Dosage Form Nomenclature

Shaping the Future of Pediatric Formulation Development Workshop

LCDR Jibril Abdus-Samad, PharmD
Nomenclature and Labeling Policy Lead
CDER/OPQ/OPPQ/Compendial Operations and Standards Staff

2026 June

Disclaimer

The views and opinions expressed in this presentation represent those of the presenter, and do not necessarily represent an official FDA position.

Agenda

- Food, Drug, and Cosmetic Act and Official Compendium
- FDA Designation of Established Name
- USP <1151> *Pharmaceutical Dosage Forms*, USP *Nomenclature Guidelines* (NG)
- Updating USP General Chapters and USP NG
- FDA Designating Names for Novel Dosage Forms
- Considerations for Mini-Tablets
- Path Forward

FDCA and USP Official Compendium

- Food, Drug, and Cosmetic Act § 502(e)
  - Ingredients and drug products (DP) must have established names
  - Established name and quantity of the active ingredient(s) are required labeling
  - Article recognized in an official compendium, then use the compendial title
  - Official compendium is the United States Pharmacopeia (USP)

If no USP official title…

FDA designates an established name based upon:

- USP *Nomenclature Guidelines* (NG)
- USP <1151> *Pharmaceutical Dosage Forms*
- USP Salt Policy and FDA guidance: *Naming of Drug Products Containing Salt Drug Substances* (June 2015)
- FDA draft guidance: *Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological Products — Content and Format* (January 2018)*

*When final, this guidance will represent the FDA's current thinking.

DP Established Name Format

[Drug] {Route of Administration} [Dosage Form]

USP <1151>

Pharmaceutical Dosage Forms

- **Purpose**
  - Provides official definitions and descriptions for pharmaceutical dosage forms (DF)
  - Lists *Official Dosage Form Terms Used in Official Article Titles*
  - Includes a glossary of definitions related to DF terminology
- **Structure**
  - DF classified by physical description
  - Preferred Terms and non-preferred terms
    - E.g., Caplet – not preferred; see Tablet

USP <1151>

Pharmaceutical Dosage Forms

Official Dosage Form Terms Used in Official Article Titles

- Aerosols
- Capsules
- Cloths
- Creams
- Emulsions
- Films
- Foams
- Gases
- Gels
- Granules
- Gums
- Implants
- Injections
- Inserts
- Irrigations
- Liquids
- Lotions
- Lozenges
- Ointments
- Pastes
- Pellets
- Pills
- Powders
- Rinses
- Shampoos
- Soaps
- Solutions
- Sprays
- Sponges
- Strips
- Suppositories
- Suspensions
- Swabs
- Systems
- Tablets

Adapted from USP General Chapter <1151> *Pharmaceutical Dosage Forms* (Official as of 01-Dec-2024). Retrieved June 15, 2026

Process for Updating <1151>

- **Responsible Body**
  - The USP Dosage Forms Expert Committee (DF EC) is responsible for maintaining and revising <1151>
  - DF EC is composed of scientific experts from industry, academia, healthcare, and regulatory agencies — including FDA staff.
- **Revision Process**
  - Proposed revisions published in Pharmacopeial Forum (PF) for public comment.
  - DF EC review of public comments
  - From proposal to official publication - *approximately* 1 to 2 years

Process for Updating USP Nomenclature Guidelines

- **Responsible Body**
  - The USP Healthcare Safety, Quality, and Nomenclature Expert Committee (HSQN EC) is responsible for maintenance and revisions
  - HSQN EC is composed of scientific experts from healthcare, industry, academia, and regulatory agencies — including FDA staff.
- **Interdependency**
  - Updates to <1151> typically require corresponding updates to USP NG.
    - A new DF term added to <1151> should be reflected in the USP NG to specify how the term is used within a DP established name
- **Revision Process**
  - USP NG updated by HSQN EC in a more flexible manner compared to <1151>

FDA Designating Names for Novel DFs

- **How this works**
  - FDA considers current nomenclature resources such as USP <1151> and USP NG
  - FDA understands there is potential for USP to develop a monograph and thus an established name
- **Questions to consider**
  - Is there a current DF term that appropriate for the proposed “novel” DF?
  - Is there a current DF term that can be modified for proposed “novel” DF?
  - Are there unique concerns with the proposed “novel” DF that necessitate a new DF term?

Considerations for Mini-Tablets

- **Current Nomenclature Gap**
  - No size-based descriptor in the current Tablets framework within <1151>
  - USP NG “Tablets can be produced in a variety of sizes and shapes.”
- **What is needed**
  - A clear, agreed upon definition for <1151> that distinguishes mini-tablets from Tablets
  - Subsequent update to USP NG
- **Key Questions**
  - Should mini-tablets be named using a current DF term?
    - e.g., Oral Pellets
  - Should mini-tablets be a standalone DF term?
  - Should mini-tablets be a {Unique Descriptor} within the existing Tablets naming framework?
    - e.g., *Chewable* Tablets, *Orally Disintegrating* Tablets

Path Forward

- **Workshop partners consider the following:**
  - Developing a clear, scientifically grounded definition for 'mini-tablet' including distinguishing physical characteristics (e.g., size threshold, description of manufacturing)
  - Submitting a concept paper to both USP (DF EC and HQSN EC) and FDA/CDER/OPQ

Summary

- FDCA § 502(e) anchors DP established names in USP
- FDA designates DP established names using USP Nomenclature Guidelines and USP <1151>
- Updates to USP General Chapters take *approximately* 1 to 2 years
- Updates to <1151> typically require corresponding updates to the USP Nomenclature Guidelines
- FDA can designate DP established names with novel DFs
- Consider developing a “mini-tablet” definition and engaging USP and FDA


FDA
U.S. FOOD & DRUG
ADMINISTRATION