage form and strength: Tablets: 5 mg, 10 mg; Oral solution: 5 mg/5 mL; Injection solution: 5 mg/mL</p> <p>Usual dose: Oral: 10 mg to 15 mg up to 4 times daily; Intravenous and intramuscular: 10 mg over 1 to 2 minutes</p>	<p>Orthographic similarity: Both names begin with ‘R’ and the letter string ‘ay’ and ‘eg’ appear orthographically similar when scripted.</p> <p>Strength: Both have multiple strengths and there is overlap in strengths between the two products during prescription writing (<i>5 mg and 1 mg vs. 10 mg</i>).</p> <p>Dosage form and route of administration: Both are tablets taken orally</p>	<p>Orthographic difference: Reglan contains an upstroke which is absent in Rayos giving the names different shapes.</p> <p>Frequency of use: Daily at bedtime vs. Up to 4 times daily</p>
<p>Ryna-12 (Phenylephrine tannate 25 mg and pyrilamine tannate 60 mg)</p> <p>Dosage form and strength: Tablets: 25 mg-60 mg</p> <p>Usual dose: Take 1 to 2 tablets by mouth every 12 hours</p> <p>Ryna-12 S (Phenylephrine tannate 5 mg and pyrilamine tannate 30 mg) per 5 mL</p> <p>Dosage form and strength: Oral suspension: 5 mg/30 mg per 5 mL</p> <p>Usual dose: Take one to two teaspoonfuls by mouth every 12 hours</p>	<p>Orthographic similarity: Both names begin with ‘R’ and contain a modifier.</p> <p>Route of administration: Both are taken orally</p>	<p>Orthographic difference: Rayos contains a downstroke in the third position vs. Ryna contains a downstroke in the second position giving the names different shapes.</p> <p>Frequency of use: Daily at bedtime vs. Every 12 hours.</p> <p>Strength: Multiple vs. single. An order for Rayos will require strength as it is available in multiple strengths vs. Ryna-12 and Ryna CX is available in single strength which may be omitted.</p>

<p><u>Proposed name:</u> Rayos (Delayed-release Prednisone)</p>	<p><u>Dosage form and strength:</u> Oral Tablets: 1 mg, 2 mg, 5 mg</p>	<p><u>Usual dose:</u> One tablet by mouth at bedtime, approximately 10 pm.</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>Rowasa (Mesalamine) Dosage form and strength: Rectal suspension: 4 gm/60 mL Usual dose: 60 mL (4 gm) at bedtime</p>	<p>Orthographic similarity: Both names begin with ‘R’ Frequency of use: Both are taken once daily at bedtime</p>	<p>Orthographic difference: Rayos (5 letters) appear shorter than Rowasa (6 letters) when scripted. Rayos contains a downstroke which is absent in Rowasa giving the names different shapes. Strength: Multiple vs. single. An order for Rayos will require strength as it is available in multiple strengths vs. Rowasa is available in single strength and may be omitted. There is no numerical overlap between the strengths. Dose: One tablet vs. ‘xx’ mL</p>
<p>Rosac (Sulfacetamide) Dosage form and strength: Topical cream with sunscreen: 10%-5 % Topical wash 10%-1% Usual dose: Apply or Use 1 to 3 times daily</p>	<p>Orthographic similarity: Both names begin with ‘R’</p>	<p>Orthographic difference: Rayos contains a downstroke which is absent in Rosac giving the names different shapes. Strength: Both have multiple strengths and there is numerical overlap between the strengths during prescription writing. However the strength for Rayos is expressed in milligrams (mg) vs. Rosac is expressed in percent (%) Dosage form and route of administration: Oral tablets vs. Topical cream or Topical wash</p>

<p><u>Proposed name:</u> Rayos (Delayed-release Prednisone)</p>	<p><u>Dosage form and strength:</u> Oral Tablets: 1 mg, 2 mg, 5 mg</p>	<p><u>Usual dose:</u> One tablet by mouth at bedtime, approximately 10 pm.</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>Reyataz (Atazanavir sulfate) Dosage form and strength: Oral capsules: 100 mg, 150 mg, 200 mg, 300 mg Usual dose: 100 to 400 mg by mouth daily</p>	<p>Orthographic similarity: Both names begin with ‘R’ and contain a downstroke ‘y’ in the third position. Dosage form and route of administration: Both are tablets taken orally Frequency of use: Both are taken once daily.</p>	<p>Orthographic difference: Rayos (5 letters) appear shorter than Reyataz (7 letters) when scripted. Reyataz contains an upstroke and an additional downstroke in the last position which is absent in Rayos giving the names different shapes. Strength: Both have multiple strengths and will require a strength for a complete prescription. There is no numerical overlap between the strengths.</p>
<p>ReoPro (Abciximab) Dosage form and strength: Injection solution 2 mg/mL Usual dose: Intravenous: 0.25 mg/kg bolus administered 10-60 minutes prior to start of PCI followed by an infusion of 0.125 mcg/kg/minute (maximum: 10 mcg/minute) for 12 hours</p>	<p>Orthographic similarity: Both names begin with ‘R’</p>	<p>Orthographic difference: Rayos contains a downstroke in the third position vs. Reopro contains a downstroke in the fourth position giving the names different shapes. Strength: Multiple vs. single. An order for Rayos will require strength as it is available in multiple strengths vs. Reopro is available in single strength and may be omitted. Dosage form and route of administration: Oral tablets vs. Injection solution given intravenously Frequency: Daily at bedtime vs. one time for 12 hours</p>

<p><u>Proposed name:</u> Rayos (Delayed-release Prednisone)</p>	<p><u>Dosage form and strength:</u> Oral Tablets: 1 mg, 2 mg, 5 mg</p>	<p><u>Usual dose:</u> One tablet by mouth at bedtime, approximately 10 pm.</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>Proquin XR (Ciprofloxacin) Dosage form and strength: Extended release tablets: 500 mg Usual dose: Take one tablet by mouth daily for 3 days</p>	<p>Orthographic similarity: ‘R’ and ‘P’ appear orthographically similar when scripted. Dosage form and route of administration: Both are tablets taken orally Frequency: Both are taken once daily. Rayos is recommended to be taken at bedtime.</p>	<p>Orthographic difference: Rayos (5 letters) appear shorter than Proquin (7 letters) when scripted. Rayos contain a downstroke in the third position that is preceded by two letters and followed by 2 letters vs. Proquin contains a downstroke in the fourth position and is preceded by 3 letters and followed by 3 letters giving the names different shapes. Strength: Multiple vs. single. An order for Rayos will require strength as it is available in multiple strengths vs. Proquin XR is available in single strength and may be omitted. There is no numerical overlap between the strengths.</p>
<p>Re-Azo (Phenazopyridine) Dosage form and strength: Oral tablets: 95 mg, 97.2 mg, 97.5 mg, 100 mg, 200 mg Usual dose: Take one tablet by mouth 3 times daily</p>	<p>Orthographic similarity: Both names begin with ‘R’ and the letter string ‘ayo’ and ‘eve’ appear orthographically similar when scripted Dosage form and route of administration: Both are tablets taken orally.</p>	<p>Orthographic difference: Rayos contain a downstroke in the third position vs. Re-Azo contains a downstroke in the fourth position giving the names different shapes. Strength: Both have multiple strengths but there is no numerical overlap in strengths during prescription writing. There is no numerical overlap between the strengths. Frequency: Daily at bedtime vs. 3 times daily</p>

<p><u>Proposed name:</u> Rayos (Delayed-release Prednisone)</p>	<p><u>Dosage form and strength:</u> Oral Tablets: 1 mg, 2 mg, 5 mg</p>	<p><u>Usual dose:</u> One tablet by mouth at bedtime, approximately 10 pm.</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>Vanos (Fluocinonide) Dosage form and strength: Topical cream: 0.1% Usual dose: Apply a thin layer 1 to 2 times daily for psoriasis; once daily for atopic dermatitis</p>	<p>Orthographic similarity: Both names end in ‘os’</p>	<p>Orthographic difference: Rayos contains a downstroke ‘y’ which is absent in Vanos giving the names different shapes. Strength: Multiple vs. single. An order for Rayos will require strength as it is available in multiple strengths vs. Vanos is available in single strength. There is no numerical overlap between the strengths. Dose: One tablet vs. Thin layer Frequency of use: Daily at bedtime vs. Twice daily</p>
<p>Depen Titratabs (Penicillamine) Dosage form and strength: Oral tablets: 250 mg Usual dose: Take one tablet by mouth daily (maximum 750 mg/day)</p>	<p>Orthographic similarity: The letter string ‘ayos’ and ‘epen’ appear orthographically similar when scripted Dosage form and route of administration: Both are tablets taken orally. Frequency of use: Both are taken once daily.</p>	<p>Strength: Multiple vs. single. An order for Rayos will require strength as it is available in multiple strengths vs. Depen is available in single strength and may be omitted. There is no numerical overlap between the strengths.</p>
<p>Daypro (Oxaprozin) Dosage form and strength: Oral tablets: 600 mg Usual dose: Take one to three tablets by mouth daily</p>	<p>Dosage form and route of administration: Both are tablets taken orally Frequency of use: Both are taken once daily. Rayos is recommended to be taken at bedtime.</p>	<p>Orthographic difference: Rayos contains one downstroke ‘y’ in the third position and Daypro contains two downstrokes ‘y’ and ‘p’ in the third and fourth position giving the names different shapes. Strength: Multiple vs. single. An order for Rayos will require strength as it is available in multiple strengths vs. Daypro is available in single strength and may be omitted.</p>

<p><u>Proposed name:</u> Rayos (Delayed-release Prednisone)</p>	<p><u>Dosage form and strength:</u> Oral Tablets: 1 mg, 2 mg, 5 mg</p>	<p><u>Usual dose:</u> One tablet by mouth at bedtime, approximately 10 pm.</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>Riopan (Magaldrate) Dosage form and strength: Oral suspension: 540 mg/5 mL Usual dose: 5 mL to 10 mL (1 to 2 teaspoonfuls) by mouth 4 times a day, maximum daily dose is 80 mL</p>	<p>Orthographic similarity: Both names begin with ‘R’ and the letter string ‘ayos’ and ‘opan’ appear orthographically similar when scripted. Route of administration: Both are taken orally.</p>	<p>Strength: Multiple vs. single. An order for Rayos will require strength as it is available in multiple strengths vs. Riopan is available in single strength. There is no numerical overlap between the strengths. Frequency of use: Daily at bedtime vs. 4 times daily</p>
<p>Ragus (Multivitamin with Iron) Dosage form and strength: Oral tablets Usual dose: Take one tablet by mouth daily</p>	<p>Orthographic similarity: Both names begin with ‘Ra’ and the letter string ‘yos’ and ‘gos’ appear orthographically similar when scripted. Route of administration: Both are tablets taken orally. Frequency: Both are taken once daily</p>	<p>Strength: Multiple vs. single. An order for Rayos will require strength as it is available in multiple strengths vs. Ragus does not have strength. There is no numerical overlap between the strengths.</p>
<p>PreQue 10 (Prenatal Multivitamin and Multimineral with Iron) Dosage form and strength: Oral tablets Usual dose: Take one tablet by mouth daily</p>	<p>Orthographic similarity: The letter string ‘Ra’ and ‘Pre’ appear orthographically similar when scripted. Route of administration: Both are tablets taken orally. Frequency: Both are taken once daily</p>	<p>Orthographic difference: Rayos contains a downstroke ‘y’ in the third position and PreQue may contain a downstroke in the fourth position. In addition, PreQue contains an additional letter ‘r’ between the ‘P’ and the ‘q’ which is absent in Rayos giving the names different shapes. Strength: Multiple vs. No strength. An order for Rayos will require strength as it is available in multiple strengths vs. PreQue 10 does not have strength. There is no numerical overlap between the strengths.</p>

<p><u>Proposed name:</u> Rayos (Delayed-release Prednisone)</p>	<p><u>Dosage form and strength:</u> Oral Tablets: 1 mg, 2 mg, 5 mg</p>	<p><u>Usual dose:</u> One tablet by mouth at bedtime, approximately 10 pm.</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>Relpax (Eletriptan Hydrobromide) Dosage form and strength: Oral tablets: 20 mg, 40 mg Usual dose: Take one tablet by mouth at onset of headache (max daily dose is 80 mg)</p>	<p>Orthographic similarity: Both names begin with ‘R’ and the letter string ‘yo’ and ‘pa’ appear orthographically similar when scripted. Strength: Both have multiple strengths and there is numerical overlap between the strengths during prescription writing (<i>2 mg vs. 20 mg</i>). Dosage form and route of administration: Both are tablets taken orally.</p>	<p>Orthographic difference: Relpax contains an upstroke ‘l’ which is absent in Rayos giving the names different shapes. Frequency: Daily at bedtime vs. as needed.</p>
<p>Reluri (Guiafenesin and Phenylephrine) Dosage form and strength: Oral tablets: 1200 mg/300 mg Usual dose: Take one tablet by mouth twice daily</p>	<p>Orthographic similarity: Both names begin with ‘R’ Dosage form and route of administration: Both are tablets taken orally.</p>	<p>Orthographic difference: Reluri contains an upstroke ‘l’ which is absent in Rayos and Rayos contains a downstroke that is absent in Reluri giving the names different shapes. Strength: Multiple vs. single. An order for Rayos will require strength as it is available in multiple strengths vs. Reluri is available in single strength and may be omitted. There is no numerical overlap between the strengths. Frequency: Daily at bedtime vs. Twice daily</p>

<p><u>Proposed name:</u> Rayos (Delayed-release Prednisone)</p>	<p><u>Dosage form and strength:</u> Oral Tablets: 1 mg, 2 mg, 5 mg</p>	<p><u>Usual dose:</u> One tablet by mouth at bedtime, approximately 10 pm.</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>Prazosin Dosage form and strength: Oral capsules: 1 mg, 2 mg, 5 mg Usual dose: Take one capsules by mouth 2 to 3 times daily (maximum dose is 20 mg)</p>	<p>Strength: Both have multiple strengths and there is overlap between the strengths during prescription writing (<i>1 mg, 2 mg, 5 mg</i>). Dosage form and route of administration: Both are tablets taken orally.</p>	<p>Orthographic difference: Rayos (5 letters) appear shorter than Prazosin (8 letters) when scripted. Frequency: Daily at bedtime vs. 2 to 3 times daily</p>
<p>Requip (Ropinirole) Dosage form and strength: Oral tablets: 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg, 5 mg Usual dose: Take 0.25 mg to 8 mg by mouth 3 times daily; Restless Leg Syndrome: Take 0.25 mg to 4 mg by mouth at bedtime</p>	<p>Orthographic similarity: Both names begin with ‘R’ and the letter string ‘ayo’ and ‘equ’ appear orthographically similar when scripted. Strength: Both have multiple strengths and there is overlap between the strengths during prescription writing (<i>1 mg, 2 mg, 5 mg</i>). Dosage form and route of administration: Both are tablets taken orally. Frequency: Both can be taken at bedtime.</p>	<p>Orthographic difference: Requip contains an additional downstroke ‘p’ which is absent in Rayos giving the names different shapes.</p>

<p><u>Proposed name:</u> Rayos (Delayed-release Prednisone)</p>	<p><u>Dosage form and strength:</u> Oral Tablets: 1 mg, 2 mg, 5 mg</p>	<p><u>Usual dose:</u> One tablet by mouth at bedtime, approximately 10 pm.</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>Rezira (Hydrocodone and Pseudoephedrine) Dosage form and strength: Oral solution: 5 mg/60 mg per 5 mL Usual dose: 5 mL or one teaspoonful by mouth every 4 to 6 hours as needed</p>	<p>Orthographic similarity: Both names begin with 'R' and contain a downstroke 'y' and 'z' in the third position. Route of administration: Both are taken orally.</p>	<p>Orthographic difference: Rayos contains the letter string 'os' at the end of the name vs. Rezira contains the letter string 'ira' which appears orthographically different when scripted. Strength: Multiple vs. single. An order for Rayos will require strength as it is available in multiple strengths vs. Rezira is available in single strength and may be omitted. Dosing units: 'xx' tablet or 'xx' mg vs. 'xx' mL or 'xx' teaspoonful Frequency of use: Daily at bedtime vs. Every 4 to 6 hours as needed</p>
<p>Reznare (Bapineuzumab) Dosage form and strength: Injection solution: 20 mg/mL Usual dose: 0.5 mg/kg to 1 mg/kg intravenously every 13 weeks (40 mg to 80 mg based on average weight)</p>		<p>Orthographic difference: Rayos (5 letters) appear shorter than Reznare (7 letters) when scripted. Strength: Multiple vs. single. An order for Rayos will require strength as it is available in multiple strengths vs. Reznare is available in single strength and may be omitted. There is no numerical overlap between the strengths. Frequency of use: Daily at bedtime vs. Every 13 weeks</p>

<p><u>Proposed name:</u> Rayos (Delayed-release Prednisone)</p>	<p><u>Dosage form and strength:</u> Oral Tablets: 1 mg, 2 mg, 5 mg</p>	<p><u>Usual dose:</u> One tablet by mouth at bedtime, approximately 10 pm.</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>Rogaine (Minoxidil) Dosage form and strength: Topical solution: 2%-5% Usual dose: Apply one mL to hair where hair growth is desired twice daily</p>	<p>Orthographic similarity: Both names begin with 'R' and the letter string 'ayo' and 'oga' appear orthographically similar when scripted</p>	<p>Orthographic difference: Rayos (5 letters) appear shorter than Rogaine (7 letters) when scripted. Strength: Multiple vs. single. An order for Rayos will require strength as it is available in multiple strengths vs. Rogaine does not have a strength. Dosage form and route of administration: Oral tablets vs. Topical solution Frequency: Daily at bedtime vs. Twice daily</p>
<p>Rozex (Metronidazole) Dosage form and strength: Topical Emulsion 0.75% Usual dose: Apply thin film to the cleansed, affected areas twice daily in the morning and evening.</p>	<p>Orthographic similarity: Both names begin with 'R' and the letter string 'ayo' and 'oze' appear orthographically similar when scripted</p>	<p>Strength: Multiple vs. single. An order for Rayos will require strength as it is available in multiple strengths vs. Rozex is available in single strength and may be omitted. Dose: Tablet vs. apply thin film Frequency: Daily at bedtime vs. Twice daily</p>
<p>Baros (Sodium Bicarbonate) Dosage form and strength: Effervescent granules for solution: 460 mg Usual dose: Take 300 mg to 2000 mg by mouth 1 to 4 times daily</p>	<p>Orthographic similarity: 'R' and 'B' appear orthographically similar when scripted. Route of administration: Both are taken orally.</p>	<p>Orthographic difference: Rayos contains a downstroke 'y' that is absent in Baros giving the names different shapes. Strength: Multiple vs. single. An order for Rayos will require strength as it is available in multiple strengths vs. Baros is available in single strength and may be omitted. There is no numerical overlap between the strengths. Frequency: Daily at bedtime vs. 1 to 4 times daily</p>

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/s/

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03/01/2012

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03/02/2012