



Health Canada Guidance on Look Alike and Sound Alike Brand Name Reviews

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Shared Objective

Health Canada

Drug Safety Institute



**Minimize
Medication
Errors**



Biotechnology, Pharmaceutical & Medical Device Manufacturers

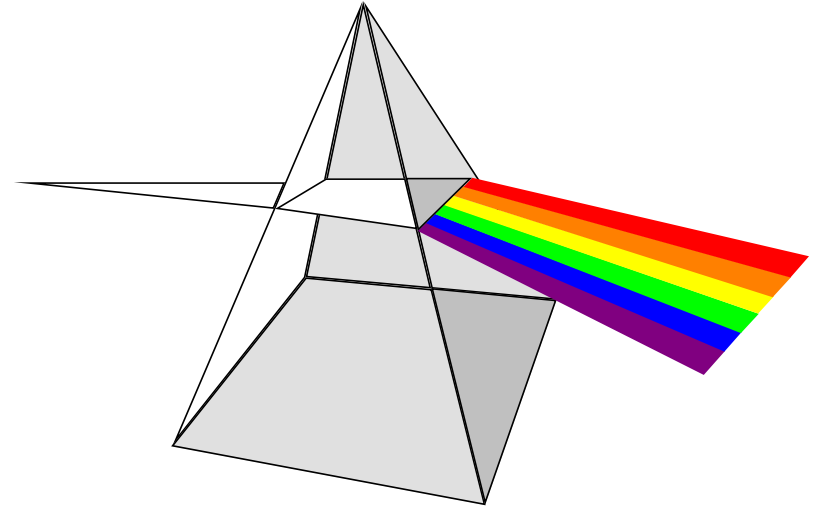
Medication Error

- ✓ 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



Medication Error

- ✓ Complex Systems
- ✓ Human Interactions
- ✓ Potential for Harm
- ✓ Safety Designs = Decreased Potential for Failure





Drug product

ERROR

The medical care “vortex”

Causes

- ✓ Poor Communication
- ✓ Product Name Similarity
- ✓ Directions for Use
- ✓ Abbreviations
- ✓ Poor Techniques
- ✓ Knowledge Deficit

Stress





Transcription of Orders

- ✓ Morphine 0.5 mg

morphine .5 mg

AM	1	2	3	4	5	6	7	8	9	10	11	12	PM	13	14	15	16	17	18	19	20	21	22	23	24
DATE	12/24/06 units regular insulin																								
TIME	by X ¹ ₇																								
PROCESSED BY:																									

Navane or Norvasc?



Transcription of Orders

Physician's Handwritten Medication Order Example

AN ARTIFICIAL WATERMARK IS ON THE BACK - HOLD AT AN ANGLE TO VIEW THIS MARK

PATIENT'S FULL NAME: [Handwritten: John Doe] PHONE NUMBER: [Handwritten: 123-456-7890] AGE: [Handwritten: 45] SEX: [Handwritten: M]

ADDRESS: [Handwritten: 123 Main St, Anytown, CA 90210] DATE: [Handwritten: 5/4/01]

Rx Take your Celexa & Celebrex as before
1 Ecotrin #100
2 Altace 5mg #30
3 Zocor 20mg #30
4 Toprol XL 50mg #30 1/2 tablet po qd
5 Plavix 75mg #30 1 po qd x 30 days only 0 refills

Dr. [Handwritten: J. Smith] M.D.

Refills 1 2 3 4
 No Refills Void After _____

DEA #: _____

VALID FOR CONTROLLED SUBSTANCES

"RX" ON BACK IS PRINTED IN DISAPPEARING INK - RUB BRISKLY TO ACTIVATE

Confusion and errors from:

Handwriting interpretation
Dispensing multiple products
Dosing, instructions, administration, etc.

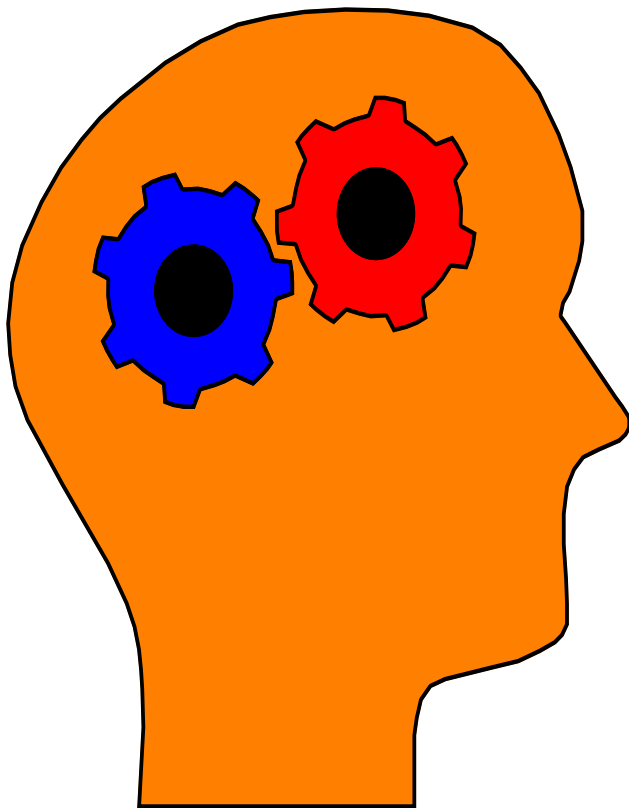
Take your Celexa and Celebrex as before
Ecotrin #100 1 po qd 4 refills
Altace 5mg #30 1 po qd 4 refills
Zocor 20mg #30 1po qd 4 refills
Toprol XL 50mg #30 1/2 tablet po qd 4 refills
Plavix 75mg #30 1 po qd x 30 days only 0 refills

Causes for Dispensing Errors

- ✓ Practitioner's Handwriting
- ✓ Phone-in Orders

"Sound-Alike" and "Look-Alike" Names	
<i>Lamictal</i>	<i>Lamisil</i>
<i>Flomax</i>	<i>Fosamax</i>
<i>Tobrex</i>	<i>Tobradex</i>
<i>Zantac Syrup</i>	<i>Zyrtec Syrup</i>
<i>Celebrex</i>	<i>Cerebyx</i>
<i>Losec</i>	<i>Lasix</i>

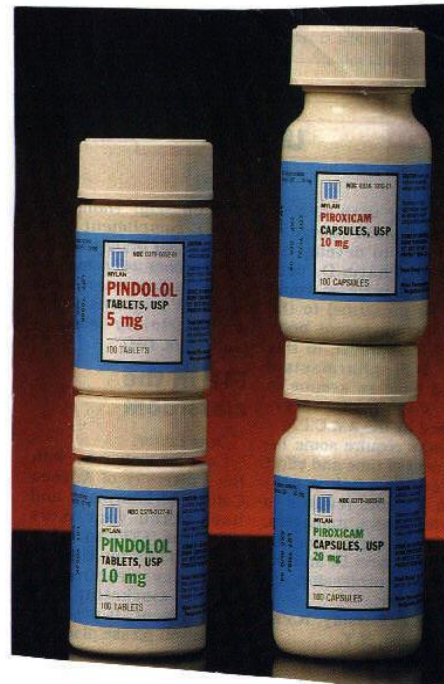
Confirmation Bias



“IT AIN’T WHAT YOU
KNOW THAT GETS
YOU IN TROUBLE, IT’S
WHAT YOU KNOW
FOR SURE THAT
AIN’T SO”

~ Mark Twain

PARIS
IN THE
THE SPRING



Goldline[®]

NDC 0182-1494-89

HYDROXYZINE HCl
TABLETS, USP

50 mg

Rx only

For full prescribing information,
see enclosed package insert.

100 COUNT
UNIT DOSE TABLETS

EACH
Hydr

WAR

Store

Man
GOL
Miar
by: S
East
0698F

Goldline[®]

NDC 0182-0555-89

HYDRALAZINE
HYDROCHLORIDE
TABLETS, USP

50 mg

Rx only

For full prescribing information,
see enclosed package insert.

100 COUNT
UNIT DOSE TABLETS

EA
Hy

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an

M
G
Mi
by:
Ea
05















Health Canada Guidance for Review of Drug Brand Names

Regulatory Authority

The *Food and Drug Regulations* require that a product name and an assessment of the brand name be provided in a drug submission as part of the information required to evaluate the safety and effectiveness of the product. The assessment is to determine that the names of drugs will not be confusable with one another. If confusion with the proposed brand name is considered likely and could result in safety concerns, then the Health Products and Food Branch (HPFB) can refuse to issue an NOC (for new drugs only) or a Drug Identification Number (for new drugs and existing drugs) as per **C.01.014 and C.08.004 of the *Food and Drug Regulations*.**

Products Covered by this Guidance

- ✓ Pharmaceutical Prescription Drugs
- ✓ Schedule D products (Biologics)
- ✓ Schedule C products (Radiopharmaceuticals, kits)
- ✓ Drugs sold to the general public with the intervention of a pharmacist (nitroglycerin, insulin, injectable epinephrine)
- ✓ Drugs sold directly to healthcare professionals for their use (e.g., anesthetics)

Products NOT Covered

- ✓ Disinfectants
- ✓ Non-prescription (OTC) products and natural health products
- ✓ Non-proprietary names (proper/common name)

A LASA Assessment is Required

- ✓ New Drug Submission (NDS)
- ✓ Supplement to a NDS (SNDS)
- ✓ Abbreviated New Drug Submission (ANDS)
- ✓ Supplement to a ANDS (SANDS)
- ✓ Applications for Drug Identification Numbers – DINA and NINB (including labeling only)

Review Timelines

- ✓ 90 day review clock for submissions that involve a target of 180 days or longer. However, our clients experience longer review times.
- ✓ An additional abbreviated review conducted 30 days prior to issuance of NOC/DIN in order to look at recent approvals for conflicts.

International Submission

- ✓ International data and submissions in lieu of Canadian data is **not recommended by DSI**, but Canada allows if:
 - The name is run through POCA within the Drug Product Database (DPN) and Licensed Natural Health Product Database (LNHPD) and the names identified in the International study are **IDENTICAL** to those identified in Canada.
 - Medication use process and indications, etc. should be the same in Canada as studied in other regions.
 - A similar FMEA process must be conducted

Initial Pre-Screen

- ✓ Is the name/modifier misleading or promotional?
- ✓ Does the name imply an ingredient not included in the product?
- ✓ Is the name identical to another product containing a different ingredient?
- ✓ Does the name have a USAN/INN stem in the position defined by USAN/INN?
- ✓ Does the name favor one ingredient?
- ✓ Does the name conflict with Schedule A of the *Food and Drugs Act*?

Other Pre-Screening Questions

- ✓ Is the name the same/similar to a discontinued product?
- ✓ Does the name have a confusable abbreviation (e.g., OD, QD)?
- ✓ Does the modifier have a single letter or number?
- ✓ Does the name imply a medical term or acronym?
- ✓ Does the name contain a letter sequence/stem that is in a different position designated by USAN/INN?
- ✓ Is the proper/common name abbreviated or truncated?
- ✓ Is the name approved in another country for a product with a different medicinal ingredient?

LASA Brand Name Assessment

- ✓ Search
 - Names with POCA scores of 50% or higher in the Drug Product Database and Licensed Natural Health Products Database
 - Published literature for error reports
- ✓ Simulate
 - Develop a process map
 - Simulations using 100 Canadian HCP's (25% French Speaking)
- ✓ Synthesize
 - FMEA (12 active HCP's)
 - Report

Summary

- ✓ Goes into effect June 13, 2015
- ✓ Data “required” for submissions
- ✓ Requires a Sample Size of 100 Healthcare Professionals and a FMEA panel consisting of 12 additional Healthcare Professionals.
- ✓ OTC products are excluded
- ✓ FDA’s POCA is required for selection of all names in Canada exceeding 50% similarity
- ✓ Robust Data Analysis required

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Thank You!!!

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