The Inside Track on Drug Naming Safety Standards

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Institute for Safe Medication Practices
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The Inside Track on Drug Naming Safety Standards

Michael R. Cohen, RPh, MS, ScD (hon.), DPS (hon.), FASHP
President, ISMP

Danielle Harris, PharmD, BCPS
Deputy Director, U.S. Food and Drug Administration (FDA)

Ana Zanoletty
Name Review Group Secretariat, European Medicines Agency (EMA)

Dorothy Linvill-Neal
Global Head, Name Creation & Regulatory Strategy, Novartis Pharmaceuticals Corporation

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Pharmacy CE Activity Information & Accreditation

This CE activity is jointly provided by ProCE, LLC and the Institute for Safe Medication Practices (ISMP). ProCE is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education.

ACPE

This CE activity is approved for 1.25 contact hours (0.125 CEU) in states that recognize ACPE providers.

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Disclosure

It is the policy of ISMP and ProCE, LLC to ensure balance, independence, objectivity and scientific rigor in all of its continuing education activities. Faculty must disclose to participants the existence of any significant financial interest or any other relationship with the manufacturer of any commercial product(s) discussed in an educational presentation.

The speaker listed below has no relevant commercial and/or financial relationships to disclose:

Michael R. Cohen, RPh, MS, ScD (hon), DPS (hon) FASHP
Danielle Harris, PharmD, BCPS
Ana Zanoletty

The speakers listed below disclosed a potential conflict of interest.

Dorothy Linvill-Neal disclosed salary from Novartis Pharmaceuticals
*Conflicts identified were resolved with a peer review process.

Please note: The opinions expressed in this activity should not be construed as those of the CE provider. The information and views are those of the faculty through clinical practice and knowledge of the professional literature. Portions of this activity may include unlabeled indications. Use of drugs and devices outside of labeling should be considered experimental and participants are advised to consult prescribing information and professional literature.

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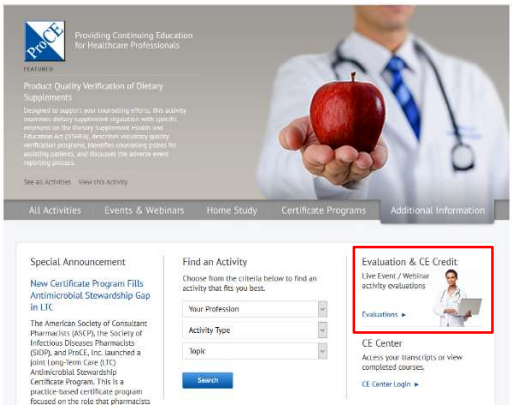
Online Evaluation and Statement of Completion

- **www.ProCE.com**
- Login with username and password (*Note: You will need to sign up for a new account if you have not previously used the ProCE CE Center)*
- Deadline:
  August 20, 2021



Attendance Code = ??????
(shown at end of program)

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Objectives

Following completion of this activity, participants will be able to:

- Discuss the FDA and EMA role in drug naming for medication safety
- Identify the benefits of safety testing prior to drug name approval
- State several steps in the development of a drug name for a pharmaceutical company
- Describe the types of problems that created a need to improve drug naming safety

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FDA U.S. FOOD & DRUG ADMINISTRATION

FDA's Role in Minimizing Proprietary Name Confusion and Medication Errors

Danielle Harris, PharmD, Acting Director
Division of Medication Error Prevention and Analysis II (DMEPA II)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
CDER | US FDA

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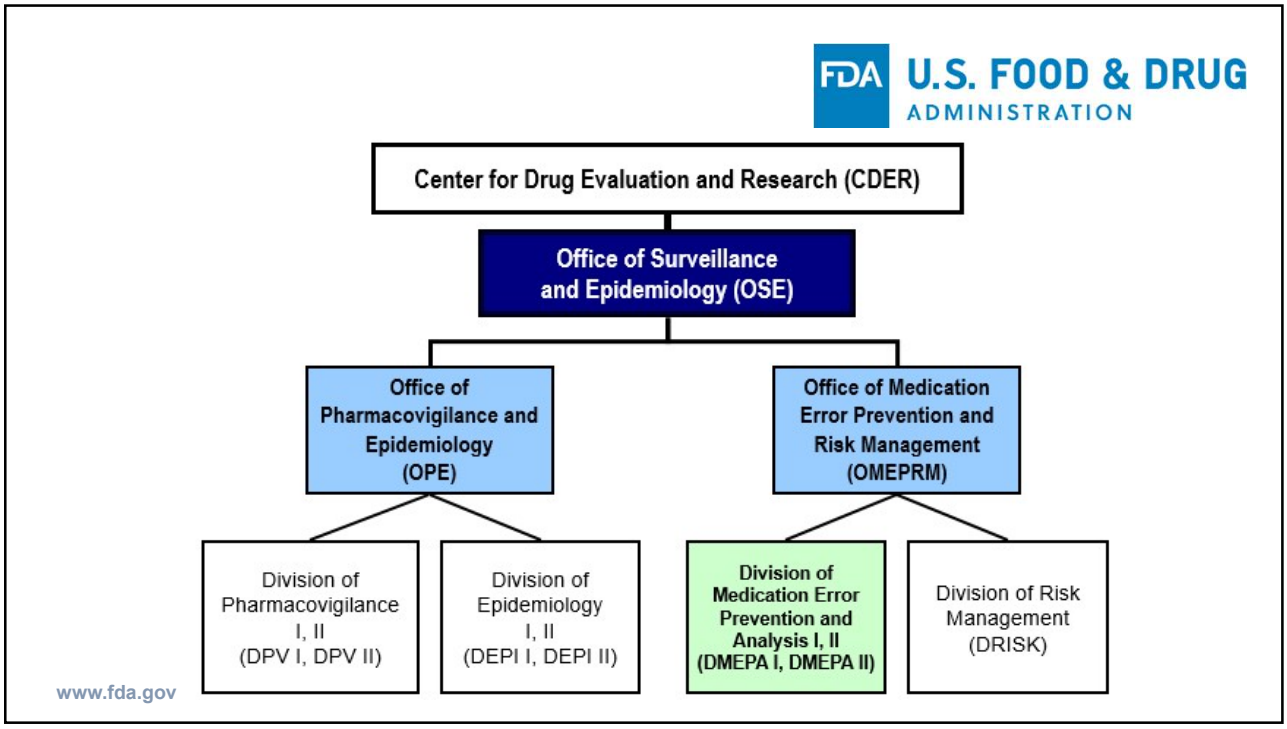

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Division of Medication Error Prevention and Analysis (DMEPA)

MISSION

To increase the safe use of drug products by minimizing use error that is related to the naming, labeling, packaging, or design of drug products

DMEPA consists of healthcare professionals with varied backgrounds

- *Pharmacists*
- *Nurses*
- *Biomedical engineer*
- *Social Scientists*

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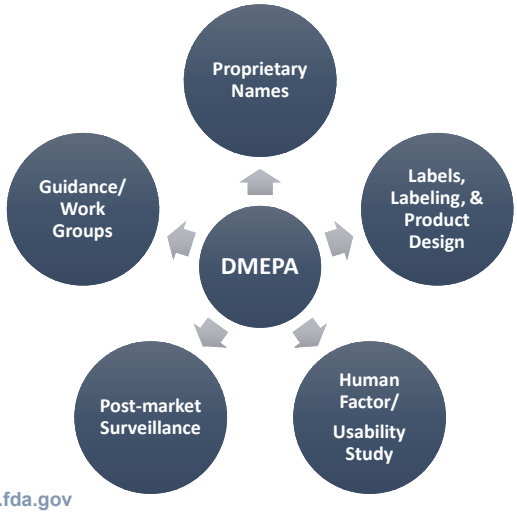
What does DMEPA do?



- Review new drug applications from a medication error perspective
- Identify strategies to prevent or mitigate medication errors
- Complete ~2000 medication error related reviews per year for drug products

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Contributing Factors

Proprietary Name Confusion…

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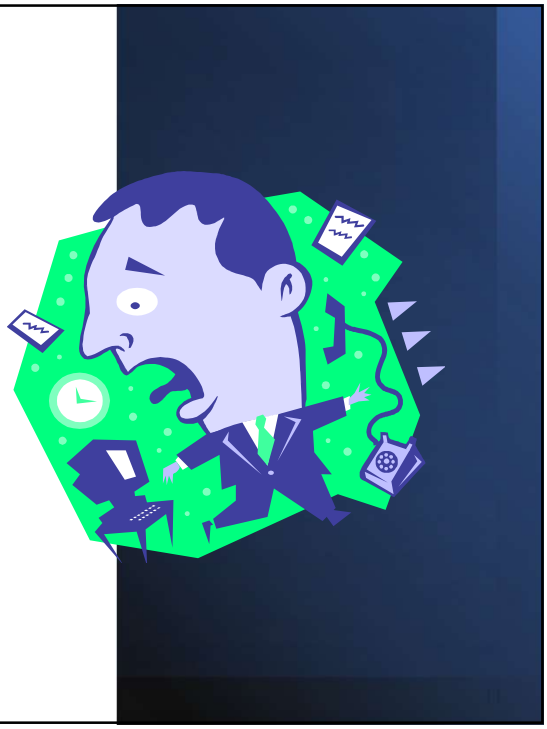
Environmental & Human Factors

- Stressful work environment
- Frequent interruptions & distractions
- Poor lighting
- Noise level



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Confirmation Bias

Aoccdrnig to rscheearch at Cmabrigde Uinervtisy, it deosn't mttaer in waht oredr the ltteers in a wrod are, the olny iprmoetnt tihng is taht the frist and lsat ltteer be at the rghit pclae. The rset can be a toatl mses and you can sitll raed it wouthit a porbelm.

Tihs is bcuseae the huamn mnid deos not raed ervey lteter by istlef, but the wrod as a wlohe.

Amzanig huh?

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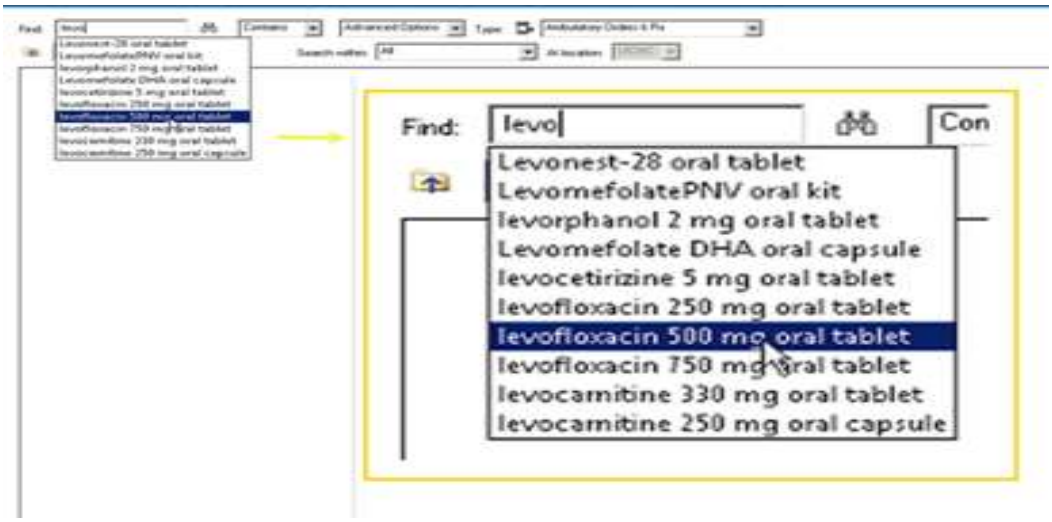
Role of Electronic Prescribing



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Role of Labels and Labeling

Consider role of similar labels when products are customarily stored side-by-side or near one another

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Proprietary Name Guidances

- **Final Guidance for Industry**: *Best Practices in Developing Proprietary Names for Human Prescription Drug Products*
- **Draft Guidance for Industry**: *Best Practices in Developing Proprietary Names for Human Nonprescription Drug Products*
- **Final Guidance for Industry**: *Contents of a Complete Submission for the Evaluation of Proprietary Names*

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Purpose of Naming Guidances

- To describe best practices to help minimize proprietary name-related medication errors and avoid adoption of proprietary names that contribute to violations of the FD&C Act
- To describe the framework FDA uses in evaluating proposed proprietary names that is also available to sponsors to use before submitting names for FDA review

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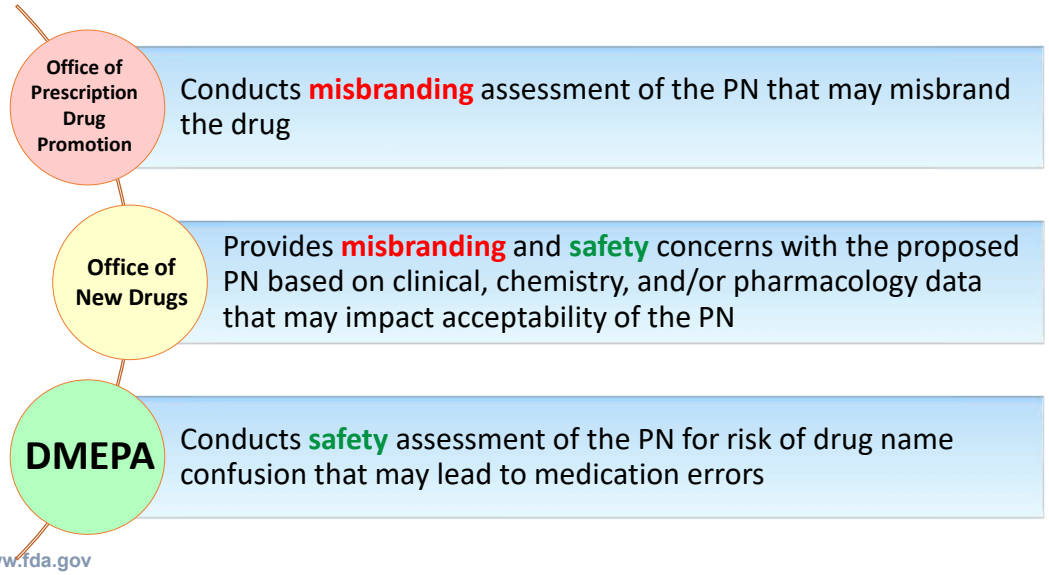
Proprietary Name Review Process



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Misbranding Review

- **Misbranding Assessment** is conducted by the Office of Prescription Drug Promotion (OPDP)

- FDA will **object** to a proposed name if it may **misbrand the product**, e.g.,:
  - The proprietary name suggests that the drug is safer or more effective than has been demonstrated by scientific evidence.
  - The proprietary name is "fanciful" and suggests that it has some unique effectiveness or composition when it does not.

Curebia

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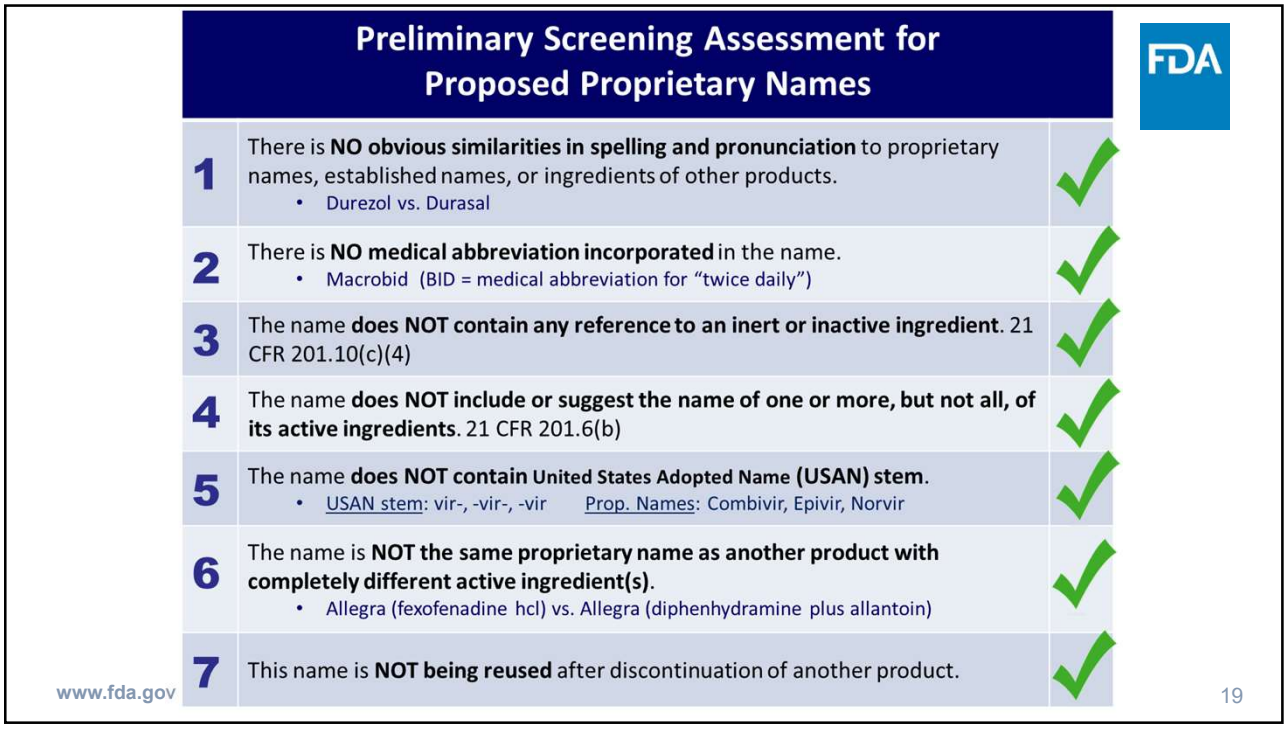

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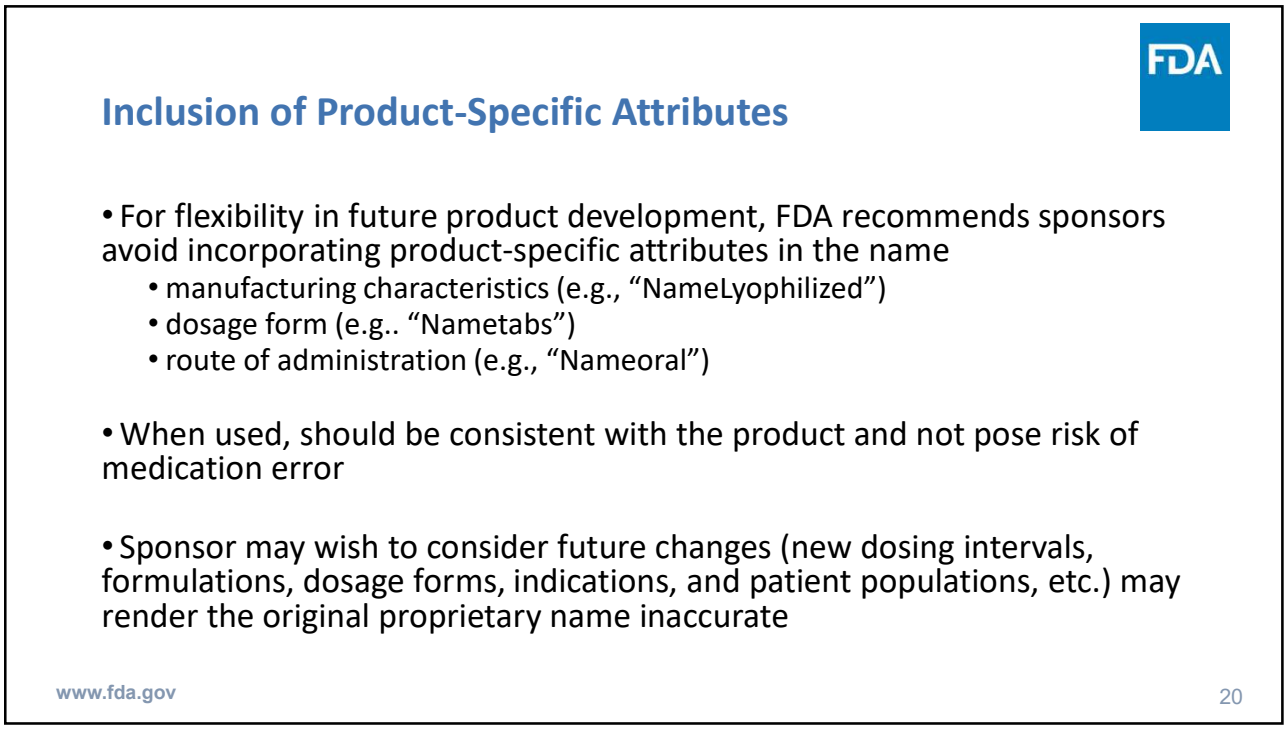

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Challenge Question #1

Which of the following proposed proprietary names are likely to generate an objection from FDA:

A. Biat**iv** for an intravenous product
B. Bia**statin** for a cholesterol lowering product
C. Posbia for an oral tablet
D. Curesacne for a topical retinoid
E. B and D

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Look-alike Sound-alike (LASA) Safety Assessment

- Consider phonetic, spelling, and orthographic similarity
- Conduct name simulation studies (NSS)
- Search for similar names using FDA's Phonetic and Orthographic Computer Analysis (POCA) program
- Use checklists for high, moderate, or low similarity pairs to help determine whether the name is safe from a LASA perspective

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Name Simulation Studies

- Intended to test how subjects respond to a proposed proprietary name by asking them to use the name in simulated real-world use conditions
- The more closely and fully the simulation approximates real-world use conditions, the more generalizable the results
- Name simulation tasks should reflect the full range and variety of tasks involved in the selecting, purchasing, prescribing, transcribing, dispensing, and administering of drugs
- Results should be analyzed carefully to identify potential errors

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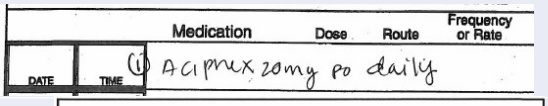
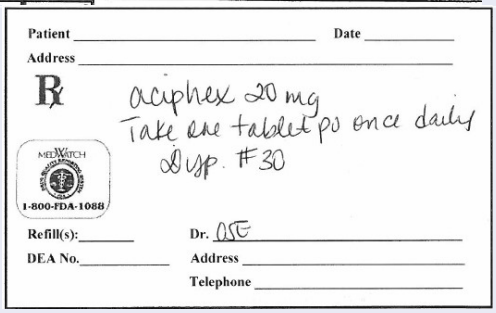
Prescription Simulation: Aciphex

Handwritten Medication Order/Prescription		Verbal Prescription
Medication Order:		Aciphex 20 mg. Take one tablet by mouth once daily. Dispense: 30
Outpatient Prescription:		
CPOE Study Sample (Font: sans-serif, 12 point, bold)		
Aciphex		

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Prescription Simulation: Aciphex

Study Name: Aciphex

Total	19	33	19	20	
INTERPRETATION	OUTPATIENT	CPOE	VOICE	INPATIENT	TOTAL
ACIFEX	0	0	1	0	1
ACIPHEN	1	0	0	0	1
ACIPHEX	18	33	17	17	85
ACIPNEX	0	0	0	1	1
ACIPREX	0	0	0	2	2
ASAFEX	0	0	1	0	1

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Phonetic and Orthographic Computer Analysis

- The Phonetic and Orthographic Computer Analysis (POCA) program is a software tool that uses an advanced algorithm to determine the orthographic and phonetic similarity between two drug names
- First released to public in Spring 2009*; available for download → POCA
- FDA uses POCA to compare a drug name against multiple drug names contained in both internal* and external data sources. Publicly available data sources in the most recent version are:
  - DrugsAtFDA (updated monthly)
  - RxNorm (updated monthly)
  - Suffixes in the proper name of approved biological products (updated monthly)
  - United States Adopted Names (USAN)

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**proposed proprietary name listings are only available to FDA - not the public*

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Evaluating Similar Name Pairs

• The POCA search will provide three data sets: (1) COMBINED orthographic and phonetic matches, (2) phonetic matches, and (3) orthographic matches

• Review the COMBINED orthographic and phonetic matches and group the name pairs into one of the following three categories:
  • Highly Similar Name Pair: combined score ≥70%
  • Moderately Similar Name Pair: combined score ≥55% to ≤ 69%
  • Low Similarity Name Pair: combined score ≤54%

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Role of Product Characteristics

- Product **strength and dose** is an important consideration
  - For similar names, the risk of medication error is potentiated when the **strengths and doses overlap**
  - However, if none of the strengths overlapped, the name similarity ***might*** not lead to errors.

- Consider: Intuniv and Invega

Confused	Not Confused
Intuniv 3 mg Invega 3 mg	Intuniv 1 mg, 2 mg, 4 mg Invega 1.5 mg, 6 mg, 9 mg

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Role of Product Characteristics

FDA

• If two products have highly similar names, differences in the product profile may not reduce the risk of error

Product	Different Product Characteristics	Combined POCA #
Cerebyx (fosphenytoin sodium injection)	***Pharmacological agent:*** anti-convulsant ***Route:*** intravenously or intramuscularly	**75%**
Celebrex (celecoxib) capsule	***Pharmacological agent:*** nonsteroidal anti-inflammatory ***Route:*** orally	
Kapidex (dexlansoprazole) delayed release capsules	***Indication:*** erosive esophagitis, gastroesophageal reflux disease (GERD) ***Dose:*** 30 mg or 60 mg once daily	**72%**
Casodex (bicalutamide) tablet	***Indication:*** prostate cancer Dose: 50 mg once daily	

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Final Determination on Name Acceptability

FDA

• The acceptability of a proposed proprietary name is based on FDA's review of all information and analyses described in the guidance along with any information submitted by the Applicant

• FDA may reject a name if, based on the information provided or in its own review, it determines the name:

- causes confusion with other products that can result in medication errors and preventable harm or
- is misleading with respect to the therapeutic effectiveness, composition, or the safety of the product.

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Challenge Question #2

Which is likely to potentiate the risk for name confusion in moderately similar names?

A. Same frequency of administration
B. Same strength and dose
C. Same route of administration
D. Same indication of use

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Managing post-market name confusion

Issue Alerts

- Communication and outreach, e.g., "Dear Health Care Provider"
- Drug Safety Communication (DSC) issued by FDA

Change Labeling

- This approach usually taken when name confusion is increased by products that have similar labeling and close proximity to each other on the pharmacy shelf
- Change in the labels requiring better visual differentiation between the two products
- Incorporation of different font size and type, layout, and color in the presentation of name, and strength on the container label

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Managing post-market name confusion

Apply TallMan Lettering

- Tall-man refers to a lettering style that uses mixed case to emphasize the differing portions of two names
- Studies show using tall-man lettering can improve health care practitioner's (HCP) ability to distinguish similar drug names*
- Tall-man is more effective when HCP are aware of the reason for its application.

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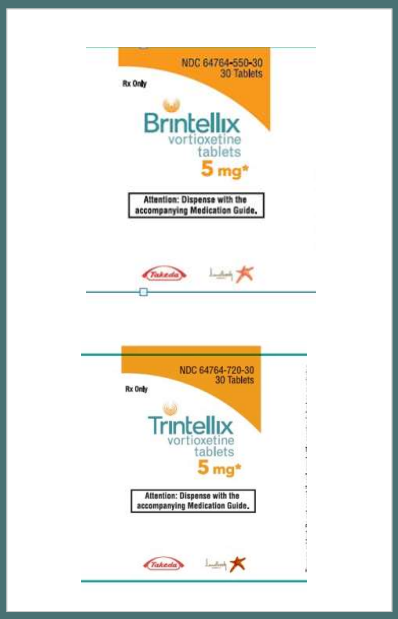

Proprietary Name Change

- July 2015: FDA issued a Drug Safety Communication
- FDA had received 50 medication error reports describing brand name confusion with Brintellix and Brilinta.
- After the July 2015 DSC, FDA received additional cases
- FDA worked with Brintellix manufacturer to change the drug's name
- Brintellix name changed to Trintellix

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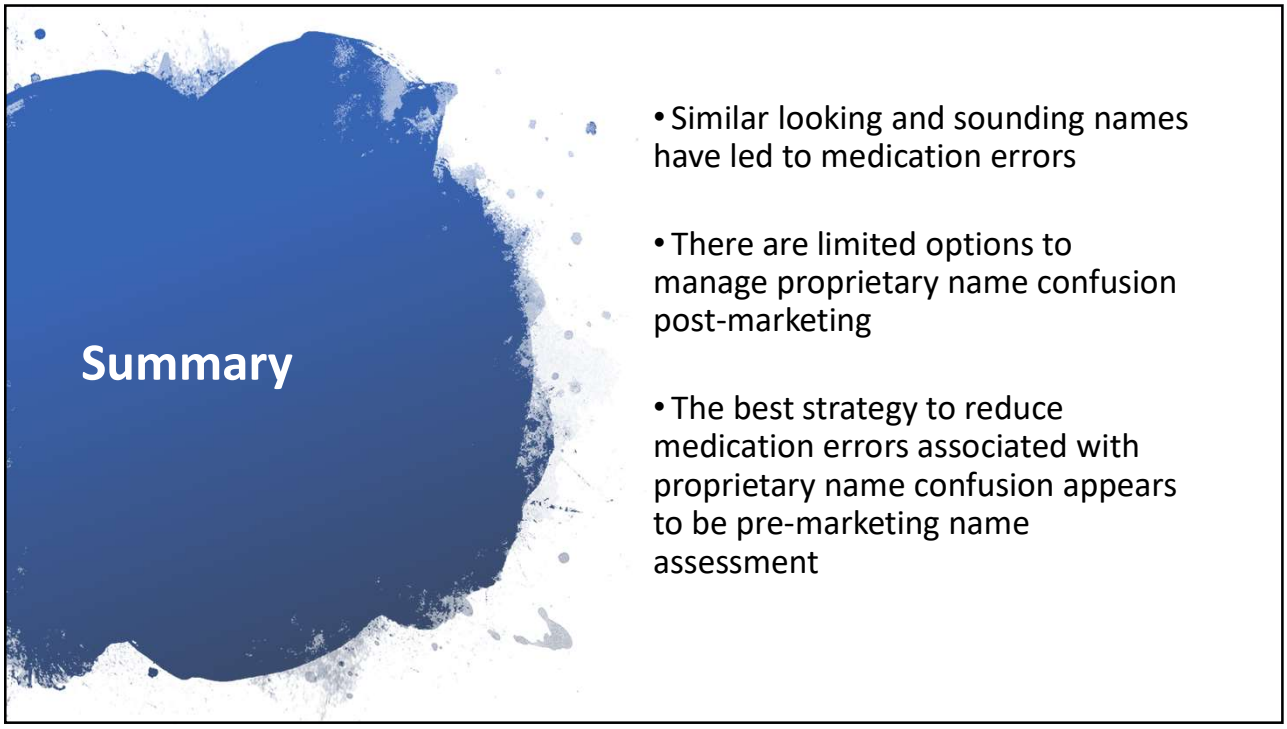

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Resources

- Best Practices in Developing Proprietary Names for Human Prescription Drug Products
- Best Practices in Developing Proprietary Names for Human Nonprescription Drug Products
- Guidance: Contents of a Complete Submission for the Evaluation of Proprietary Names
- MAPP 6720.2, Rev. 1, Procedures for Handling Requests for Proprietary Name Review.
- MAPP 6720.4- Procedures for Sharing Non-public Information on Pending Proposed Proprietary Names
- Proprietary Name Review Concept paper (PILOT PROGRAM)

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SCIENCE MEDICINES HEALTH

The Inside Track on Drug Naming Safety Standards
EMA perspective

Presented by Ana Zanoletty
Name Review Group

An agency of the European Union

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EUROPEAN MEDICINES AGENCY

Contents

- Legal basis
- Composition and role of the Name Review Group (NRG)
- Procedural aspects
- Recent changes and statistics
- Specific issues

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Legal basis

Single name rule – Centralised procedure

- Article 6(1) of Regulation (EC) No 726/2004: '…shall include the use of a single name for the medicinal product.'
- Article 1(20) of Directive 2001/83/EC : 'Name of the medicinal product: The name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorisation holder.'
- It is also understood by legislation that a common name is, according to Article 1(21) of Directive 2001/83/EC, as amended, "The international non-proprietary name (INN) recommended by the World Health Organization, or, if one does not exist, the usual common name."

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Name Review Group (NRG)

Single name rule – Centralised procedure

- Established by the Committee of Human Medicinal Products (CHMP) in 1999 to perform reviews of the (invented) names* of medicines assessed by EMA.
- Composed of ≈50 contact points in all Member States; of those, 15 regular attendees representing the main language groups + an expert on patient safety
- Chaired by an EMA representative
- * The terms '(invented) name' in this format aim to cover two possible scenarios, i.e. invented names and INN + Marketing Authorisation Holder (MAH)/TM

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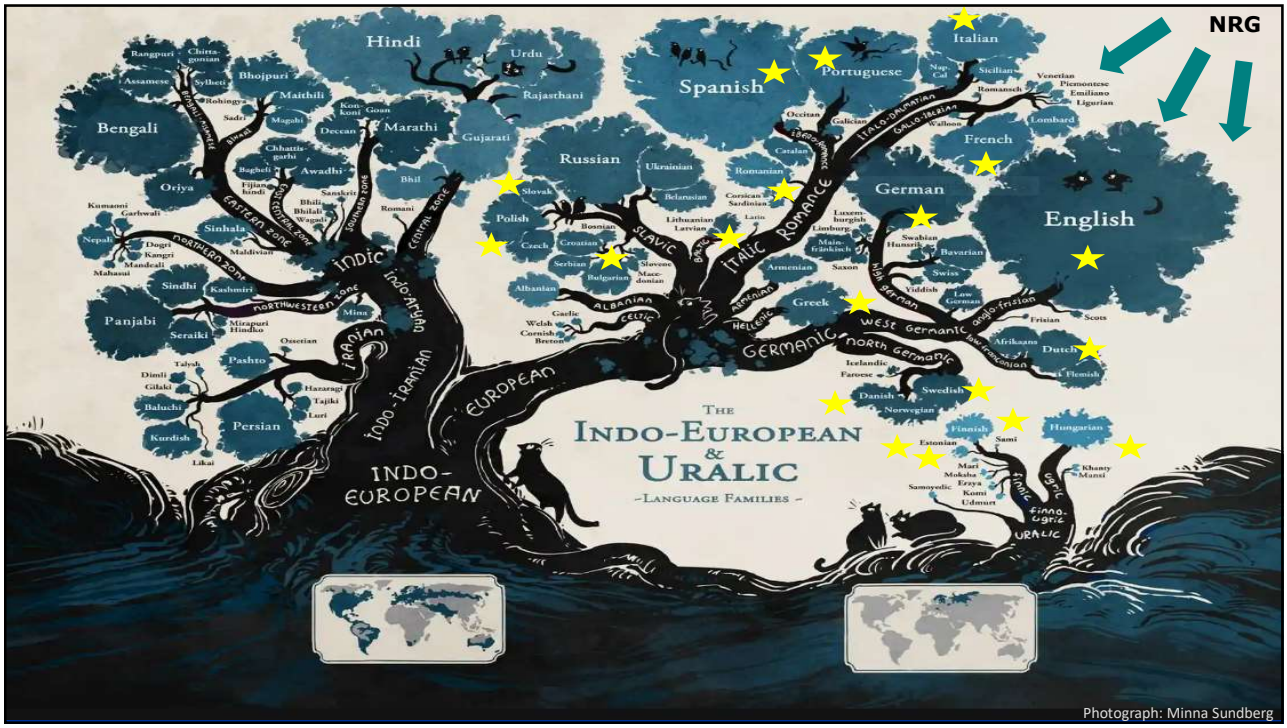

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Name Review Group (NRG)

Language family	Member States
Romance	IT, FR, ES, PT, RO
Slavic	PL, CZ, SK, SI, HR, BG
Baltic	LT, LV
Greek	EL, CY
Semitic	MT
Uralic	HU, EE, FI
Germanic	DK, SE, IE, BE, DE, NL, AT, IS, NO

+ 2 experts on patient safety

EC and WHO consulted on a case-by-case basis

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Role of the NRG

To prevent name-related medication errors

- To consider whether the (invented) name proposed by a sponsor could create a public-health concern or potential safety risk.
  - Confusion with existing medicinal product
  - Misleading therapeutic/pharmaceutical connotations/composition
  - Promotional names
  - Offensive / inappropriate connotation
  - Protection of INN/INN stems
- Support/development of naming policy
- Procedural guidance for variant strain(s) update to vaccines intended for protection against Human coronavirus (June 2021)
- Change of name of liposomal medicines at high risk of medication errors (Sept. 2019)

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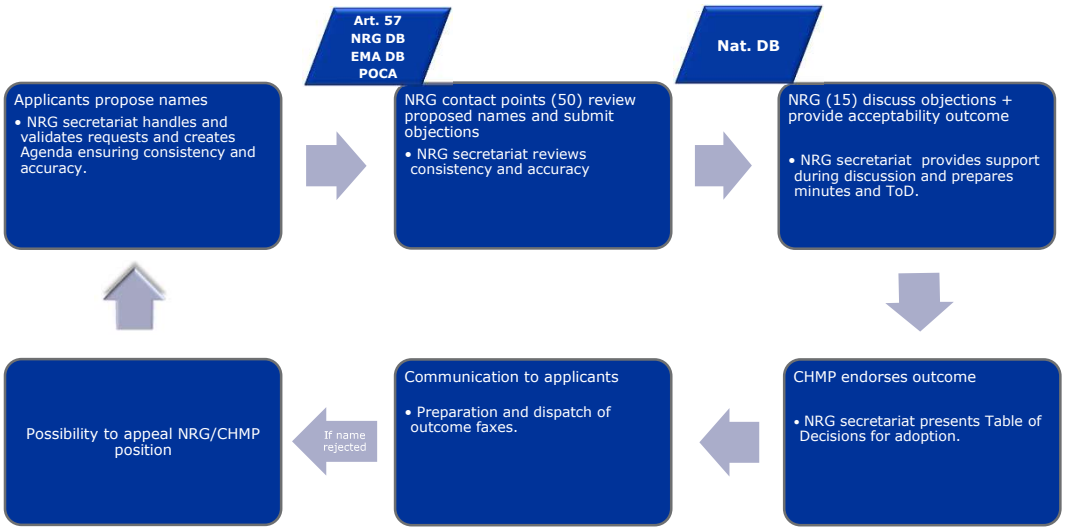
How does the NRG operate?



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2/3-month process; 4-6 times a year

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NRG guideline revision 7.

- Certain areas clarified based on the experience since last revision ('07)
  - Submission rules – reduction from 4 names to 2 names
  - Requirements for acceptability
- Use of checklist for the decision making when discussing the link between orthographic/phonetic similarity and potential for medication errors.
- Aim: For a streamlined decision making with more substantiated and transparent name review outcomes.
- Most MSs apply the same principles at national level


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Guideline on the acceptability of names for human medicinal products processed through the centralised procedure

Draft agreed by NRG	18 April 2013
Adopted by CHMP for release for consultation	30 May 2013
Start of public consultation	07 June 2013
End of consultation (deadline for comments)	30 August 2013
Agreed by NRG	26 March 2014
Adopted by CHMP	22 May 2014
Date for coming into effect	1 January 2015

This guideline replaces the guideline CPMP/328/98, Revision 5.

Keywords	EMA, CHMP, NRG, invented name

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NRG guideline revision 7 (planned)

Challenges & next steps

- Similarity with INN and INN stem
- Phonetic based objections on the rise
- Qualifiers: exemptions in placement, translation
- Promotional use
- MAH names – clarity on legal aspects
- Quality of submissions – Art 57 awareness
- Understanding of EU regulation
- Umbrella branding
- Differences in national practices

- Review postponed due to Brexit relocation, COVID-19 pandemic
- Agreement to commence review 2021
- Discussion planned with Interested Parties - November 2021.

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Further information

Ana.zanolettyperez@ema.europa.eu

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

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Key Considerations in Pharmaceutical Drug Naming: An Industry Perspective

Dorothy Linvill-Neal, Global Head
Name Creation & Regulatory Strategy
Novartis Pharmaceuticals Corporation

July 20, 2021

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Presentation Objectives

- ✓ Pharmaceutical Branding
- ✓ Brand Name Goals & Trends
- ✓ Naming Styles
- ✓ Challenges for Global Brand Names
- ✓ Regulatory Review
- ✓ Rejection Rates
- ✓ Process & Timing
- ✓ Name Safety & Research
- ✓ Summary
- ✓ Q & A

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Pharmaceutical Branding

Pharmaceutical/Device branding presents unique challenges versus typical consumer goods.

Pharmaceutical Industry must strive to develop names that balance Patient Safety/Health Authority Review and Drug Development Goals/Commercialization

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Brand Name Goals

- Initiate Global Name Development process approximately 3 years prior to regulatory submission.
- The name must be:
  - Safe for Use in the Global Healthcare Environment
  - Available for Global Trademark Registration
  - Approvable by Global Regulatory Authorities
  - Acceptable to Healthcare Professionals and Patient Audiences
  - Appropriate for a Diverse Global Marketing Environment
  - Supported by Internal Stakeholders
- Global Uniformity/communication/traveler safety

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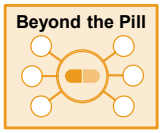
What can we name?

Nonproprietary (generic) names	**Beovu™ (brolucizumab)** **Stem**: -mab meaning: monoclonal antibodies **Stem subgroup**: -zumab meaning: humanized **Infix**: -ci- for circulatory system targets (e.g. inhibiting angiogenesis)
Proprietary (brand) names	Entresto® (sacubitril/valsartan) tablets 24/26mg · 49/51mg · 97/103mg
Clinical trials	(**CANOPY-N**) Canakinumab or Pembrolizumab as Monotherapy or in Combination as Neoadjuvant Therapy in Subjects With Resectable Non-small Cell Lung Cancer
Devices	Diagnostic: **NIJI** Near Patient Testing System 
Digital assets (e.g. apps, therapeutics)	**Beyond the Pill**   NOVARTIS **ViaOpta Daily** A personal assistant to help low vision patients with daily activities
Drug Classes	ABL001, asciminib **STAMP** **S**pecifically **T**argeting BCR-**ABL** **M**yristoyl **P**ocket
Pharmacopeial terms	**Prescido**, precision delivery *eHealth functionality**   *Conceptual designs

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FDA 4-letter biologic suffix

aimovig® (erenumab-aooe) injection 70 mg/mL • 140 mg/mL

Per the 2019 Nonproprietary Naming of Biological Products: Update Guidance for Industry[1], the FDA recommends a random 4-letter suffix be issued on a per product basis for all biologic products.

The intent is for the suffix to be used on all packaging and labelling, communication, prescribing, adverse event reporting for a product. The suffix's aim is "To improve pharmacovigilance and safety of biologic substances by adding an additional way to distinguish between biologics in light of the entry of similar biologic product into the US marketplace as treatment options for patients."

Type of Screening required:

- Stakeholders create and perform required screening prior to submission to ensure appropriateness and safety (e.g. avoiding sponsor promotion, similarity to medical acronyms or abbreviations)
- 10 suffixes are submitted in prioritized order, from most (#1) to least (#10) preferred

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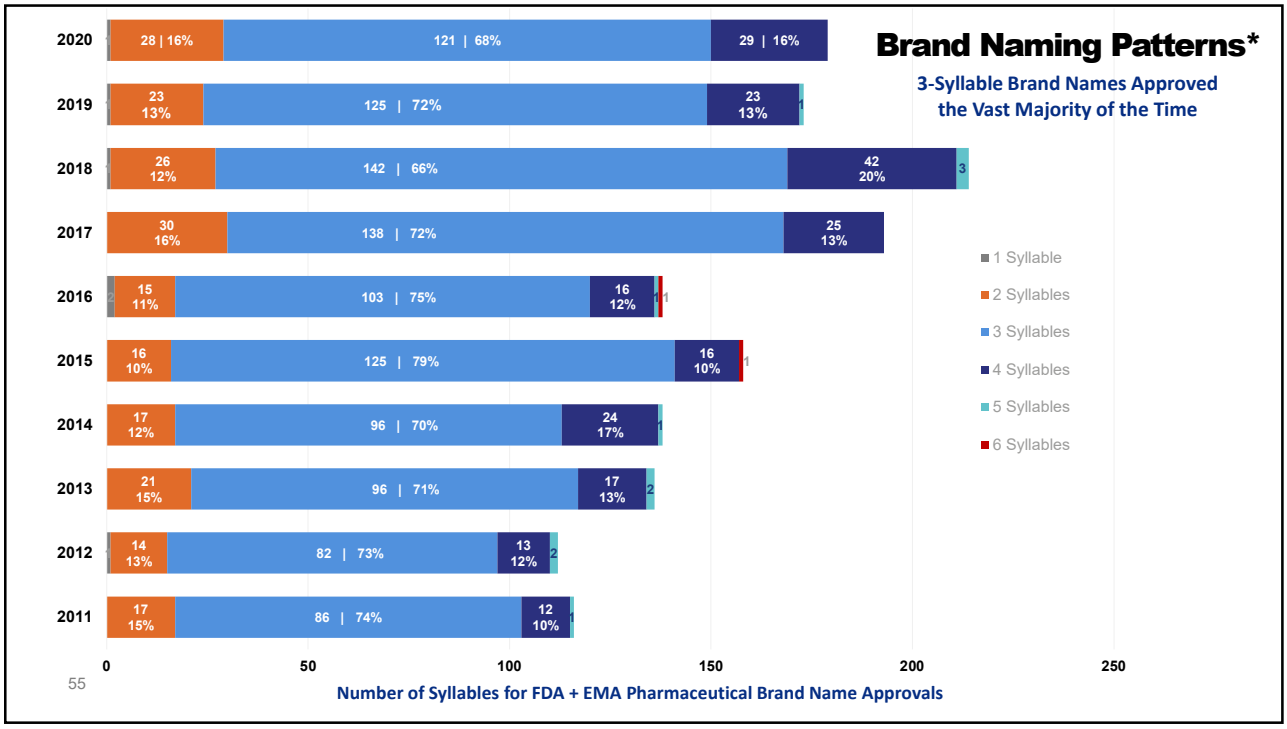

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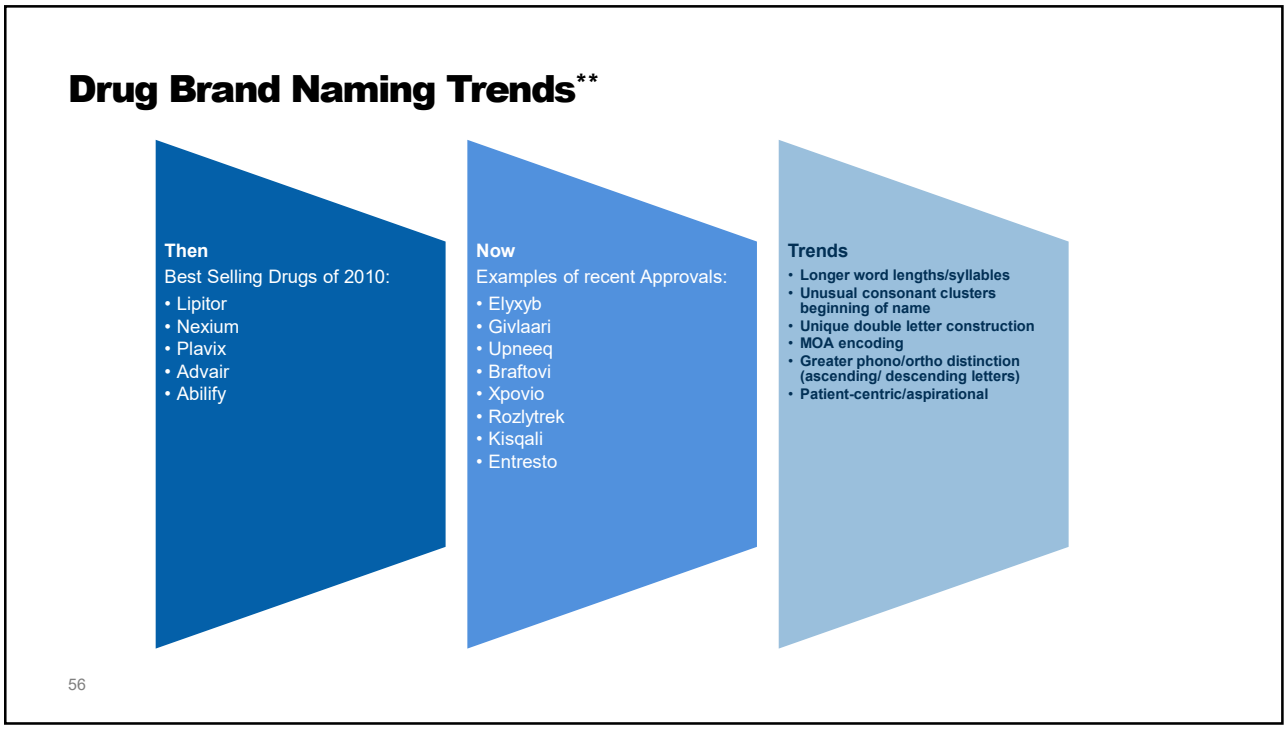

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Drug Brand Naming Styles

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Challenges for Global Brand Names

Competition
- Battle for brand uniqueness
- INN consideration

Legal Clearance
- Struggle for TM availability & ownership

Name Safety / MR
- Internal Buy-in
- Global NS/MR
- Critical factor guide decision & selection

Regulatory
- FDA/EMA nomenclature review
- Health Canada
- Mexican Health Ministry
- Brazil/S. Africa/ Russia/Japan/ Australia/Israel

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Regulatory Nomenclature Review

The following Health agencies/countries have established a formal review of trademarks:

- FDA/DMEPA – US (Multifactorial approach/data driven)
- EMA/NRG – EU – 27 Member States – Single TM Rule
- MHRA – UK
- Health Canada - Revised guidance with new, data requirements
- South Africa – MoH
- Brazil - ANVISA
- Japan – Ministry of Health (MoH), Labour and Welfare
- Mexico – COFEPRIS
- Australia – Therapeutic Goods Administration (TGA)
- Russia – Roszdravnadzor
  - Varied methods / 3-letter rule / proliferation of unused names

✓ All share same common goal – error minimization

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Regulatory Considerations

While all agencies evaluate nomenclature with the same objective **(Patient Safety),** their opinions and the methods used to determine the acceptability of proposed names is not always consistent.

The complexity is increased by the differentiating pharmaceutical nomenclature landscape and prescribing practices.

- ***Therefore*, for example, name approval with FDA does not constitute/guarantee approval with EMA or any other HA**
- **The brand name for a new product may not be certain until shortly before FDA/EMA approval**
- **We must always plan for possible exceptions to the global name, and for last-minute name changes**

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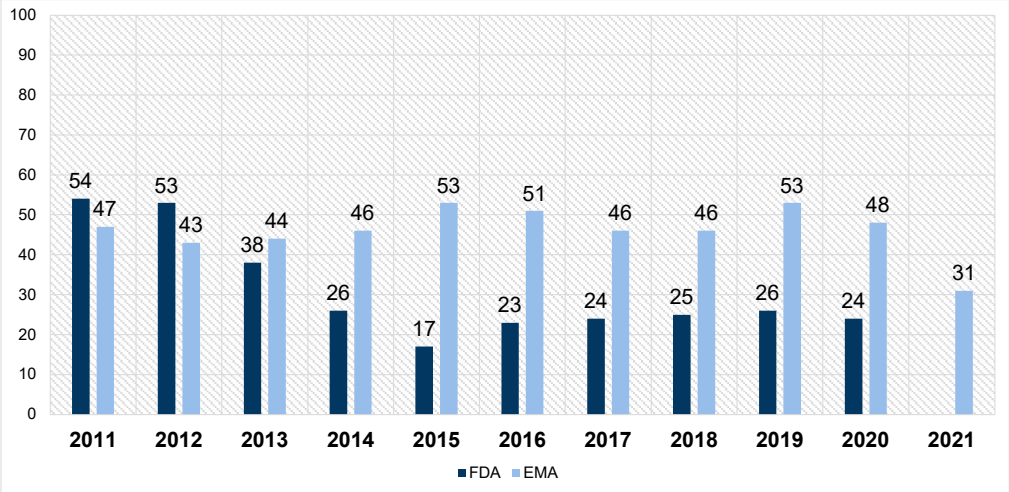
FDA & EMA Name Rejection Rates (%)



FDA Fiscal Year Data (1 Oct 2019 through 30 September 2020)
EMA data as of 25 Mar 2021

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Brand Name Development Process – Timeline

Creative	TM Legal	Global Research	HA Submission
▪ Naming Agency & Cross Functional Team ▪ Brand Strategy & Insights ▪ Pre-Screening & Name Review ▪ Develop Multiple Naming Platforms & Varied Names	▪ Cursory Legal ▪ Full Trademark & Clearance ▪ Filing & Registering Trademarks and Domain Names	▪ Name Safety ▪ Market Research ▪ Linguistics ▪ HCPs, Patients, Caregivers	▪ Internal Final Endorsement ▪ Activate submissions to HAs - EMA,FDA etc. ▪ preliminary approvals lead and back-up names ▪ Rejection/Appeals process ▪ Final Approvals ▪ Global HA submissions

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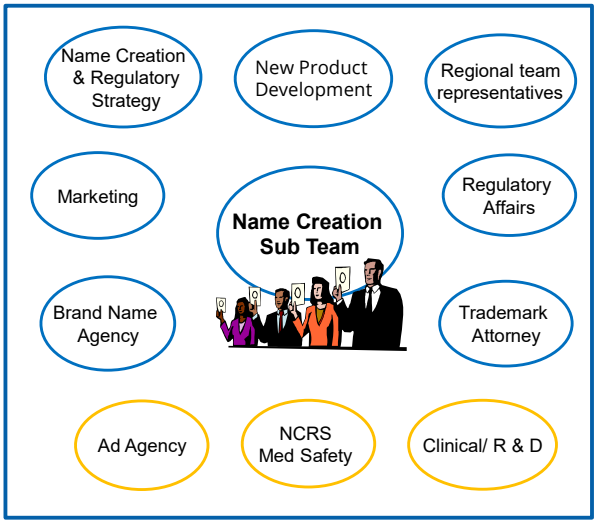
Name Creation Sub-Team

- Ensure a cross-functional, transparent and coordinated process
- Enhance buy-in and make full use of internal/external resources
- Provide empowered voice of representation for region, LOC, functional unit
- Team participants contribute based on area of expertise, communicate progress and information



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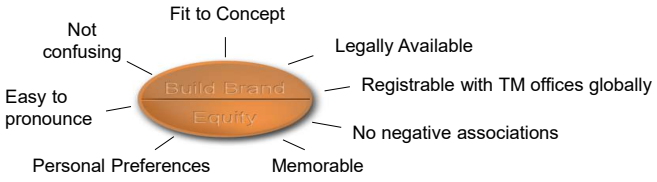
Name Safety/Market Research Testing Metrics What's in a Name?



Name Safety Metrics Physicians/Pharmacists/Nurses (NS&MR) Patients & Caregivers (MR only)		Marketing Metrics	Language/Culture
▪ Prescription simulation ▪ Oral Rx Interpretation ▪ Handwriting Rx interpretation ▪ Look Alike/Sound Alike Similarity ▪ POCA ▪ Associations	▪ Medical term similarity ▪ Exaggerative / inappropriate meaning ▪ FMEA ▪ Expert Panel ▪ Global Compendiums / databases searching	▪ Associations ▪ Fit to concept ▪ Attribute Evaluations ▪ Memorability ▪ Personal preferences ▪ Ease of Scripting/ Pronunciation	▪ Inappropriate / negative connotations ▪ Translations / Transliterations ▪ 40+ Languages with Native Speakers

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Verbal identity screening***

Linguistic screening

Brand names are the true globe-trotting, “one market” ambassadors of today, conveying consistency of message and promises of quality across numerous geographic and language borders.

Linguistic acceptability screening is an essential due diligence step to help avoid candidate names that may have unfortunate associations.This type of screening is designed to identify problematic name candidates, while ensuring multiple market acceptability and uncovering valuable cultural insights and perceptions.

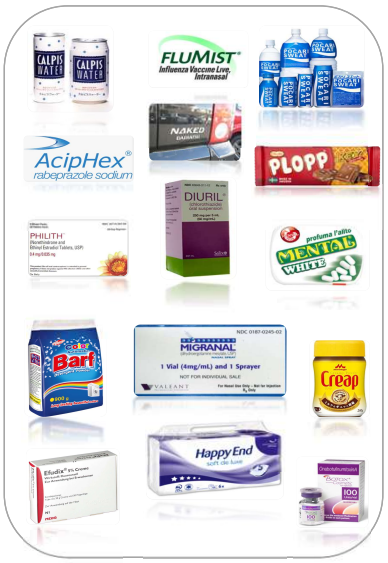
Two types of linguistic checks can be conducted:

Basic Screen

- Pronunciation
- Direct translation
- Negative associations
- Linguistic acceptability

Full Screen

- Pronunciation/Transliteration
- Direct translation
- Morpheme review
- Semantic coherence
- Stylistic syntax
- Overall acceptability



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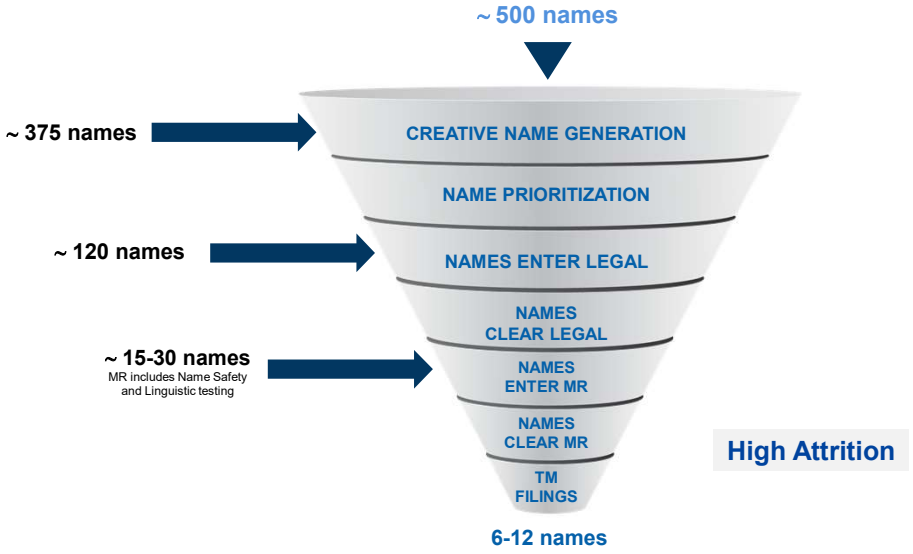
Brand Name Development Process



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Strategies for Success

- Perform proper due diligence during Name Development
- Be Proactive – Conduct Name Safety and Market Research Evaluations designed to identify safety concerns and linguistic issues.
- Understand Global Nomenclature Review Processes (Distinctions/ Overlaps and new procedures)
- Establish local network to assist with national product nomenclature review and investigation (MA Listings, Compendiums)
- Maintain open communication with internal stakeholders
- Partner with and maintain open and transparent dialogue with Health Authorities/be willing to conduct additional studies
- Be responsive to inquiries, and provide proper data and analysis to support appeals
- Abandon name candidates which present risk
- Love your back-ups!

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Summary

- Patient safety continues to be the high priority for Industry, FDA, EMA, other regulators and other key stakeholders
- Continued partnership is critical among Health Authorities, Industry, Patient Safety organizations and other stakeholders on how best to continuously improve patient safety, reduce medication errors, and create and review proposed proprietary names
- Goal – Reduce Errors/Enhanced predictability

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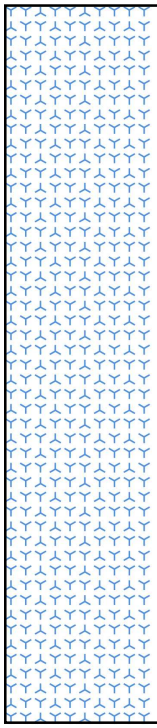

Questions?

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References

1. FDA. Nonproprietary Naming of Biological Products: Update Guidance for Industry
2. Special thanks to : Brand Institute*, Leaderboard Branding**, and Purple Fire Branding***

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Institute for Safe Medication Practices
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Drug Product Container Labeling and Wrong Drug Medication Errors

Michael R. Cohen, RPh, MS, ScD (hon.), DPS (hon.), FASHP
President, Institute for Safe Medication Practices
mcohen@ismp.org

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ISMP National Medication Error Reporting Program

- Medication Error Reporting Program (MERP)
- Vaccine Error Reporting Program (VERP)
- Consumer Error Reporting Program (C-MERP)

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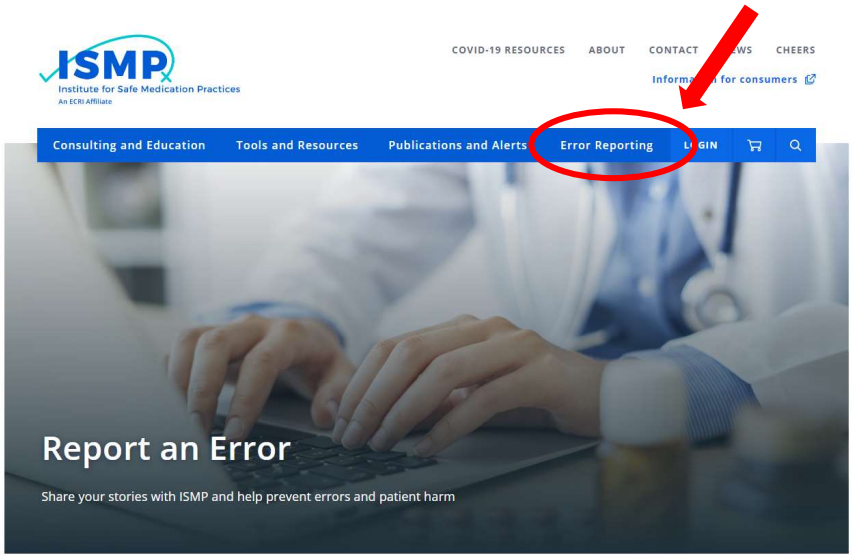
ISMP National Medication Errors Reporting Program (MERP)



https://ismp.org/report-medication-error

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National Medication Error Reporting System


Acute Care
ISMP Medication Safety Alert!

Medical abbreviations that have contradictory or ambiguous meanings

SAFETY briefs

Become an ISMP Fellow

- Early warning system
  - Issue nationwide hazard alerts and press releases
- Learning
  - Dissemination of information and tools
- Change
  - Product nomenclature, labeling, and packaging changes, device design, practice issues
- Standards and Guidelines
  - Advocates for national standards and guidelines

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NATIONAL ALERT NETWORK (NAN)

NANALERT

This alert is based on information from the National Medication Errors Reporting Program operated by the Institute for Safe Medication Practices.

March 23, 2015

Warning! Potentially dangerous confusion between Bloxiverz (neostigmine) injection and Vazculep (phenylephrine) injection

ISMP is alerting hospitals, ambulatory surgical centers, and anesthesia professionals about the potential for dangerous mix-ups between two relatively new presentations of older medications, neostigmine injection and phenylephrine injection.

Eclat Pharmaceuticals is currently manufacturing **BLOXIVERZ** (neostigmine) and **VAZCULEP** (phenylephrine). Bloxiverz became the first FDA-approved neostigmine product in 2013. It is a cholinesterase inhibitor indicated for the **REVERSAL** of non-depolarizing neuromuscular blockade after surgery. Vazculep is a phenylephrine injection product approved in 2014 for treatment

Figure 1. Mix-ups between Bloxiverz and Vazculep have occurred at hospitals around the US.

The pharmacy bulk packages are intended for use in the pharmacy during sterile compounding of infusions.

In the past 3 months, ISMP has received 8 practitioner reports expressing concern about look-alike packaging of Bloxiverz 10 mg/10 mL (1 mg/mL) and Vazculep 50 mg/5 mL (10 mg/mL). The vials and outer cartons look similar in size, color, and design (**Figure 1**). Several hospitals have reported that vials or cartons of the 10 mg Bloxiverz product were found mixed in with Vazculep 50 mg/5 mL (10 mg/mL) vials or cartons. Of the 8 reports, five were close calls in which the wrong product was actually used during sterile compounding. Fortunately, in each reported case,

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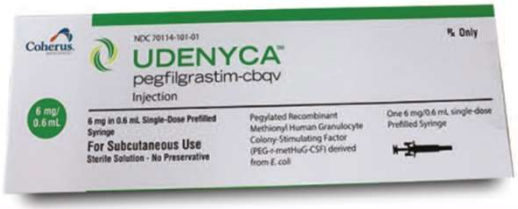
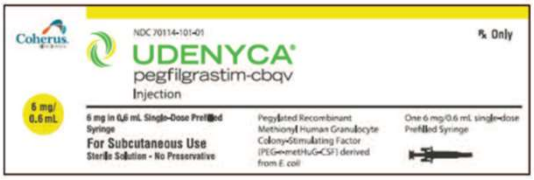
Look-Alike Products

Different Manufacturers

- Multiple mix-ups reported between Prolia and Udenyca prefilled syringes.
- Each packaged in similar green and white cartons, with the concentration listed in a green circle in the same location.
- Both products stocked in oncology and infusion centers, are refrigerated, and may be stored near each other.





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ISMP Medication Safety Alert! 2019;24(17):1-2.
ISMP Medication Safety Alert! 2020;25(2):4.

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Look-Alike Products

Same Manufacturer

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ISMP Medication Safety Alert! 2017;16(1):2-3.
ISMP Medication Safety Alert! 2019;24(17):1-2

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Look-Alike Products

Same Manufacturer

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ISMP Medication Safety Alert! 2020;25(18):1-2. *ISMP Medication Safety Alert!* 2020;25(25):5. *ISMP Medication Safety Alert!* 2019;24(10):1-2. *ISMP Medication Safety Alert!* 2019;24(8):2.

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Look-Alike Products

Cap Color

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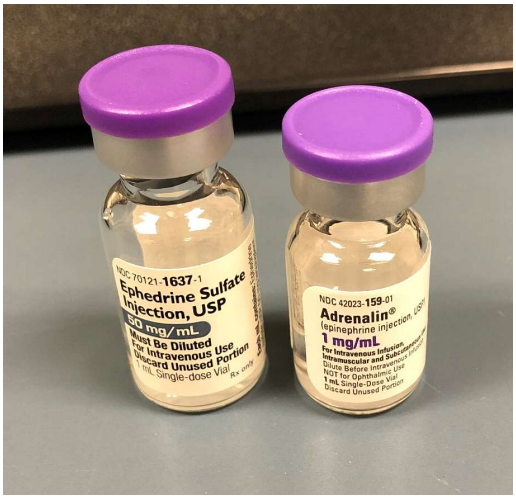
Look-Alike Products

Different Manufacturers



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ISMP Medication Safety Alert! 2020;25(21):3-4.

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ISMP Medication Safety Alert! 2021;26(11):1-2.

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Figure 1. Imdevimab (left) and casirivimab (right) vial labels list only product code numbers, not drug names, and the manufacturer's barcodes do not differentiate the products. A pharmacy has affixed barcoded labels with drug names to the vials.

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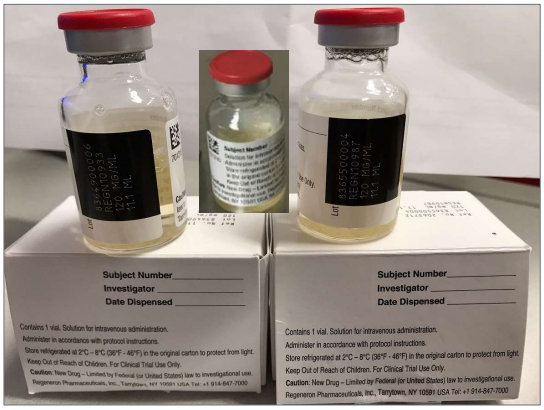

Casirivimab and imdevimab monoclonal antibodies

Moderna COVID-19 vaccine

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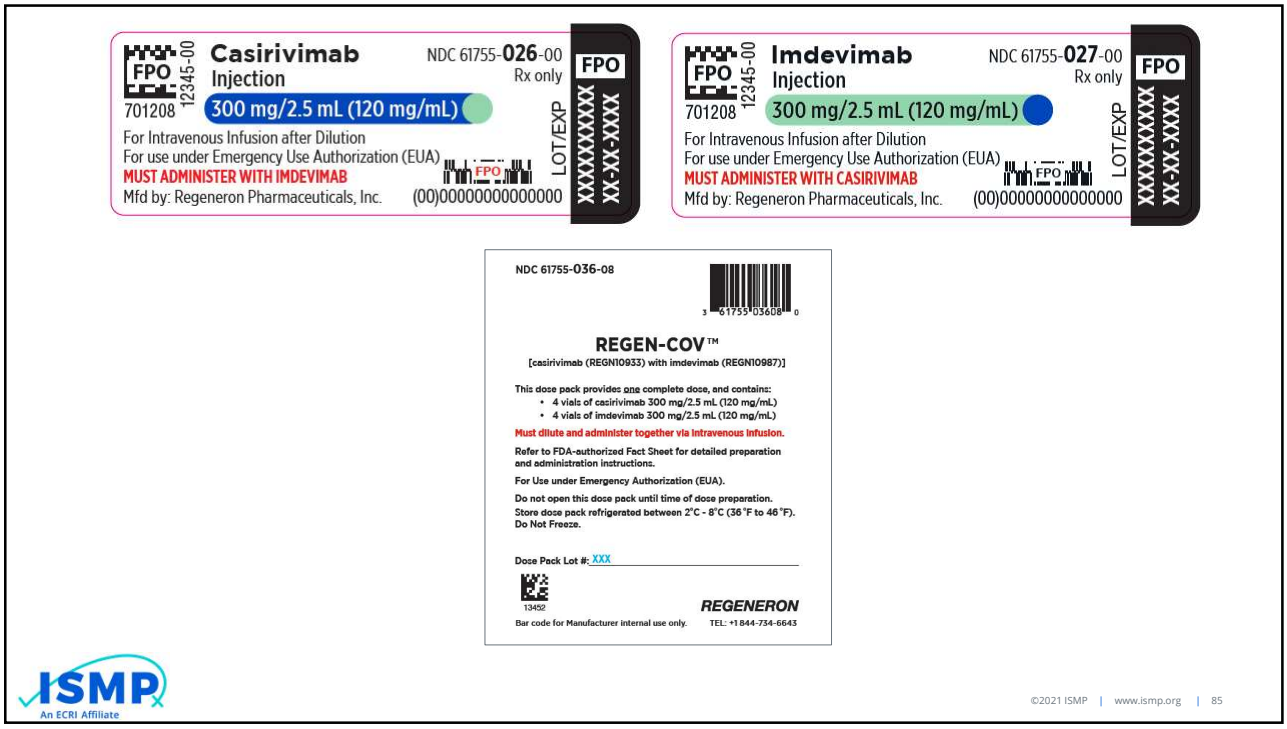

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Coformulation available, June 2021

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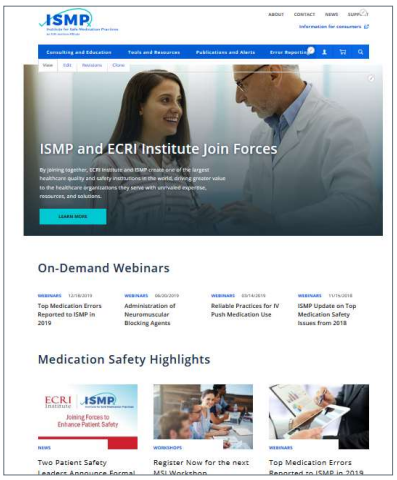
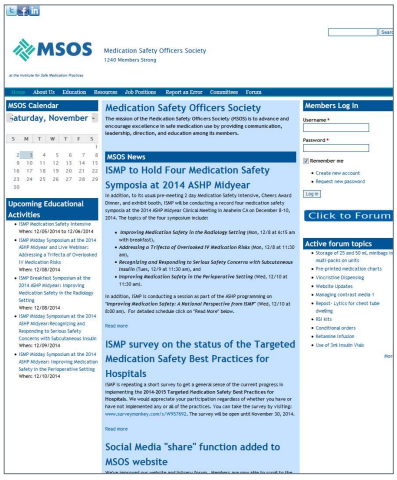
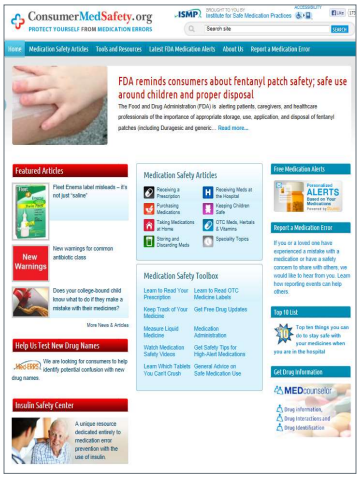
ISMP Websites



www.ismp.org



www.medsafetyofficer.org



www.consumermedsafety.org

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Harmonizing Safe Medication Container Labeling and Packaging

Create a minimum set of best practices for labeling and packaging aimed at reducing medication errors

- On June 19 and 20, 2018, at the US Food and Drug Administration (FDA) campus in MD, created a minimum set of best practices for labeling and packaging aimed at reducing medication errors.
- Participants agreed that guidelines are needed regarding the presentation of critical label information to deal with look-alike labels, noting that logos and highly stylized graphics detract from readability of the label.

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Are we making progress?

- Elimination of handwritten prescriptions
  - NY State Rule
  - More than 90% of US Hospitals e-Prescribe
  - More than 90% of Pharmacies accept e-Prescribing
  - More than 80% doctor offices have available e-prescribing
- Adoption of safety technologies
  - Bedside bar code scanning (drug and patient)
  - Community pharmacy bar coding, screen imaging, DUR, adjudication of Rx, etc.
  - "Smart" infusion pumps in hospitals
  - Automated dispensing cabinets for drug distribution
  - IV workflow systems (imaging, scanning, weighing, of compounded sterile products, etc.)

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Are we making progress?

- Drug name development
  - Practitioner testing
  - Published FDA guidance for industry
  - POCA
  - FDA review
  - Use of "Tall Man" letters (metroNIDAZOLE vs. metFORMIN)
  - Indication-based prescribing
- Role of trademark testing firms and premarket testing of labeling & packaging
- Improvements in container labeling and packaging
  - Published FDA guidance for industry
  - USP <7> Labeling and Nomenclature

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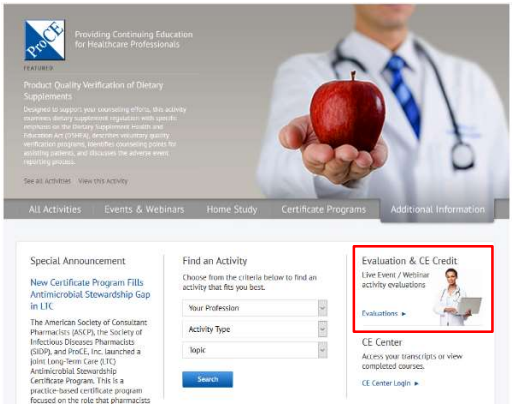
Online Evaluation and Statement of Completion

- **www.ProCE.com**
- Login with username and password (*Note: You will need to sign up for a new account if you have not previously used the ProCE CE Center)*
- Deadline:
  August 20, 2021



Attendance Code = 4DUGEW

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