USP Errata Process

Sarah Gaskin
Senior Manager, Publications

200 usp
The standard of trust

What changes are considered errata?

- The definition of Errata is accessible to stakeholders in the *USP Guideline on Use of Accelerated Processes for Revisions to the USP-NF and FCC* (posted at *https://www.uspnf.com/ official-text/accelerated-revision-process*)

- "Errata refer to an accelerated revision vehicle used to correct published content in a USP compendium that does not accurately reflect the intended requirements of a standard as approved by the responsible Expert Committee."

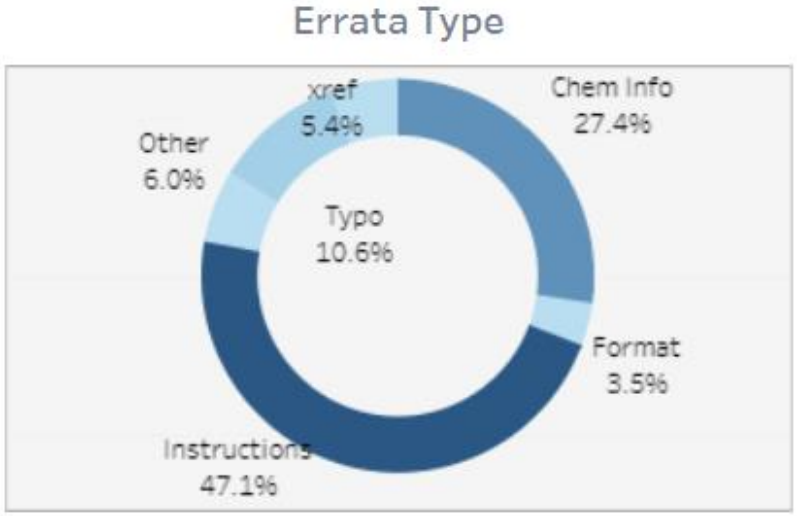
What is errata? (Continued)

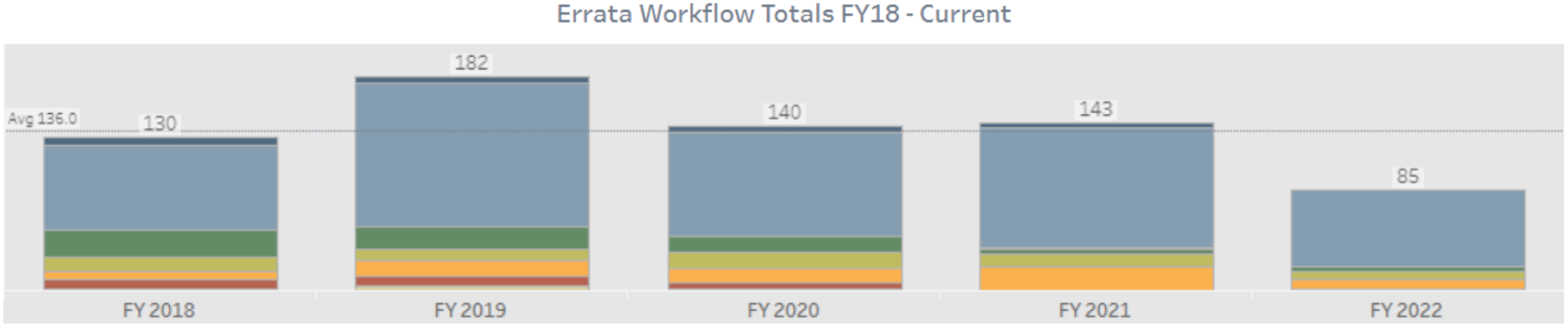
- “The Errata process is used to address errors, clarifications, or missing information.
- “These typically are minor changes that … do not have a broad impact.
- "Errors that are substantive and have a broad impact are corrected using other appropriate revision processes as determined on a case-by-case basis.”

Errata numbers and trends

FY2018 to Current

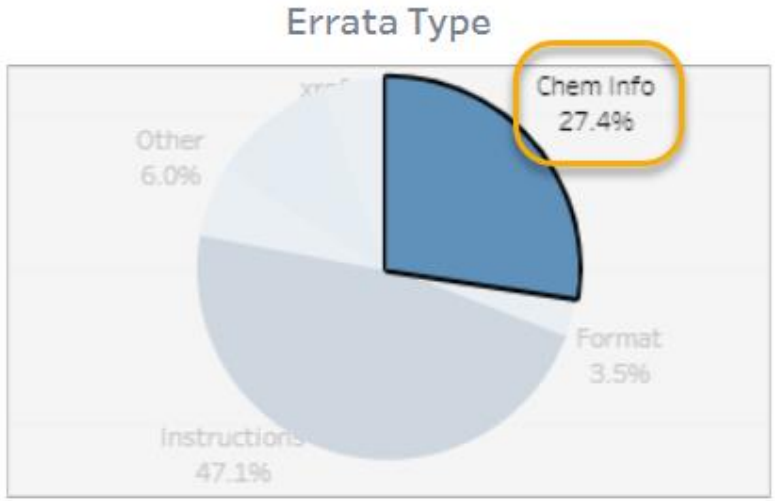
- The total number of errata published for each FY is displayed below.
  - Average number of errata per FY: **136**
- **About 45%** do not involve actual errors but are minor clarifications to content
  - The rest involve updates to chem info, fixes to broken links, spelling typos, cross-references, and formatting

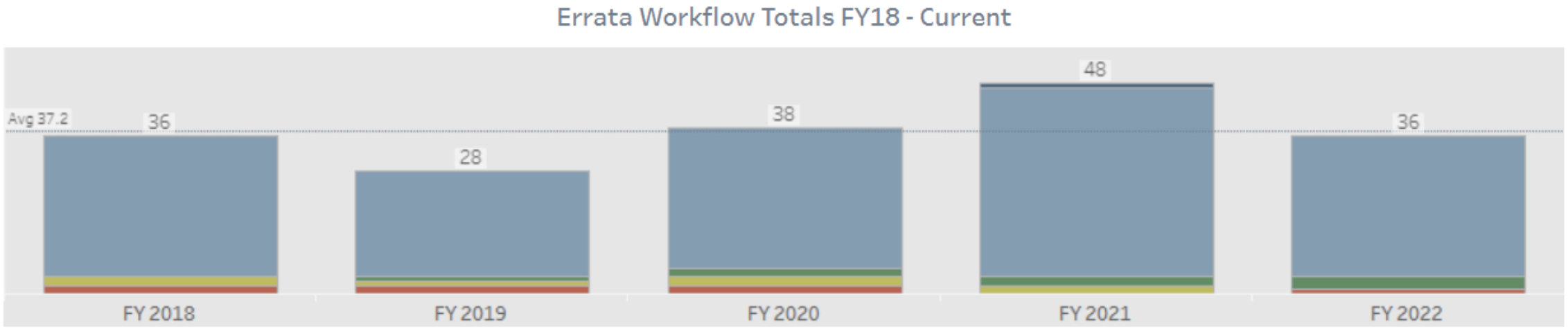




Chemical information errata totals

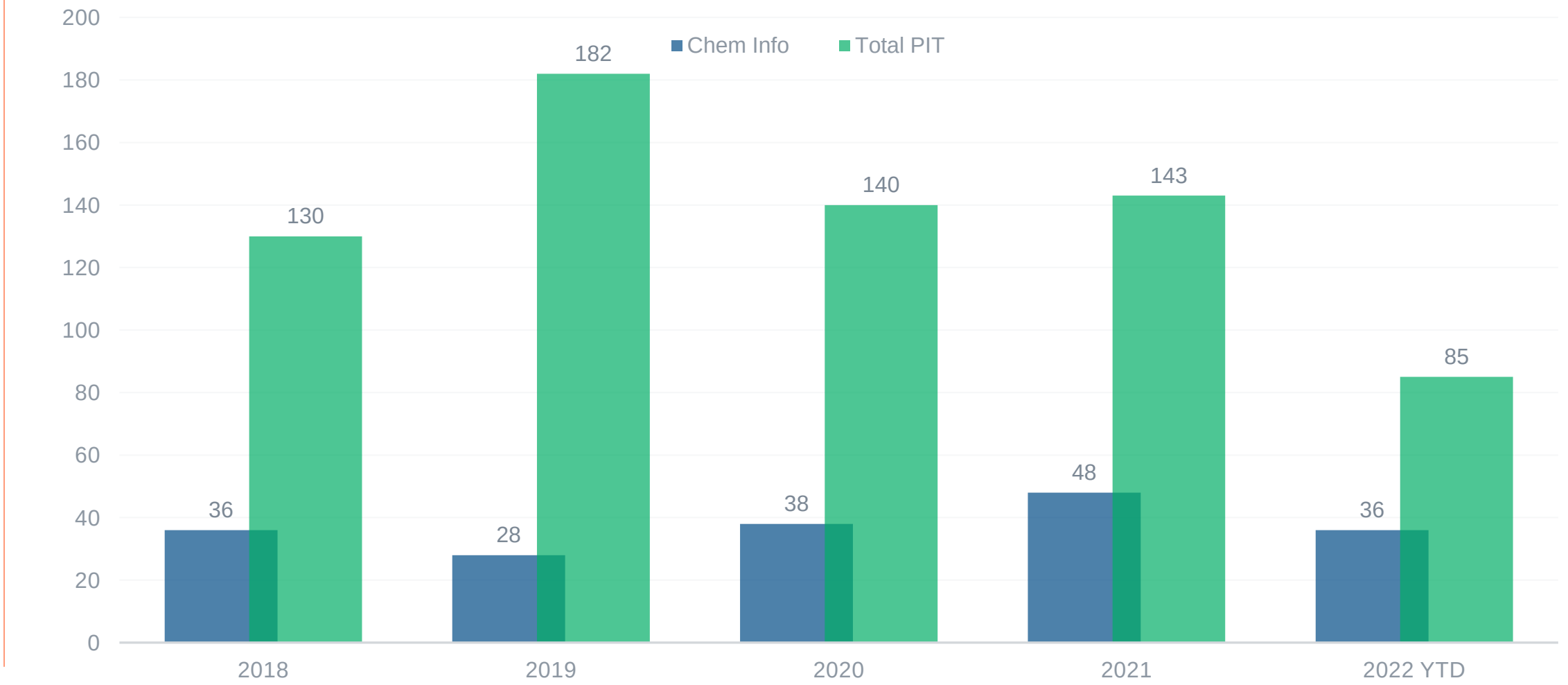
- Chemical Information at the beginning of monographs are not official requirements (see Preface and GN 3.10)
- Out of all errata from **FY18 to FY22 YTD**, chem info-type make up about **27%**
- The total number of chem info errata for each FY is displayed below.
  - FY18 to FY22 Q3: **average per FY YTD = 37**





Chemical Information corrections and updates entered as errata

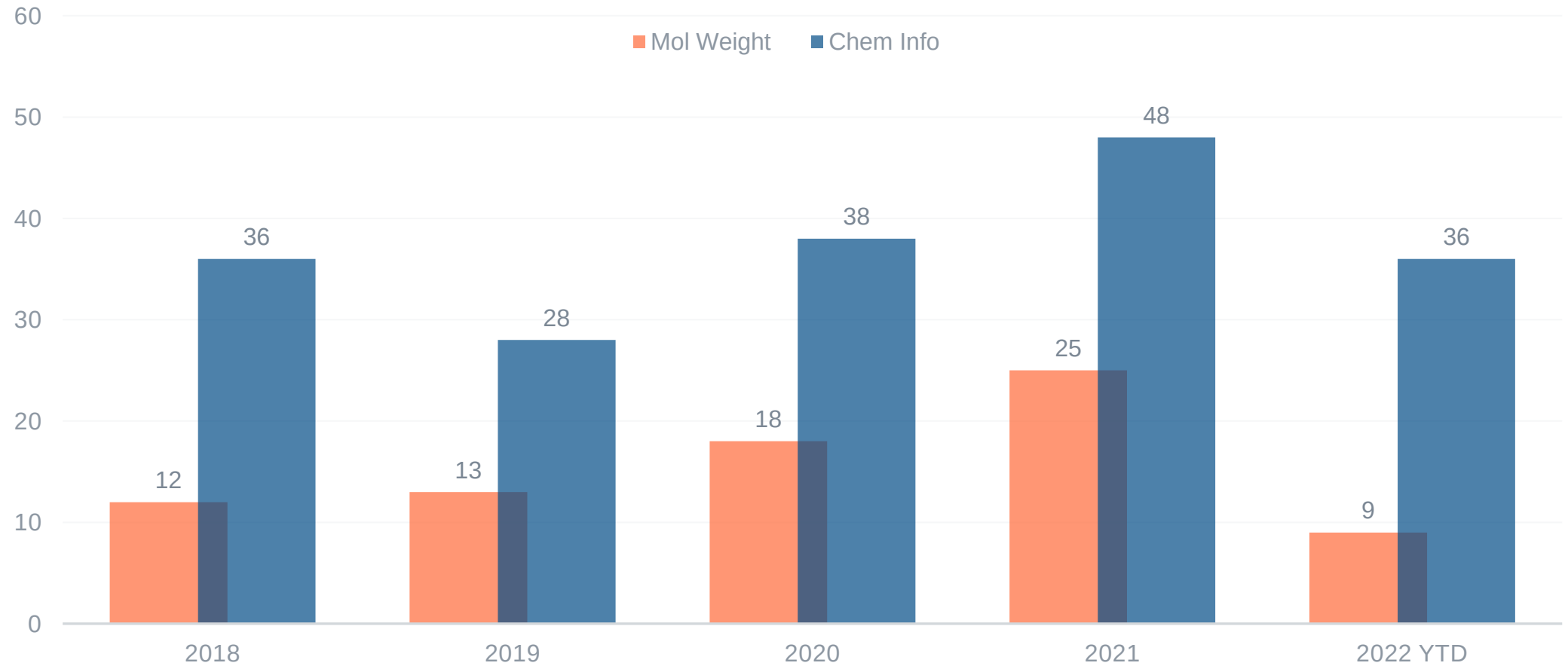
FY18 – FY22 YTD



Chemical Information Updates: Molecular weights

FY18 – FY22 YTD

- 77 workflows involve updates to **molecular weights = 41% of total chem info errata**



Chemical Information Updates

- *USP Mission and Preface*
- Chemical names typically reflect the naming conventions at the time of the monograph development or revision. If the nomenclature rules of CAS or IUPAC are significantly changed, the chemical names can be revised or added to implement those rules.
- Molecular weights are derived from the chemical formula and are based on the table of atomic weights. Atomic weights are recommended by the IUPAC and reflect the isotopic composition of normal terrestrial material. When the IUPAC recommended values are changed, it is understood that the changes in molecular weights will be made in due course.

- **Monograph:** DORZOLAMIDE HYDROCHLORIDE
- **Description:**
  In USP Dorzolamide Hydrochloride Related Compound A RS: Change
  360.91
  to
  360.89
- **Monographs:** QUAZEPAM, QUAZEPAM TABLETS
- **Description:**
  In USP Quazepam Related Compound A RS: Change
  7-Chloro-1-(2,2,2 trifluoroethyl)-5-(2-Fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepine-2-one.
  to:
  7-Chloro-5-(2-fluorophenyl)-1,3-dihydro-1-(2,2,2-trifluoroethyl)-2*H*-1,4-benzodiazepine-2-one.

Beginning in July: Chem Info Updates

Compendial Notice published on March 25, 2022

- Beginning in July 2022, updates to chemical information such as chemical name, structure, or molecular weight will no longer be corrected via errata
- Chemical information will be updated using the Compendial Notice process (similar to General Chapter Dependencies)
- Updated content will appear in the three major USP-NF publications on November 1, February 1, and June 1
- A list will be published with each compendium to indicate which standards have been updated
- 6-month implementation date, marked as (CN 1-May-2023)

Thank You

The standard of trust