Pilot Program to Evaluate Proposed Name Submissions

Public Workshop

June 5 and 6, 2008

CDER's Current Process for Proprietary Name Analysis

Public Workshop
June 5 and 6, 2008

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Office of Surveillance and Epidemiology

Medication Error Definition

"Any **preventable** event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer" **(NCCMERP.org)**

Rationale for Proprietary Name Analysis

- Drug names are a critical "identifier" of the intended product in the U.S. market
- Drug name confusion or identification failures lead to error
- Medication errors have been shown to cause patient harm

CDER Proprietary Name Analysis

- Review Begins:
  - Phase II of IND, NDA/BLA, or ANDA
  - Two proposed names
    - Primary (1st choice)
    - Secondary (2nd choice)
- Re-reviewed:
  - IND to NDA/BLA
  - 90 days prior to NDA/BLA/ANDA approval

Primary Areas of Focus

- Promotional
  - Conducted by Division of Drug Marketing, Advertising, and Communications (DDMAC)
  - Opinion included in OSE review
- Safety
  - Conducted by Division of Medication Error Prevention

Focus of Safety Review

- Avoidance of Error
- Identify error prone aspects of product
  - Name
  - Label
  - Labeling
  - Packaging
  - Product design

Safety Review Process

- Hypothesis Generation
  - Orthographic (Look-alike)
  - Phonetic (Sound-alike)
- Risk Assessment
  - Failure Modes and Effects Analysis (FMEA)

Consider Entire Medication Use System

- Procuring and Storing
- Prescribing/Ordering
- Dispensing
- Administering
- Monitoring

CDER Proprietary Name Analysis

- Product characteristics must be provided for analysis
- Any or all product characteristics can increase or decrease risk

Product Characteristics

- Drug name (Proprietary & Established name, Suffix, etc.)
- Indications
- Patient population, prescriber population
- Dose, strength(s), dosage form
- Unit of measure, typical quantity or volume
- Route of administration
- Frequency of administration
- Instructions for Use
- Product Packaging
- Physical attributes
- Storage conditions
- Setting of use
- Contraindications, etc.

Preliminary Screening

- US Adopted Name (USAN) stem
- Dosing interval (e.g., NameBID)
- Dosage form/route of administration (e.g., Nametabs)
- Medical and/or product name abbreviations
- Misleading or ambiguous

Hypothesis Generation

- Search for Look-alike and/or Sound-alike confusion
  - Literature
  - Textbook
    - (e.g., Drug references)
  - Computer databases for existing or proposed names
    - (e.g., Internet, Saegis, POCA, etc.)

Hypothesis Generation (2)

- Expert Panel Discussion
  - Safety Evaluators
  - Rely on clinical, regulatory, and professional experiences
- Name Simulation Studies
  - Studies are conducted with ~120 FDA volunteers
  - Provide qualitative information for predicting orthographic and/or phonetic vulnerability of a name

Risk Assessment

Failure Modes and Effects Analysis (FMEA)

- Identifies failure causes
  - Where and how confusion might occur in the medication use system
  - Everyone in the medication use process considered
- Determines failure effects
  - Can confusion conceivably result in error in the usual practice setting?

Risk Assessment (2)

Failure Modes and Effects Analysis (FMEA)

- Labeling and Packaging Analysis
  - also apply principles of Human Factors

Criteria for Objecting to a Proprietary Name Include:

- USAN Stem
- Misleading or ambiguous
- DDMAC objection
- 21 CFR 201.10 (c)(5)
  - spelling & pronunciation similarity
- FMEA findings
- Other

Overall Safety Recommendations

- Acceptability of Name
- Areas of concern with Label, Labeling, Packaging, and Product design
- Other safety concerns

Summary

- Drug names, labels, packaging, and product design are major contributors to medication error
- Risk for error must consider how the drug name and its product characteristics are used in the medication use system
- The predictable nature of errors provides opportunity for better name and product design to enhance safety

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CBER's Current Process for Proprietary Name Analysis

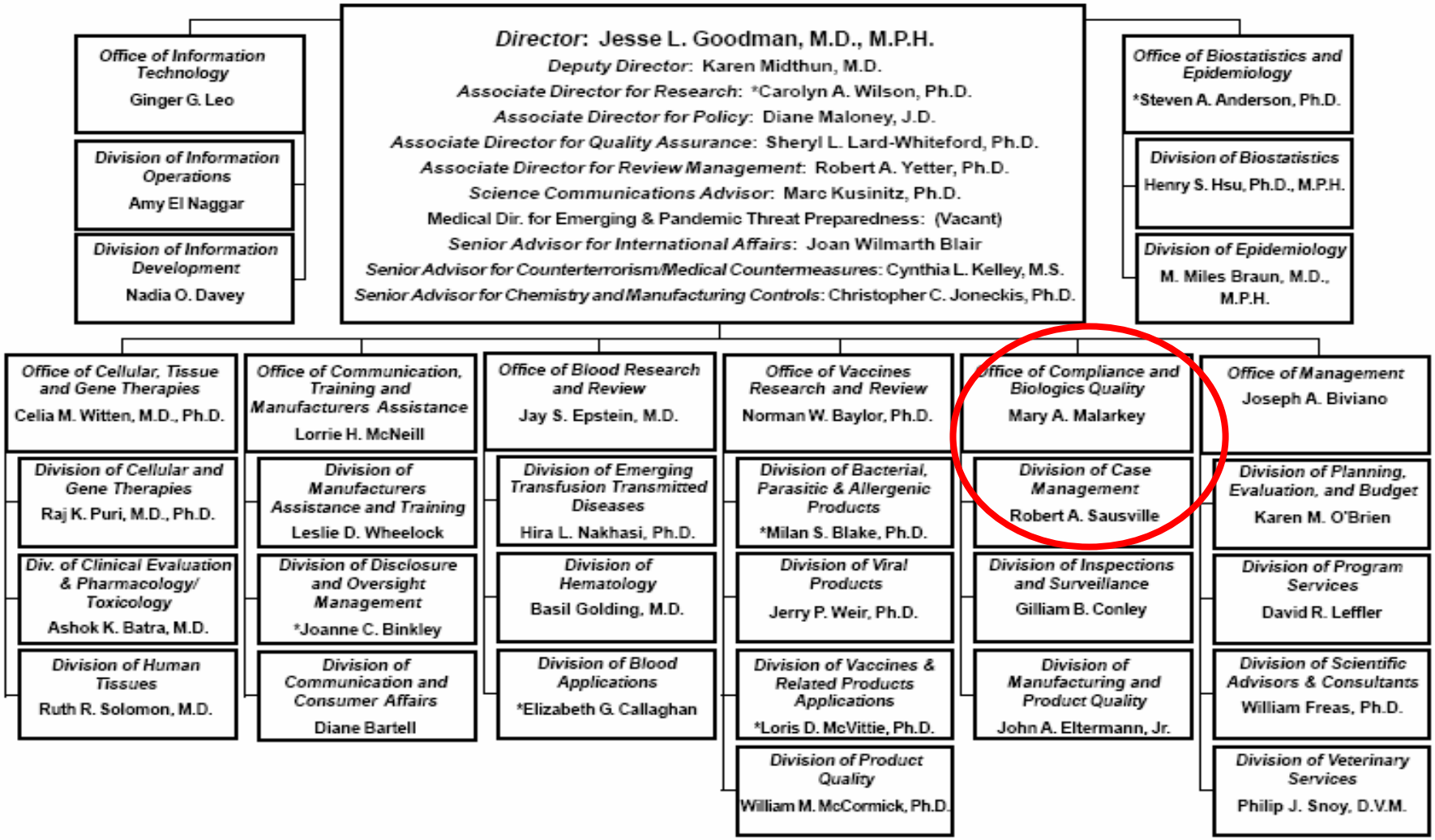
Public Workshop
June 5 and 6, 2008

Ele Ibarra-Pratt, R.N., M.P.H.
Branch Chief
Advertising and Promotional Labeling Branch
Division of Case Management
Office of Compliance and Biologics Quality

Objectives

- APLB Overview
- CBER PNR Review Process
- Resources

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH



*Acting

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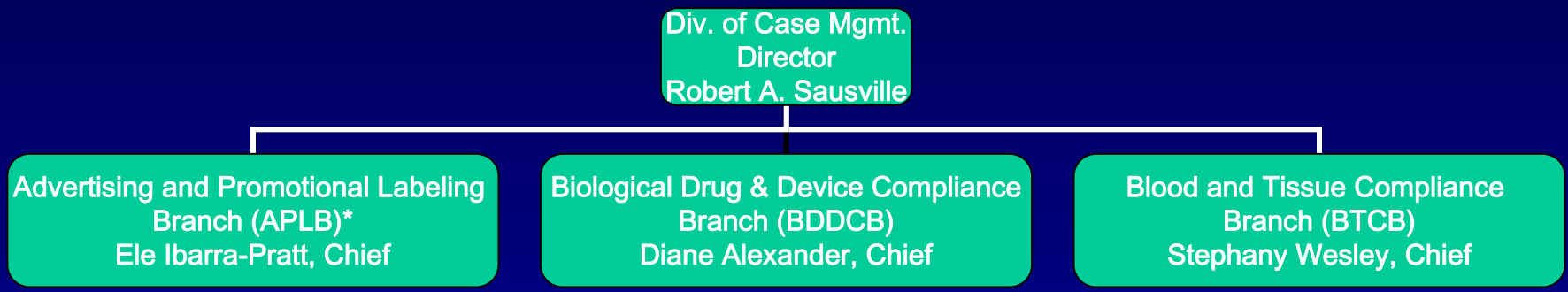
Who We Are: APLB Staff



***5 APLB Reviewers**
One Vacancy

What We Do

- Evaluate proposed proprietary names
- Review final and draft promotional materials
- Evaluate complaints
- Assist in the review of proposed labeling
- Evaluate blood donor incentive programs

CBER's Proprietary Name Review (PNR) Process

- **Policy**
  - APLB conducts the primary analysis of proposed proprietary names
  - The Product Office makes the final decision on the acceptability of the names, in collaboration with APLB

CBER's PNR Process (2)

- **Review Process**
  - Analysis from both safety and promotional perspectives
  - Search of various databases for sound-alike/look-alike names
  - Name simulation studies are not conducted

CBER's PNR Process (3)

- **Review Process**
  - APLB works with the product office and/or other staff (e.g., medical officers, OBE staff, CDER)
  - Recommendations are signed-off by APLB Reviewer, APLB Branch Chief, Division Director (DCM) with concurrence by the Office Director (OCBQ)

Resources

- APLB Questions
  - Phone: 301-827-3028
  - Fax: 301-827-3528

- CBER Questions
  - 1-800-835-4709 or 301-827-1800
    octma@cber.fda.gov or matt@cber.fda.gov

Resources (2)

- Website
  - http://www.fda.gov/cber
- Guidances
  - http://www.fda.gov/cber/guidelines.htm
  - http://www.fda.gov/cder/guidance/index.htm

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Assessing Proposed Proprietary Names in Pilot Program: Safety Review

Kellie Taylor PharmD, MPH
Division of Medication Error Prevention
Office of Surveillance and Epidemiology (OSE)

Pilot Program: Safety Review

- To enable pharmaceutical firms to evaluate their proposed proprietary name and submit the data gathered from those evaluations to FDA for review

- May help to ensure that pharmaceutical firms choose appropriate proprietary names for their products and avoid names that are likely to lead to medication errors

Pilot Program Design

- Recommend best practices that pharmaceutical firms may use when carrying out their own proprietary name reviews

- Best practices largely based on FDA's current review process

Safety Review Process Objectives

- Generate a list of names that could be confused with the proposed proprietary name

- Test the likelihood of confusion between these names and the proposed names

Conduct Preliminary Screening

- Dosing Interval (e.g. NameBID)
- Dosage form and Route of Administration (e.g. Nametabs)
- Medical and/or Product Name Abbreviations
- Names that include or suggest the composition of a drug product

Search USAN's Stem List

- Reserve stems for established names
- Proposed proprietary names that contain USAN Stems may not be viable candidates

Identify Names with Orthographic and Phonetic Similarities

Consider:

- Spelling of the name
- Appearance of the name when scripted
  - Examine handwriting samples
- Pronunciation of the name when spoken
  - Consider sponsor's intended pronunciation along with unaided pronunciation to account for variations

- Compare to existing proprietary and established names in publicly available databases

Employ Computational Methods

- Algorithms can detect the similarity of product names from a phonetic perspective, orthographic perspective, or both
- Useful in hypothesis generation, but not testing

Collect Medication Error Data

- If active ingredient is marketed domestically or abroad
- Relevant information would include any error reports related to the product nomenclature, active ingredient, package, and/or the label and labeling
- Obtain data from the published literature or relevant medication error databases

Conduct Name Simulation Studies

- Goal: to provide a descriptive assessment
- Test the response of practitioners to a proposed name by asking them to use the name in a simulation environment
- Simulate real use conditions: lined paper, prescriptions pads, handwriting, etc.
- Present the name with corresponding product characteristics that are likely to be used to communicate prescriptions and orders

Name Simulation Studies (NSS)

- To detect close to zero percentage error rate with statistical significance would require a prohibitively large sample size (FDA statisticians calculated ~26,000)
- Instead, assess performance through a well-designed parallel group observational study in which each group represents different prescribing scenarios

NSS: Participants

- Current prescribers, transcribers, dispensers and administrators
- Representative of the full range of persons involved
- Include generalists, even if the proposed drug is a specialty product
- Each participant should participate only once

NSS: Testing Scenario Recommendations

- Minimum of 20 scenarios
- Represent each possible prescribing condition for the proposed drug
- Test each prescribing condition several times
- Embed test name into a list of two to three other names of marketed drugs to mimic real world setting
- Verbal scenarios should include unaided pronunciation in addition to sponsor's intended pronunciation

NSS: Data Collection

- Interview participants at the end of testing to gather additional qualitative data
- Record all *verbatim* responses
- Code responses and analyze data

Safety Review Process Objectives

- Generate a list of names that could be confused with the proposed proprietary name

- Test the likelihood of confusion between these names and the proposed names

Failure Modes and Effects Analysis

- Systematic, prospective method used to examine the nomenclature for possible ways in which a failure (i.e. error) can occur
- Consider the intended indication and product characteristics and anticipate the use of the product under the proposed prescribing conditions
- Identify failure modes and analyze effects

Assemble FMEA Team

- Multidisciplinary
- Should include health professionals with experience in actual-use settings and members with expertise in the field of medication error prevention
- Typically, 8 to 12 members

FMEA: Identify Failure Modes

- Compare the proposed proprietary name to all the names gathered during the safety review

- Ask two questions to assess the vulnerability of the proposed name to misinterpretation and confusion

Identify Failure Modes

- Could the similarity of this proposed proprietary name to other proprietary or established names cause the names to be confused with one another at any point under the proposed prescribing conditions?

- Are the other potential aspects of the proposed proprietary name, unrelated to the orthographic and phonetic similarity that could be misleading and cause confusion at any point under the proposed prescribing condition?

Identify Failure Modes (2)

- If the answer is “no,” provide Centers with relevant information to determine the similarity will not lead to confusion or error

- A “yes” response indicates a failure mode and potential effect should be evaluated to determine if the confusion may lead to medication error

FMEA: Analyze Failure Effects

- Could this confusion result in medication error in the usual practice setting?

FMEA: Analyze Failure Effects

- Submit the FMEA findings if the confusion is unlikely to ultimately cause a medication error

- If the effect of the failure is determined to be a source of medication error under the proposed prescribing conditions
  - Evaluate an alternate name
  - Justify why the findings might not lead to error
  - Justify why the risk of error is acceptable
  - Suggest other risk-reduction strategies (e.g. product reformulation, modifiers)

Questions for Panel 1

- Describe the strengths and limitations of the proposed approach as outlined in the previous presentation

- Identify alternate approaches and methods to FDA's proposal, if any, and describe what they can offer

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Nonprescription Drug Regulation

Susan Johnson, Ph.D.
Associate Director

Office of Nonprescription Products (ONP)
Office of New Drugs (OND)
June 5, 2008

www.fda.gov/cder/Offices/OTC/default.htm

Over the Counter (OTC) Topics

- Regulatory Processes
  - New Drug Application (NDA)
  - OTC Drug Review (Monograph)
- Labeling
- Proprietary Names

To Market an OTC Under an NDA

- NDA process is generally the same for OTC and prescription drugs
- Industry applicant submits NDA to FDA containing:
  - Clinical data to support safety and efficacy
  - Proposed labeling, including proprietary name
  - Sometimes, consumer studies are required
    - Labeling Comprehension
    - Self Selection
    - Actual Use

To Market an OTC Under an NDA (2)

- FDA reviews NDAs based on a timeline mandated by Congress (PDUFA)
- An FDA approval:
  - Is required prior to marketing
  - Is specific to a product
  - May provide marketing exclusivity
- NDA is mechanism for switch from Rx to OTC status

To Market an OTC Under an NDA (3)

- Safety review is conducted by DMEDP on proposed proprietary name
- One or more proprietary names are initially approved with the NDA
- Industry has been allowed to:
  - Change or add a proprietary name (e.g., for line extensions)
  - Market the same product with multiple proprietary names (e.g., for various distributors)

To Market an OTC Under the OTC Drug Review

- The OTC Drug Review is a regulatory system that:
  - Is based on ACTIVE INGREDIENTS rather than products
  - Was established to pertain to OTC drugs marketed prior to 1972
  - Has provisions for new ingredients to be added
  - Is based on FDA evaluation and a series of public rulemaking steps
  - Defines allowable conditions for marketing in OTC Monographs

To Market an OTC Under the OTC Drug Review (2)

- Active ingredients that have been found to be Generally Recognized As Safe and Effective (GRASE) under the monograph can be used in drug products that:
  - Can be marketed with indications and other labeling specified in the monograph
  - Do not require FDA approval prior to marketing
  - Require product registration and compliance with monograph regulations

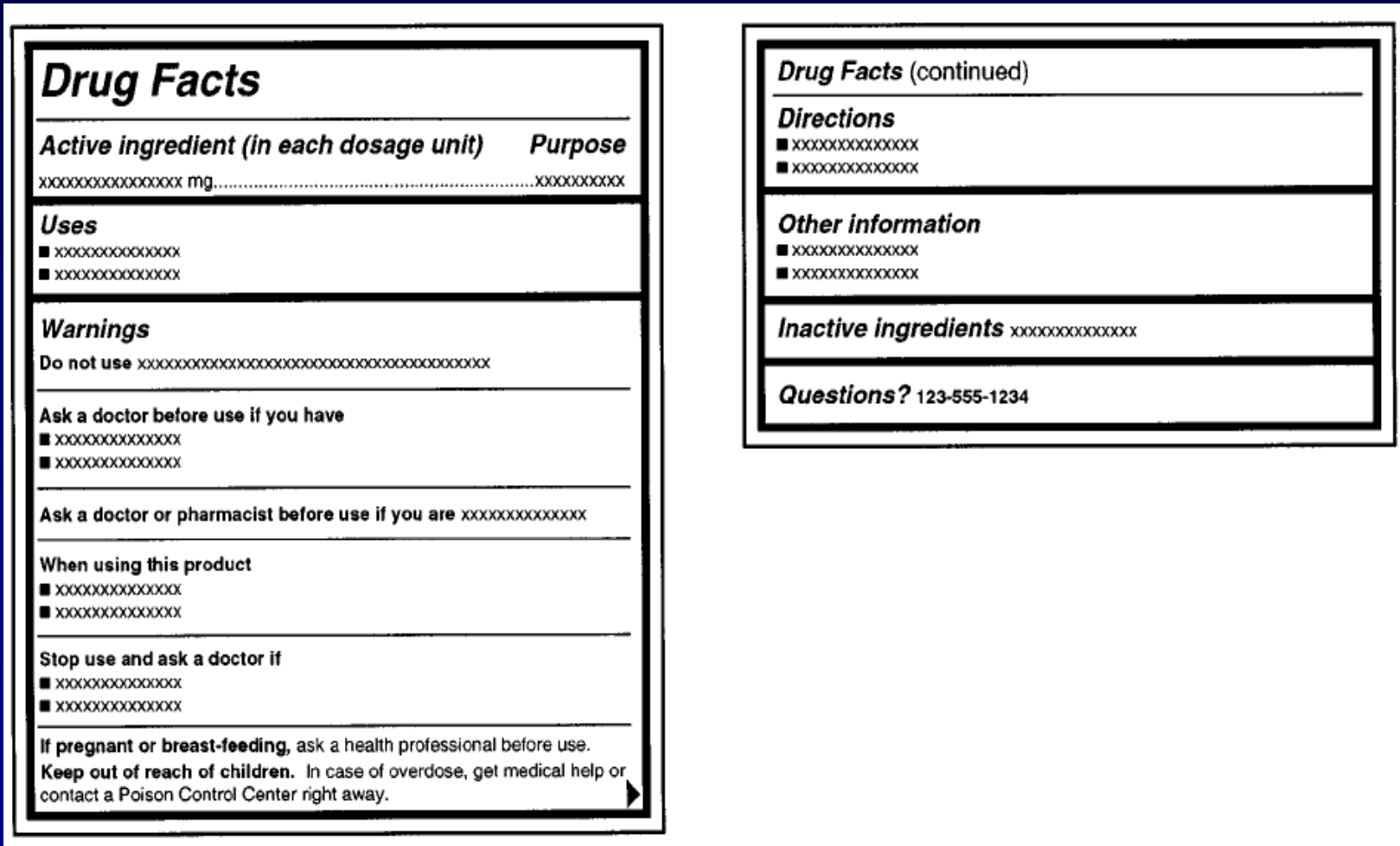
To Market an OTC Under the OTC Drug Review (3)

- Proprietary names for OTC monograph products are not reviewed by FDA prior to product marketing

Labeling for All OTC Products

- All labeling is directed to the consumer
- Content of labeling needs to ensure that consumers can adequately diagnose and treat their condition, without healthcare provider supervision
- “Drug Facts” format is required
- FDA regulates OTC labeling
- Federal Trade Commission (FTC) regulates OTC advertising

Drug Facts



Drug Facts

Active ingredient (in each dosage unit) **Purpose**

xxxxxxxxxxxxxxxx mg.....xxxxxxxxxx

Uses

- xxxxxxxxxxxxxx
- xxxxxxxxxxxxxx

Warnings

Do not use xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Ask a doctor before use if you have

- xxxxxxxxxxxxxx
- xxxxxxxxxxxxxx

Ask a doctor or pharmacist before use if you are xxxxxxxxxxxxxx

When using this product

- xxxxxxxxxxxxxx
- xxxxxxxxxxxxxx

Stop use and ask a doctor if

- xxxxxxxxxxxxxx
- xxxxxxxxxxxxxx

If **pregnant or breast-feeding,** ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Directions

- xxxxxxxxxxxxxx
- xxxxxxxxxxxxxx

Other information

- xxxxxxxxxxxxxx
- xxxxxxxxxxxxxx

Inactive ingredients xxxxxxxxxxxxxx

Questions? 123-555-1234

Proprietary Names for All OTCs

- Part of labeling
- May affect consumers' ability to identify products, self-select and use products
  - Additional data are needed
- Manufacturers may be subject to enforcement actions if marketing a product with a proprietary name that is found to be false or misleading (e.g., CureItAll)

Questions for Panel 2

- Nonprescription drug products approved under an NDA may participate in the pilot program. Given differences between nonprescription and prescription product regulation and use, should proposed proprietary name review and methods be the same? Please explain why or why not.

- Identify any additional studies that could generate relevant data to support the safety review for nonprescription products.

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Overview of Current Promotional Review Process for Proposed Proprietary Names

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Carrie Newcomer, PharmD
Consumer Promotion Analyst
Michelle Safarik, PA-C
Regulatory Review Officer
Division of Drug Marketing, Advertising, and Communications
Office of Medical Policy

Objectives

- Provide an overview of how the Division of Drug Marketing, Advertising, and Communications (DDMAC) in the Center for Drug Evaluation and Research (CDER) is involved as a consultative Division in the review of proposed proprietary names

- Discuss the process of how DDMAC evaluates proposed proprietary names from a promotional perspective

Consultative Process

- The Office of New Drugs (OND) consults the Division of Medication Error Prevention to evaluate proposed proprietary names from a safety perspective

- The Division of Medication Error Prevention consults DDMAC to evaluate proposed proprietary names from a promotional perspective

DDMAC Consultative Team

- DDMAC Reviewers
- Social Scientists
- Regulatory Counsel

Evaluation Process

- All DDMAC Reviewers are given the opportunity to comment on proposed proprietary names

Evaluating Proposed Proprietary Names

- DDMAC evaluates proposed proprietary names using the same analysis it employs for promotional materials
  - Overstate the efficacy?
  - Minimize the risk?
  - Broaden the indication?
  - Unsubstantiated superiority claims?
  - Overly fanciful?

Evaluating Proposed Proprietary Names (2)

- Analysis for each proposed proprietary name includes
  - Comparison of sounds and words formed by the proposed proprietary name to the proposed indication
  - Review of proposed proprietary names in different languages
    - Latin and Spanish

DDMAC Consult

- Lists unobjectionable and objectionable proposed proprietary names
  - Explains rationale for any objections

Regulatory Provisions

- Please note that the Federal Food Drug and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made, whether through a proposed trade name or otherwise; this includes suggestions that a drug is better, more effective, useful in a broader range of conditions or patients, safer, has fewer, or lower incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence or substantial clinical experience
- *See* 21 U.S.C 321(n); *see also* 21 U.S.C. 352(a) & (n); 21 CFR 202.1(e)(5)(i);(e)(6)(i)

Regulatory Provisions (2)

- The proposed proprietary name suggests that the drug has some unique effectiveness or composition attributable to the product when in fact the drug is a common substance, the limitations of which are readily recognized when it is listed by its established name

- *See* 21 CFR 201.10(c)(3)

DDMAC Response Forwarded to OND

- If the Review Division objects to the proposed proprietary name, the Division of Medication Error Prevention does not begin its safety review of the proposed proprietary name and the sponsor is notified by the Review Division
- If the Review Division does not object to the proposed proprietary name, the Division of Medication Error Prevention begins its safety review of the proposed proprietary name

Sponsor Informed of Objection

- Sponsor may submit an alternative proposed proprietary name for review
- Sponsor may submit a rebuttal to the Review Division
  - DDMAC reviews rebuttal to determine if the objection will be maintained
  - Review Division notifies sponsor of outcome

In Summary

- DDMAC serves as consultants to the Division of Medication Error Prevention and the Review Divisions in OND in evaluating proposed proprietary names from a promotional perspective
- DDMAC evaluates proposed proprietary names using the same analysis as it employs for its review of promotional materials, and enlists social science and legal perspectives in its evaluation

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Assessing Perceptions of Tradenames from a Promotional Standpoint: Proposed Study Design

Kathryn J. Aikin, Ph.D.
Social Science Analyst
Division of Drug Marketing, Advertising and Communications, FDA

Presentation Outline

- Current Legislation
- Draft Study Design

FDAAA of 2007

TITLE I—PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

SEC. 101. SHORT TITLE; REFERENCES IN TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ‘‘Prescription Drug User Fee Amendments of 2007’’.

(b) REFERENCES IN TITLE.—Except as otherwise specified, amendments made by this title to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated toward expediting the drug development process and the process for the review of human drug applications, including postmarket drug safety activities, as set forth in the goals identified for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

PDUFA IV Drug Safety Five Year Plan (Draft, March 2008)

6.7 Increasing Timely, Consistent Review of New Drug Trade Names to Prevent Name Confusion

6.7.3 Conducting a Pilot Program

Within the PDUFA IV program, FDA committed to developing and implementing a pilot program to enable pharmaceutical firms participating in the pilot to evaluate proposed proprietary names and submit the data generated from those evaluations to the FDA for review

www.fda.gov/cder/pdufa/PDUFA_IV_5yr_plan_draft.pdf

Five Year Plan (2)

6.7.3 Conducting a Pilot Program (continued)

The public meeting will include discussion of:

- Elements necessary to create a concept paper describing the logistics of the pilot program,
- Contents of a proprietary name review submission, and
- Criteria to be used by FDA to review submissions under the pilot program

www.fda.gov/cder/pdufa/PDUFA_IV_5yr_plan_draft.pdf

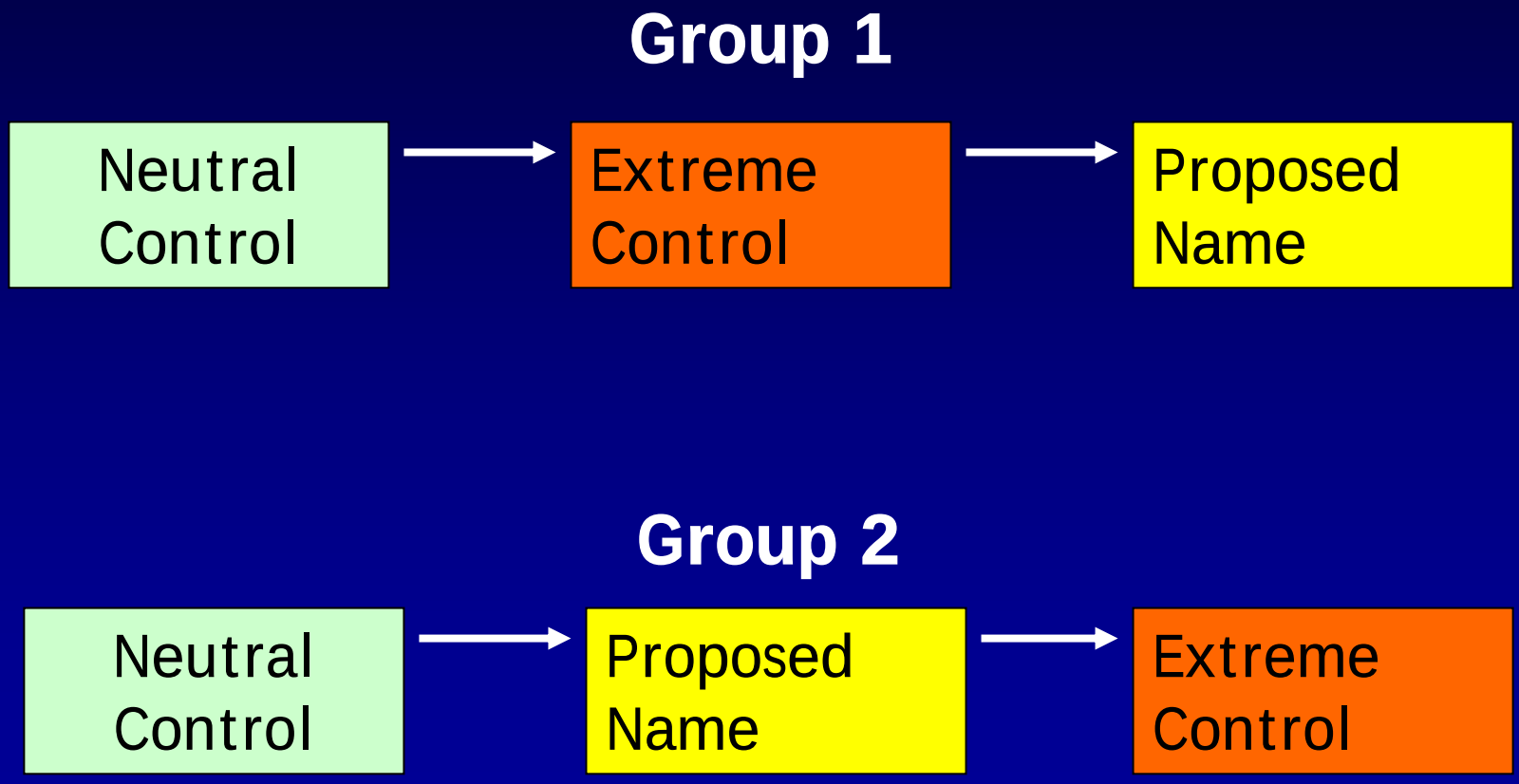
Evaluation Approach

- Safety perspective
- Promotional perspective
  - Empirical measurement

Proposed Study Design: Variables

- Neutral Control = makes NO representations or suggestions about product
- Extreme Control = makes CLEAR representations or misrepresentations about product
- Proposed Proprietary Name

Proposed Study Design



Questionnaire and Sample

- Open ended and closed ended questions
  - Open ended ex: "What does the name DRUG X say or suggest about its effectiveness in treating CONDITION Y ?"
  - Closed ended ex: "How effective or ineffective do you think DRUG X would be in treating CONDITION Y?"
    - 1(very ineffective) to 5 (very effective)
- Try to avoid:
  - Leading Questions
  - Yea-Saying

Questionnaire and Sample (2)

- Choose an appropriate test sample
  - Healthcare professionals
    - Consider who will be prescribing the product
  - Consumers

Questions for Panel 3

- Describe the strengths and limitations of the proposed approach as outlined in the previous presentation

- Identify alternate approaches and methods to FDA's proposal, if any, and describe what they can offer

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Overview of Pilot Program

Public Workshop
June 5 and 6, 2008

Carol Holquist, RPh
Director, Division of Medication Error Prevention
Office of Surveillance and Epidemiology

Objectives

- Pilot Logistics
- Parallel Review
- Regulatory Decision
- Pilot Evaluation

Pilot Logistics

- 2 year Pilot
  - Begin by end of ~ FY '09
- Representative Sample
  - Large & small companies
  - IND, NDA, BLA, & ANDA
- Voluntary Enrollment
  - Advanced registration
  - 25 to 50 total submissions

Pilot Logistics (2)

- 120 day notice prior to submission
  - Answer written questions
- Alternate Methods
  - Promptly inform Centers
  - No prior approval of methods
  - Evaluation will occur during review cycle

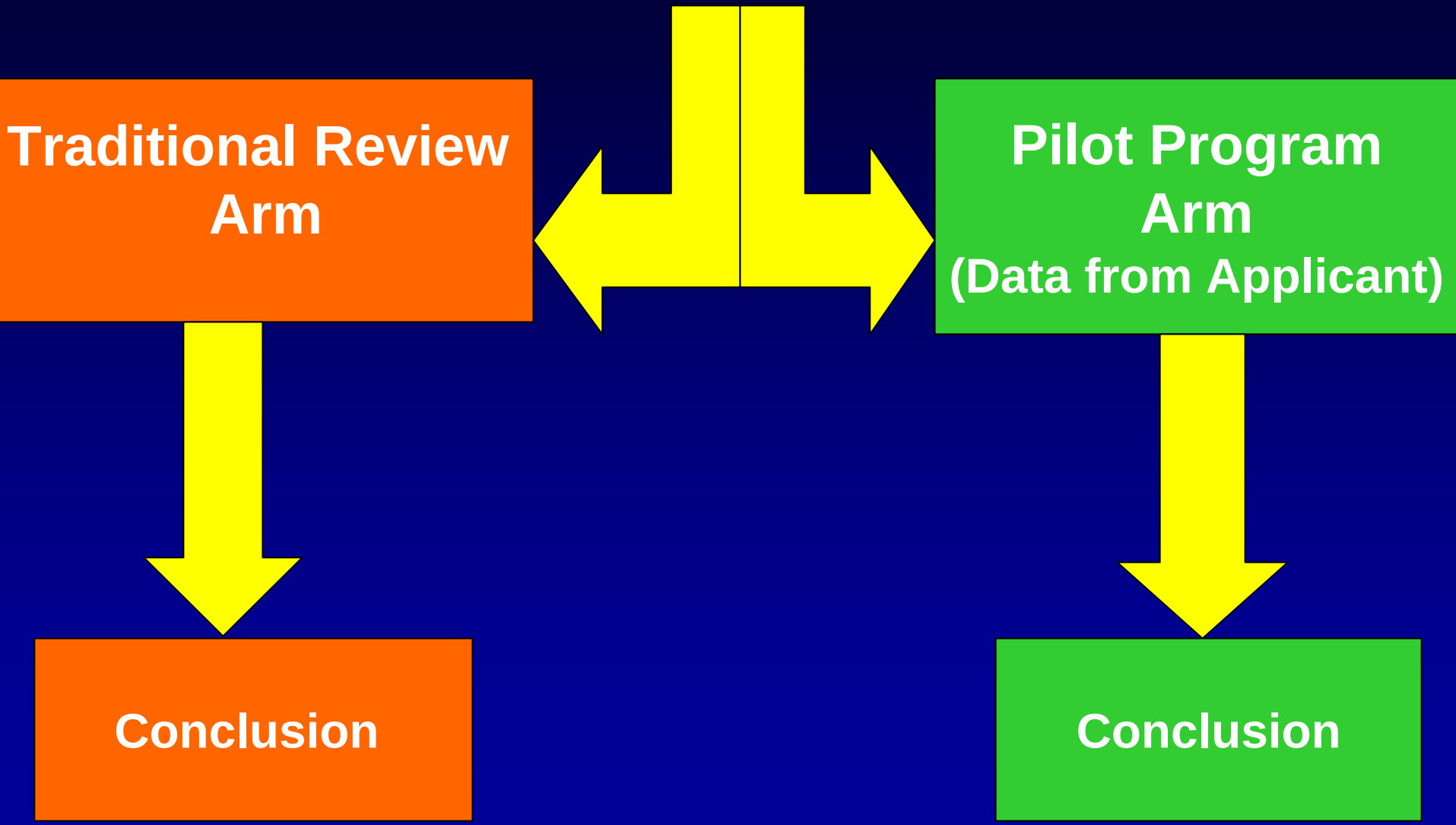
Pilot Logistics (3)

- Comprehensive Submission
  1. Data Required for Traditional Review
     - Labels & Labeling
  2. Applicant's Comprehensive Data Driven Analysis
     - Clear description of methods & analysis
     - Data sources
     - Data
- Primary and Alternate Name Identified

Pilot Logistics (4)

- Review clock begins once comprehensive submission received
- Review Timelines
  - PDUFA IV
    - 180 days for IND
    - 90 days for NDA/BLA
  - ANDA
    - No PDUFA timeline
    - Reviewed similar to IND

Parallel Review



Parallel Review (2)

- Reviews Compared
  - Note differences in data, analyses & findings
- Acceptability of the name will be based on all available data

Criteria for Objecting to a Proprietary Name Include:

- USAN Stem
- Misleading or ambiguous
- DDMAC objection
- 21 CFR 201.10(c)(5)
  - spelling & pronunciation similarity
- FMEA findings
- Other

Decision Rendered

Applicant Notified
Review Clock Stops

Acceptable
Name Re-reviewed:
At NDA if reviewed as IND & 90 days prior to approval for NDA/BLA/ANDA

Unacceptable
Notified in Writing with Rationale

New Review Clock Starts:
Confirmed that alternate name is still viable
OR
New alternate name submitted

Pilot Evaluation

- End of FY ‘11 or upon 2 years of accumulated data
- FDA will assess:
  - Adequacy & limitations of data submitted in support of name
  - Focus on differences between FDA & Applicant’s data, findings & conclusions
- Public Meeting to discuss overall findings
  - ~ FY ‘13
  - Determine if pilot review is better model for evaluation of names

Questions?

Questions for Panel 4

- Describe the strengths and limitations of the proposed approaches to the proposed pilot

- Given our proposal for evaluation describe the strengths and limitations of this approach of the pilot

Back Up

Drug Name Review in OTC Context: Regulatory Overview

OTC Drugs Are Regulated Under Two Systems

- New Drug Applications (NDA) under Section 505 of FDCA (21 U.S.C. § 355)
- OTC Drug Monograph

NDA OTC Drug Name Review

- FDCA requires pre-marketing approval for NDA OTC products (21 USC § 355)
- Review of NDA OTC drug products is same as review of NDA prescription drug products
  - = same drug name review

OTC Monograph Drug Review

- OTC monograph drug products do not require pre-marketing approval
- Drug products are “generally recognized as safe and effective” and not misbranded if they meet criteria set forth in specific drug category monographs (21 CFR 330.1)
- Must meet labeling content and format requirements (21 CFR 201.66)

OTC Monograph Drug Name Review

- Labeling -- including the drug name -- is not reviewed prior to marketing
- FDA invokes statutory enforcement authority to regulate names of OTC monograph drug products

FDA Enforcement Authority

- Section 301(a) of FDCA prohibits the marketing of misbranded products (21 USC § 331(a))
- Section 502 defines a product as misbranded if it has "false or misleading" labeling (21 USC § 352(a))
- Certain drug names can render labeling false or misleading

- Criteria applied in NDA name analysis can be used to support enforcement action on OTC monograph drug name
- Example: 21 CFR 201.10 describes potentially misleading names:
  - fanciful names used to imply unique effect or composition
  - names similar to different drug or ingredient
- FDA is not restricted to these criteria