

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Points to Consider

USP Hemiquinquennial ~ March, 2003

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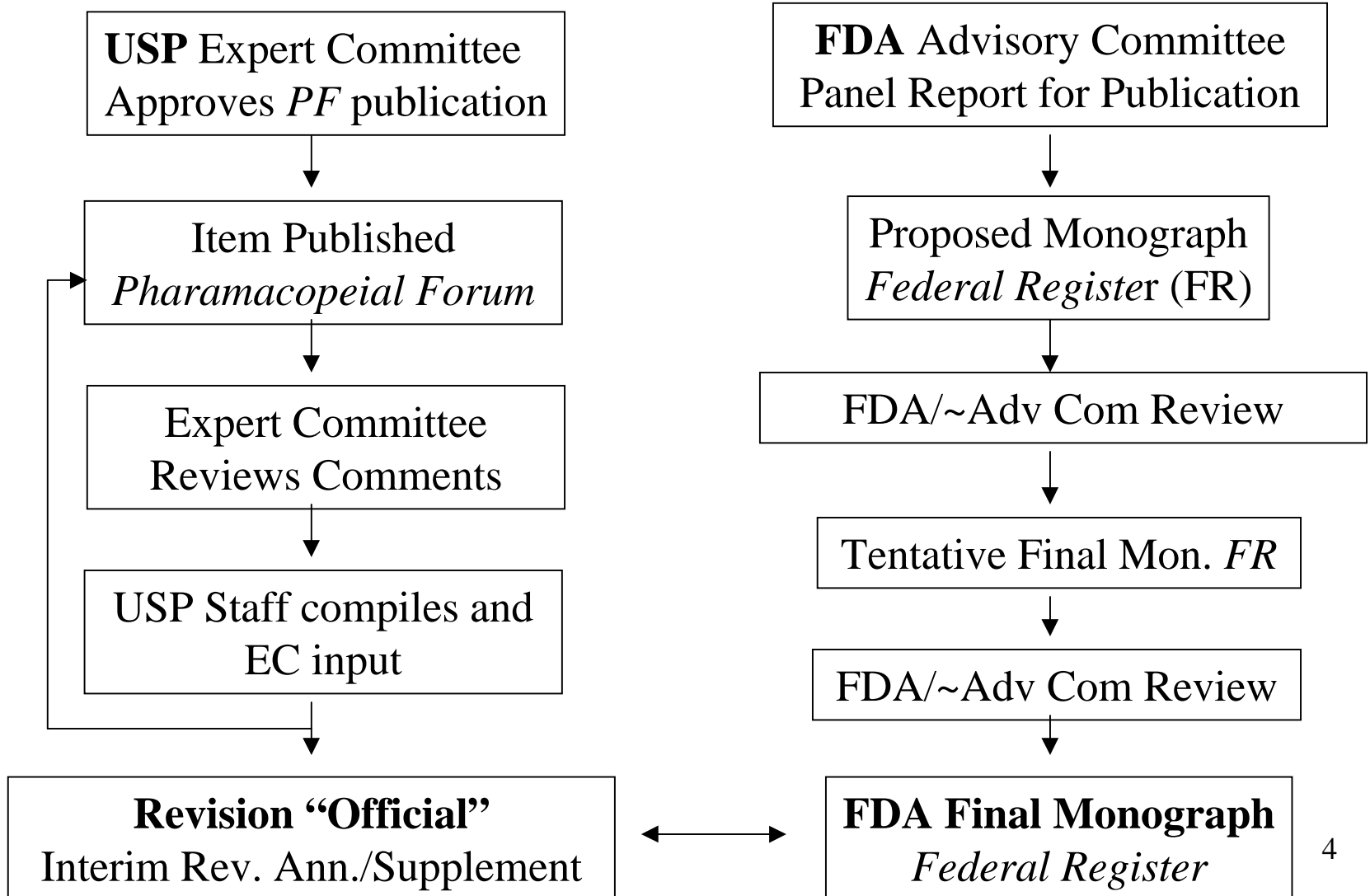
Overview

- Background on OTC Drugs
- Points to Consider
 - Risk Management
 - Evidence-based Decision Making
 - Customer Service

Background

- U.S. Regulation of OTC Drugs Under the OTC Review
 - OTC Review Monographs
- Practical Application of “USP” on the OTC Label

Drug Monograph Systems

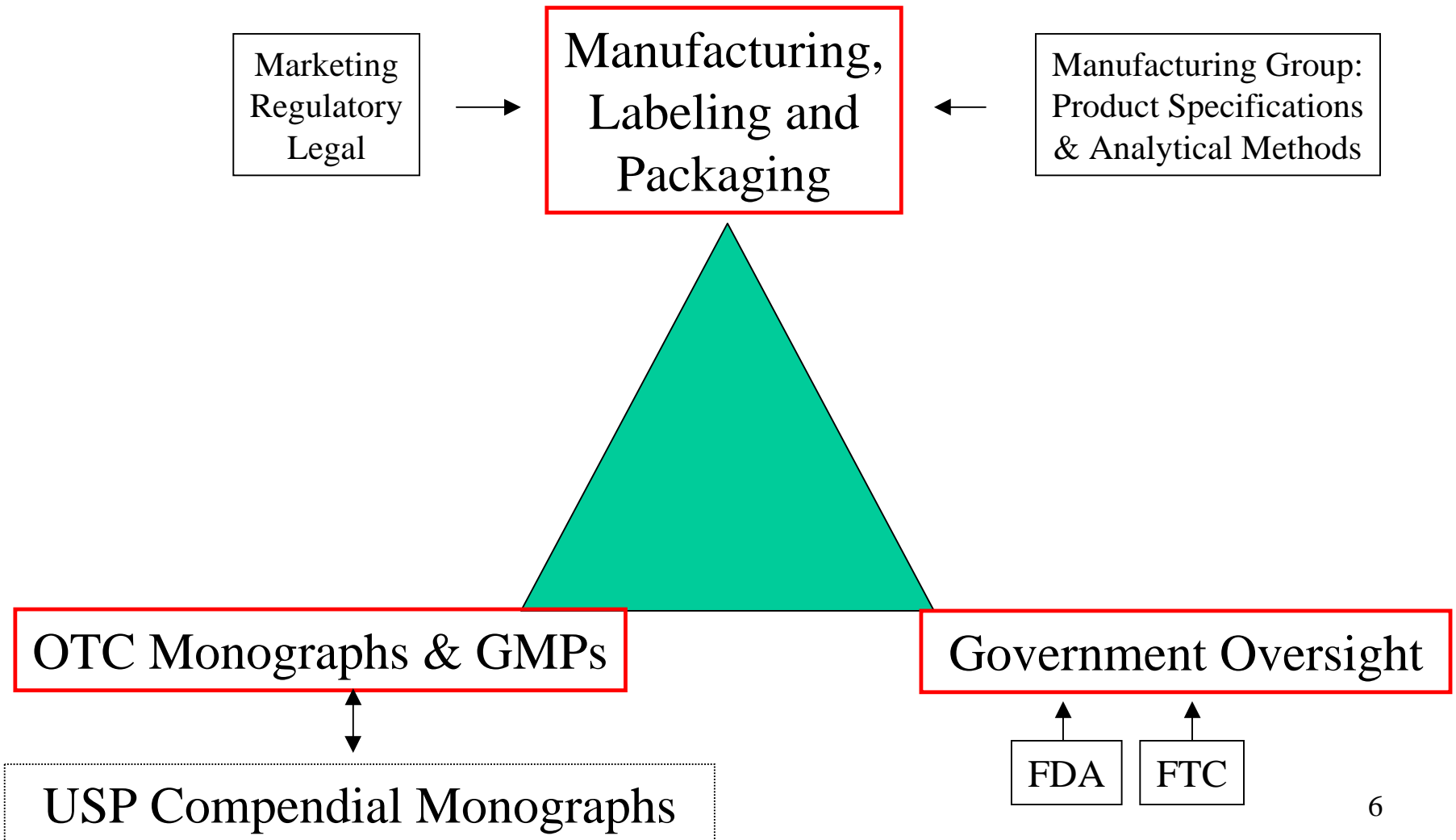


§330.10 Procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing monographs.

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- **Section (a)(2): OTC DRUG REVIEW INFORMATION:**
VII. An official United States Pharmacopeia (USP)-National Formulary (NF) drug monograph for the active ingredient(s) or botanical drug substance(s), or a proposed standard for inclusion in an article to be recognized in an official USP-NF drug monograph for the active ingredient(s) or botanical drug substance(s). Include information showing that the official or proposed compendial monograph for the active ingredient or botanical drug substance is consistent with the active ingredient or botanical drug substance used in the studies establishing safety and effectiveness and with the active ingredient or botanical drug substance marketed in the OTC product(s) to a material extent and for a material time. If differences exist, explain why.
 - **Monograph-specific performance requirements:** e.g., internal analgesics, antacids

The OTC Monograph System

Adulteration & Misbranding



Pivot Point: “USP” on the Label

- **FDA’s Inspectional Approach:**
 - Depends on whether company specifies USP on the label, in which case the company must meet the relevant USP monograph
 - If USP is not specified, the company must have validated specifications, processes and methods to support identity, strength, quality, purity, packaging, storage, and labeling

Points to Consider

- **Points to Consider:**
 - Risk Management
 - Evidence-based Decision Making
 - Customer Service

Risk Management

- **Risk** - combination of the probability of occurrence of harm and the severity of that harm [ISO/IEC Guide 51:1999, definition 3.2].
- **Risk management:**
 - CDER: Patient safety and quality initiatives
 - CFSAN: Operational Risk Management
 - Other government agencies, as well
- **Message:** “*RM*” *defines relevance, today*

Risk Management

- **Examples:**

- **CDER:** 21 CFR Part 11: [Electronic Records and Signatures]

- **USP:**

- An Example: Implementation Times for “Official” Revisions to the USP/NF

- Risk-based approach supports different implementation times

- FDA allows different time frames (90 days - several years), depending on the issue

 *Longer time frames for issues with lower potential risk*

Evidence-Based Decision Making

- A popular term, used frequently by some government agencies/groups
 - Evidence based practice guidelines: AHRQ
- A part of formal decision making by many groups, even if by a different term
 - USP, ASTM, FDA, CDC, CPSC

Evidence-Based Decision Making

- **Relevance for the Quinquennial Process**
 - Hemiquinquennial is 2.5 years from Q'05
 - Resolutions can be “baseless”
 - Result:
 - Data-lite debates
 - “Explore the feasibility of and need for ...” language
 - Opportunity is now, to:
 - Promote the strategic plan
 - Solicit evidence-based resolutions
 - Explain difference of resolutions that initiate programs vs. explore feasibility

Evidence-Based Decision Making

- **Potential Benefits**

- Tighter discussions at the “Q”
- Better relations with those offering resolutions, because expectations pre-defined
- A chance to get better evidence to support USP initiatives, thereby helping to self-define relevance of programs

Customer Service/Focus

- ***USP does a lot right!***
- **CHPA Member Survey**
 - Some perception gaps in customer service
 - Disclaimer: *should be validated more broadly*
 - Perceptions:
 - Reported delays/inconsistencies in responses
 - Length of time of reviews; changes to anal.methods slow
 - Limited transparency to internal processes
 - Expanded global agenda may be taking focus away from U.S. concerns
 - Seems the posting of comments to revisions has less emphasis. Should there be a more public process?

Customer Service/Focus

- **Message:**
 - *“Don’t shoot the messenger”*
 - A lot is right with USP!
- Look on as an opportunity to explore even better feedback vehicles with your customers
 - Benchmarking & outcomes research ... ?

Balancing Basics Against New Directions

- What's important for the public health (“RM” approach)
- Alignment of core strengths against what is important
- Use evidence-based rationales to engage USP's strengths
- It's customer service, whatever the new strategic directions.