USP Updates

Preview of the upcoming USP-NF/PF integrated platform

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200 usp
The standard of trust

Today's Agenda

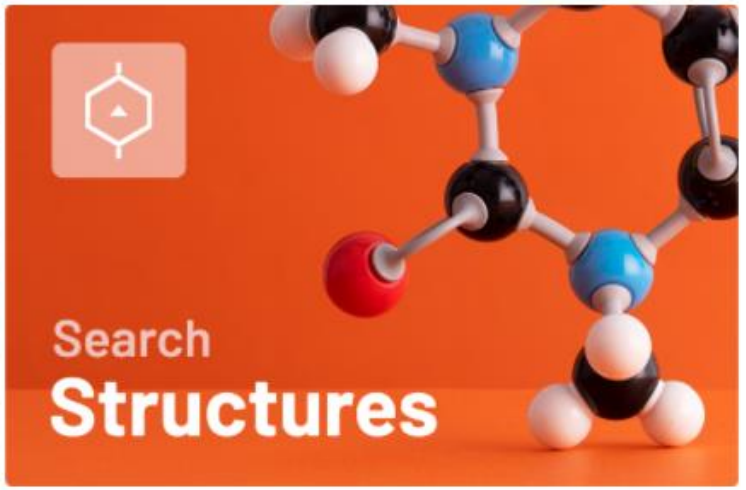
- Recent Updates
  - Updated USAN Launch
  - DOIs in the USP-NF Online
  - Updates to USP-NF Online contact information
- Preview of USP-NF/PF Integration

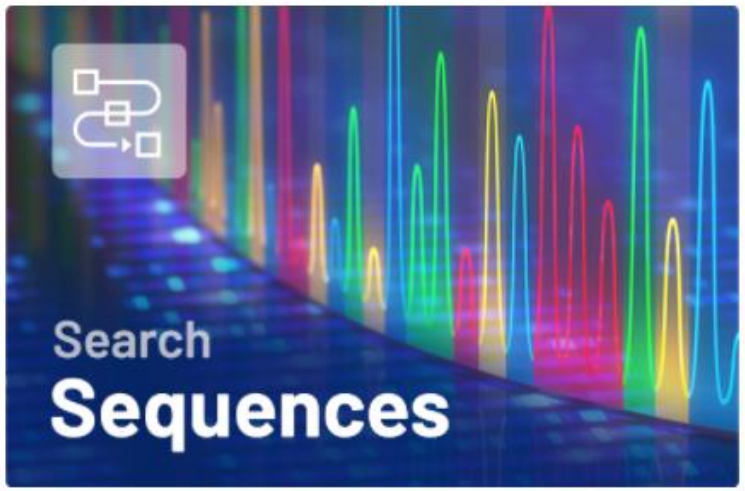
Click to add text

A Trusted Resource for the Pharmaceutical Community

The USP Dictionary helps to:

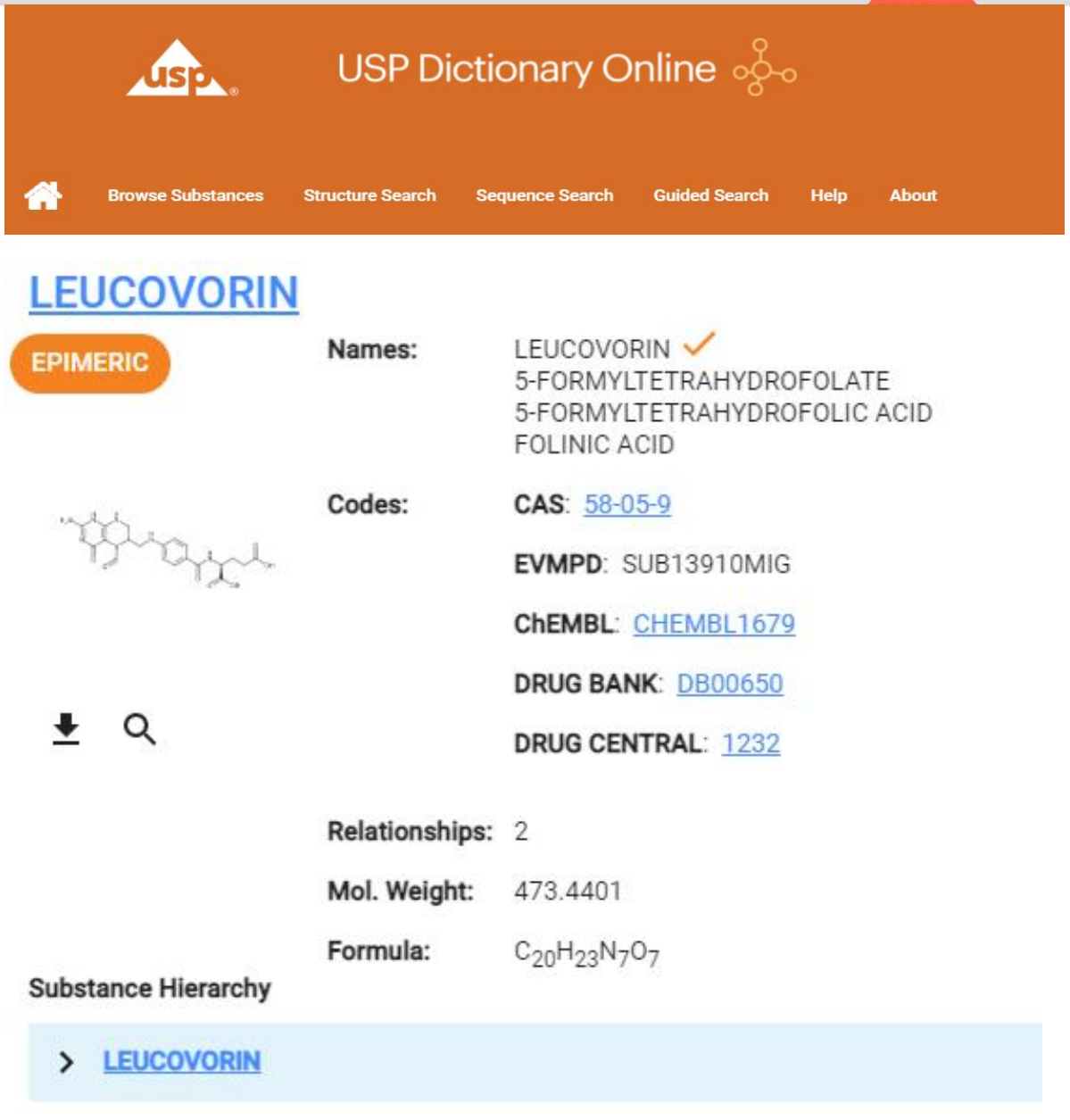
- ✓ Ensure compliance in labeling to obtain new drug approval
- ✓ Reference generic drug names for use in advertising and labeling
- ✓ Preserve trademarks to drug brand names by using proper generic names
- ✓ Filing accurate INDs, NDAs, and ANDAs
- ✓ Avoid verbal and written medication errors in reports, correspondence, articles, and package inserts
- ✓ Group drug products into families
- ✓ Verify names, chemical structures, and compositions





USP Dictionary Redesign and Launch Goals

- Bolster USP strategic role in nomenclature science and solutions to include:
  - USP Dictionary Online
  - USAN / INN institutional data / services
  - Nomenclature services (e.g., POCA) and other cheminformatics offerings
- Meet customer needs with modernized cheminformatics platform
  - Current platform is > 15 years old and is not on par with other competitive offerings



Change Summary and FAQs

Feature	Current Platform	New Platform
# of compounds	~ 13,000	~40,000
Search by Name	✓	✓
Search Facets • USAN / INN Stems • USAN Adoption Dates • Mol Weights • Stereochemistry • Substance class (proteins, polymers, mixtures, etc.)		✓
Search by UNII / CAS-RN	✓	
Search by Pubchem, ATC Class, CHEBI, RxNorm, USAN ID, INN, RS Catalog #		✓
Search by Structure or Structure Similarity	✓	✓
Search by SMILES / InCHI Key		✓
Dynamic Addition of Content (e.g. Excipients, USP Drug Classes, links to monographs)		✓
Volume Pricing		✓
Access Point account integration		✓

https://www.usp.org/products/usp-dictionary#faqs

Latest *USP-NF Online* Features

Digital Object Identifiers (DOIs)

What are Digital Object Identifiers (DOIs)?

A Digital Object Identifier (DOI) is a unique alphanumeric string assigned by a registration agency to identify content and provide a persistent link to its location on the Internet.

- **How is USP implementing DOI in USP-NF Documentary Standard content?**

Beginning with USP-NF 2022 Issue 1, USP will assign a DOI to all new and revised content in the USP-NF when it is made available electronically.

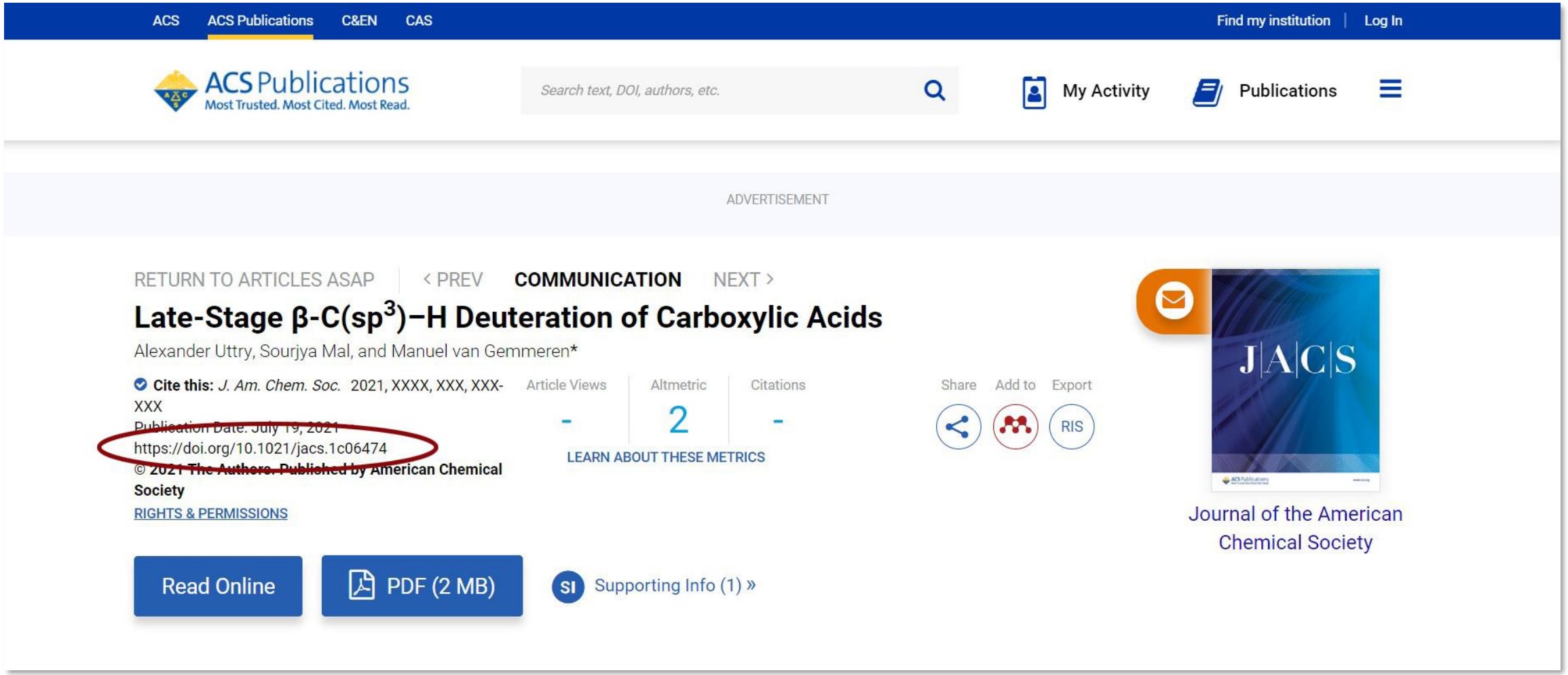
- **Is the DOI system a Standard?**

Yes. The DOI system was created by the International DOI Foundation and was adopted as International Standard ISO 26324 in 2012.

What are the benefits of using DOI?

- DOIs provide a robust mechanism for sharing and citation of scientific content, including the USP-NF. Additionally, DOI implementation in the USP-NF means that current Documentary Standard content will, for the first time, be indexed by public search engines and data providers, making it easier to find on the Internet.

Example of DOI



DOI: Standard Form and Abbreviated Form

How DOI is displayed within a document:

Current DocID: GUID-33AD0880-7404-4169-BDD5-F74D808EE77F_4_en-US

DOI: https://doi.org/10.31003/USPNF_M150_04_01

DOI ref: dsv5r

How DOI is displayed within a PDF:

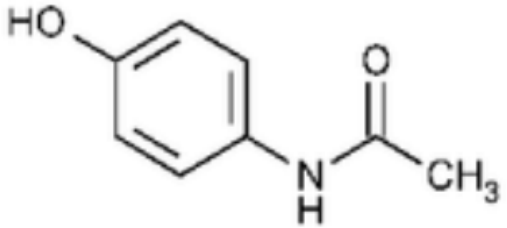
Printed on: Wed Oct 27 2021, 05:16:05 AM(EST)
Printed by: Rebecca Cambronero

Official Status: Currently Official on 27-Oct-2021
Official Date: Official as of 01-May-2020
DOI Ref: dsv5r

DocId: 1_GUID-33AD0880-7404-4169-BDD5-F74D808EE77F_4_en-US
Document Type: USP
DOI: https://doi.org/10.31003/USPNF_M150_04_01

1

Acetaminophen



$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*
r_S = peak response from the *Standard solution*
C_S = concentration of USP Acetaminophen RS in the *Standard solution* (mg/mL)
C_U = concentration of Acetaminophen in the *Sample solution* (mg/mL)

DOI: Printout

Printed on: Wed Oct 27 2021, 06:16:05 am
Printed by: Rebecca Cambronero
Official Status: Currently Official on 27-Oct-2021
Official Date: Official as of 1-May-2020
Document Type: USP
DocId: 1_GUID-33AD0880-7404-4169-BDD5-F74D808EE77F_4_en-US
DOI: https://doi.org/10.31003/USPNF_M150_04_01
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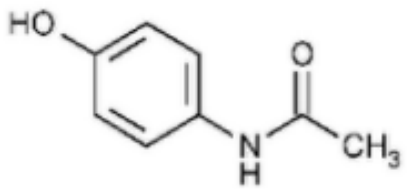
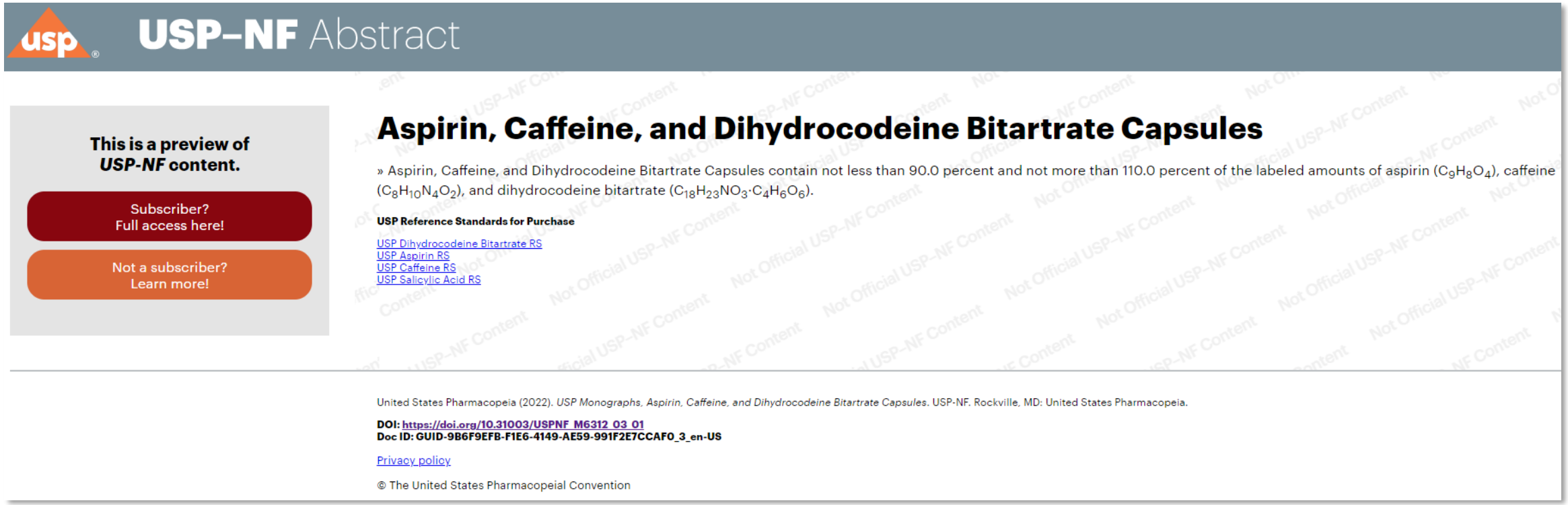
Acetaminophen



$C_8H_9NO_2$ 151.16

Acetamide, *N*-(4-hydroxyphenyl)-;
4'-Hydroxyacetanilide [103-90-2]; UNII: 362O9ITL9D.

DOI Landing Page – Google Searchable!



USP–NF Abstract

This is a preview of *USP-NF* content.

Subscriber? Full access here!

Not a subscriber? Learn more!

Aspirin, Caffeine, and Dihydrocodeine Bitartrate Capsules

» Aspirin, Caffeine, and Dihydrocodeine Bitartrate Capsules contain not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of aspirin ($C_9H_8O_4$), caffeine ($C_8H_{10}N_4O_2$), and dihydrocodeine bitartrate ($C_{18}H_{23}NO_3 \cdot C_4H_6O_6$).

USP Reference Standards for Purchase

USP Dihydrocodeine Bitartrate RS
USP Aspirin RS
USP Caffeine RS
USP Salicylic Acid RS

United States Pharmacopeia (2022). *USP Monographs, Aspirin, Caffeine, and Dihydrocodeine Bitartrate Capsules*. USP-NF. Rockville, MD: United States Pharmacopeia.

DOI: https://doi.org/10.31003/USPNF_M6312_03_01
Doc ID: GUID-9B6F9EFB-F1E6-4149-AE59-991F2E7CCAF0_3_en-US

Privacy policy

© The United States Pharmacopeial Convention

USP-NF Contact Information Updates

Currently . . .

Contact Information Updates

Stakeholders contact SM liaisons listed at the bottom of monographs in USP and the questions are forwarded to Technical Services to be answered.

Coming Soon!

Technical Services / Scientific Support (stdsmonographs@usp.org) will be added to the bottom of the SM monographs.

PF Contact Information Updates

Currently . . .

Contact Information Updates

Stakeholders contact SM liaisons listed at the bottom of proposals in PF instead of the using the Comment Form and the comments are forwarded to other Scientists to be addressed.

Coming Soon!

Single address for PF Comments (PFComments@usp.org) will be added to the bottom of the SM PF proposals.

Why Are We Making These Changes?

- For over 2 years USP has been moving toward a single point of contact for scientific support.
  - More efficient
  - Promotes consistency in our responses to stakeholders
  - Improved quality assurance tracking
  - SM Scientists still consulted if needed

Sneak-peek into the Upcoming USP-NF Online + PF

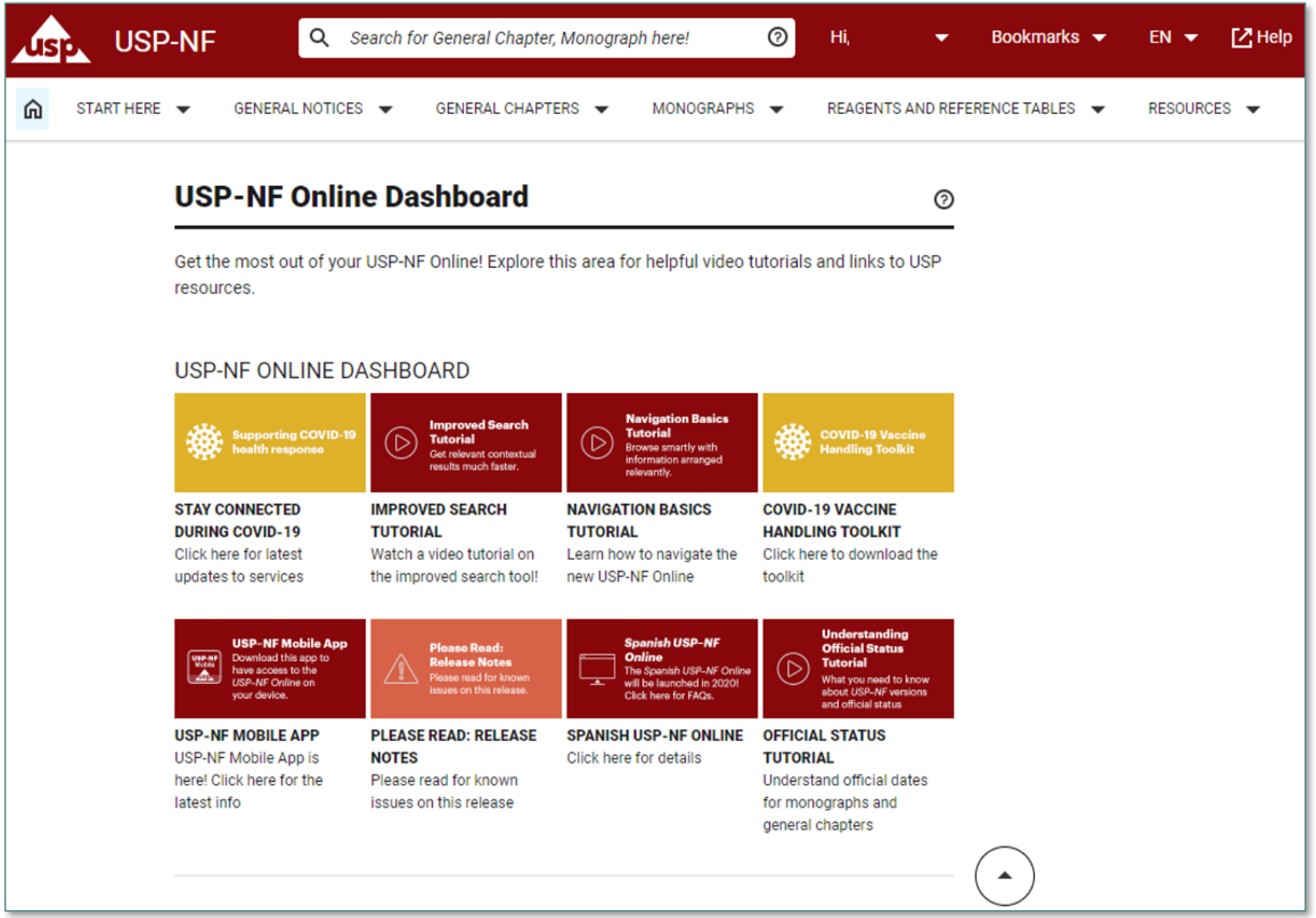
How We Got Here…

- **Goal: To improve the user experience, particularly for "less experienced users," and to update the UI to current industry standards.**
- Design done by *Atomic Object*, which has extensive UX expertise, and has worked on the USP-NF Online since 2017.
- Inputs included:
  - Almost 4 years of feedback from users, including emails with comments, suggestions, and complaints from users in many different roles at a wide range of companies inside and outside the US
  - Analysis of navigation and usage patterns from the Nabu platform
  - Multiple surveys, with responses from >2500 individuals
  - Focus groups and one-on-one "live usage" interviews from more than 30 users

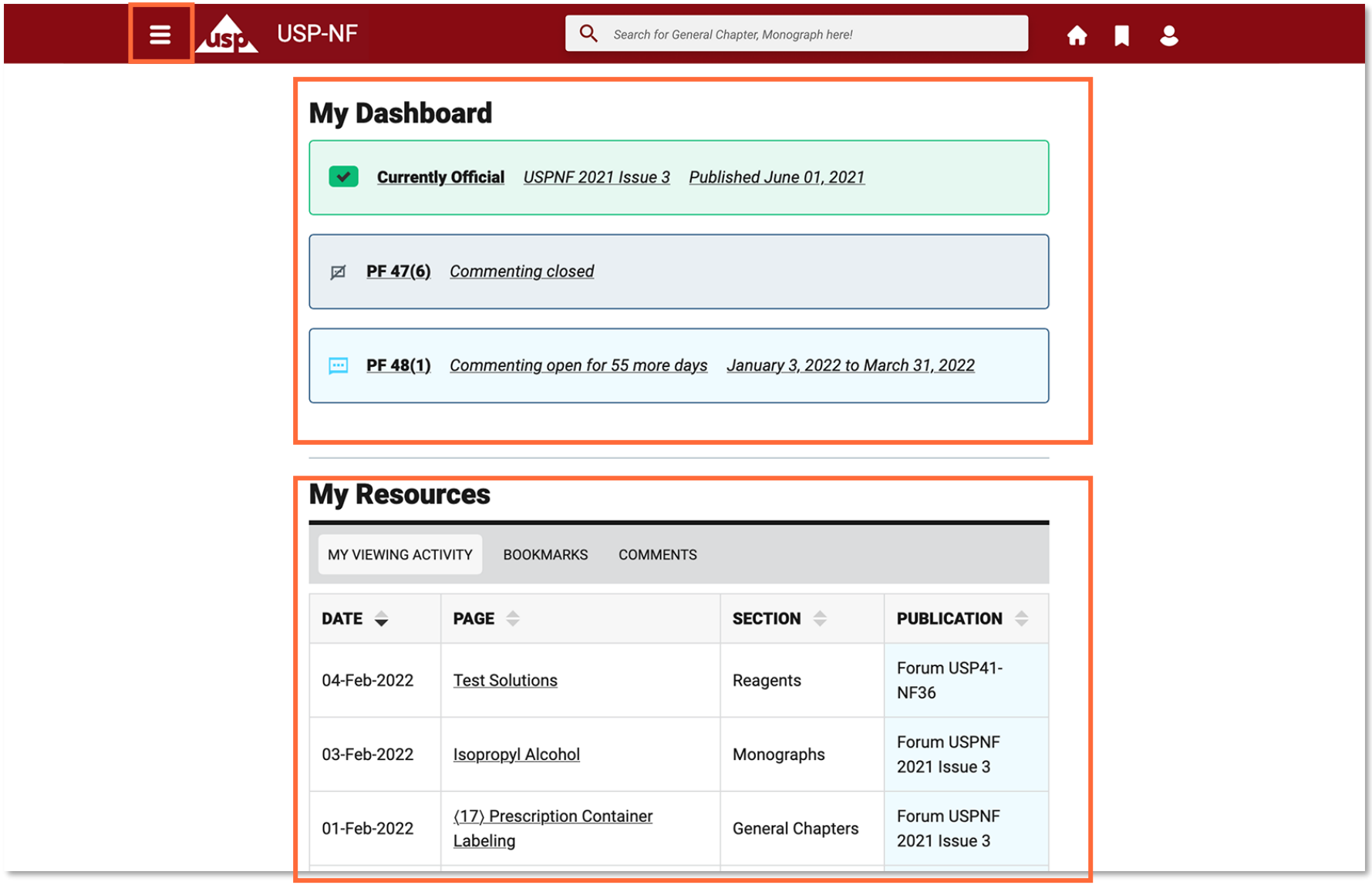
DISCLAIMER

- The following images are design mock-ups – **NOT the actual pages**
- The final look and feel may be slightly different
- Please disregard dates and document status – these are examples only, NOT actual USP-NF documents

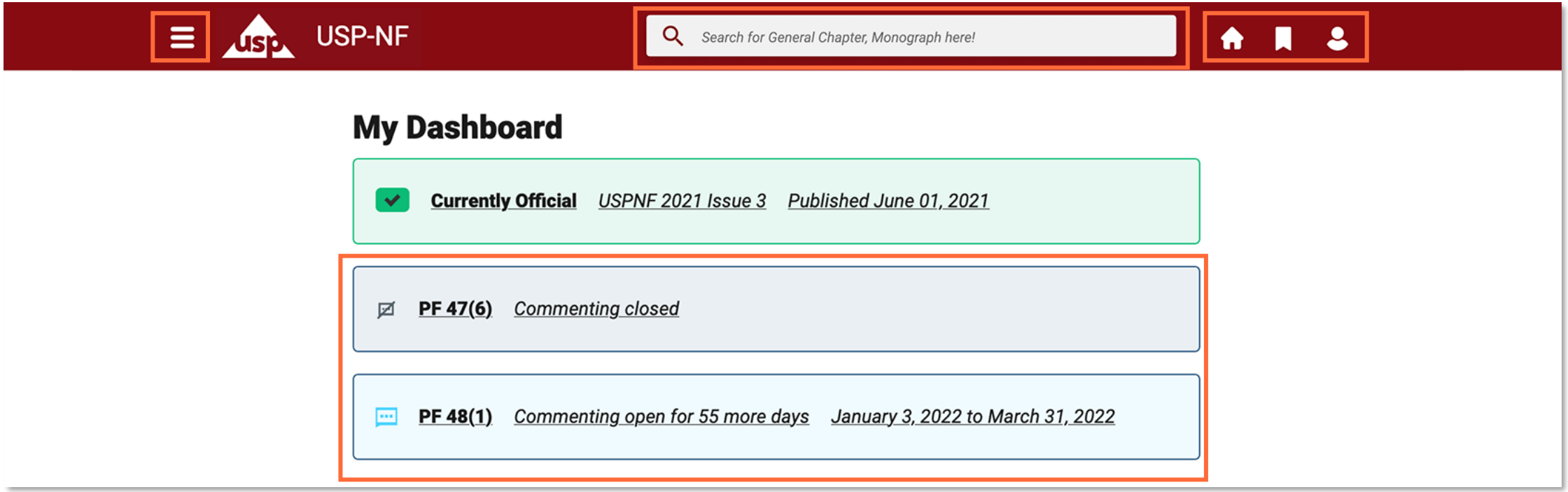
USP-NF Online Home Page- Current



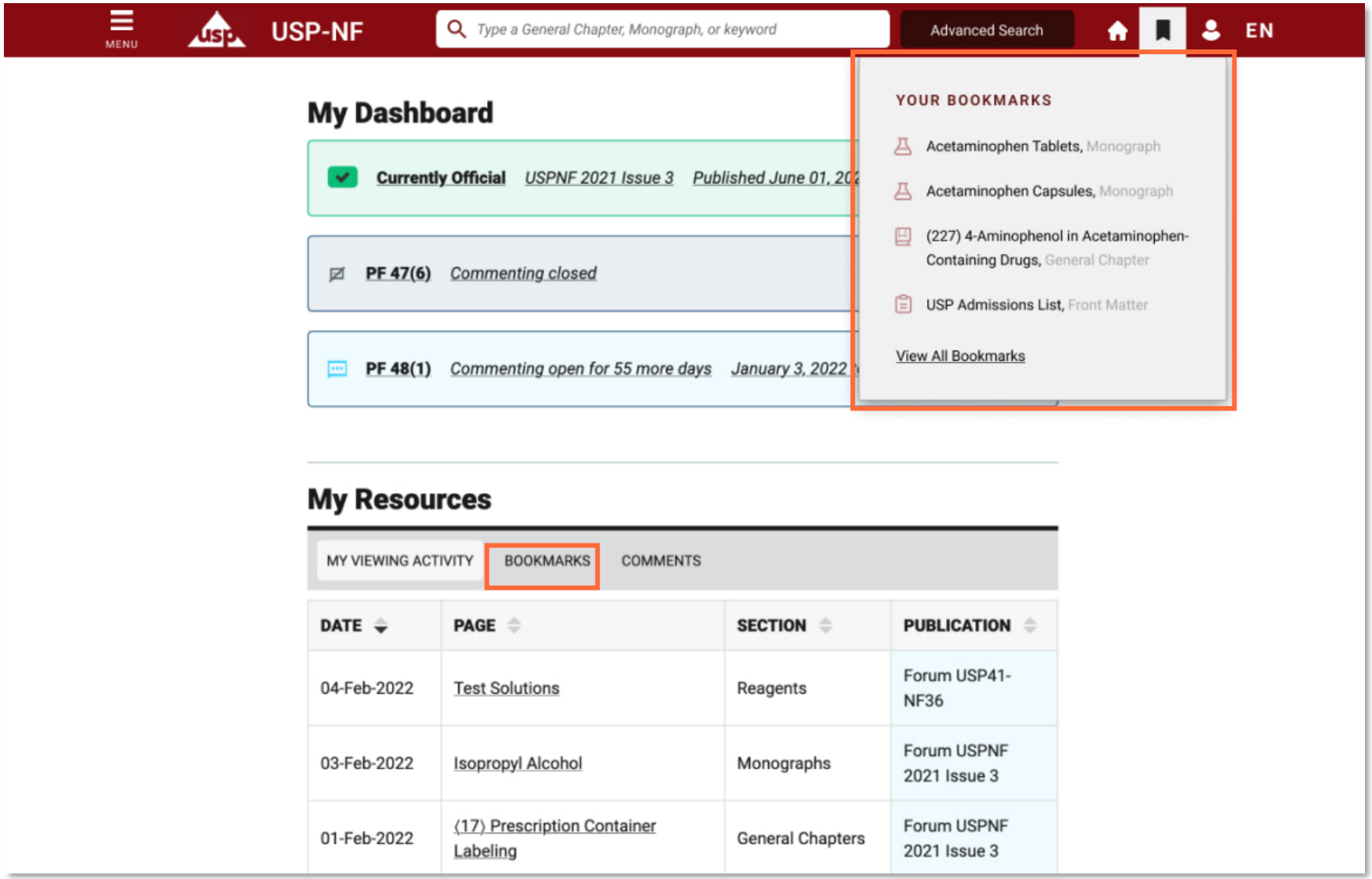
Dashboard View: USP-NF + PF



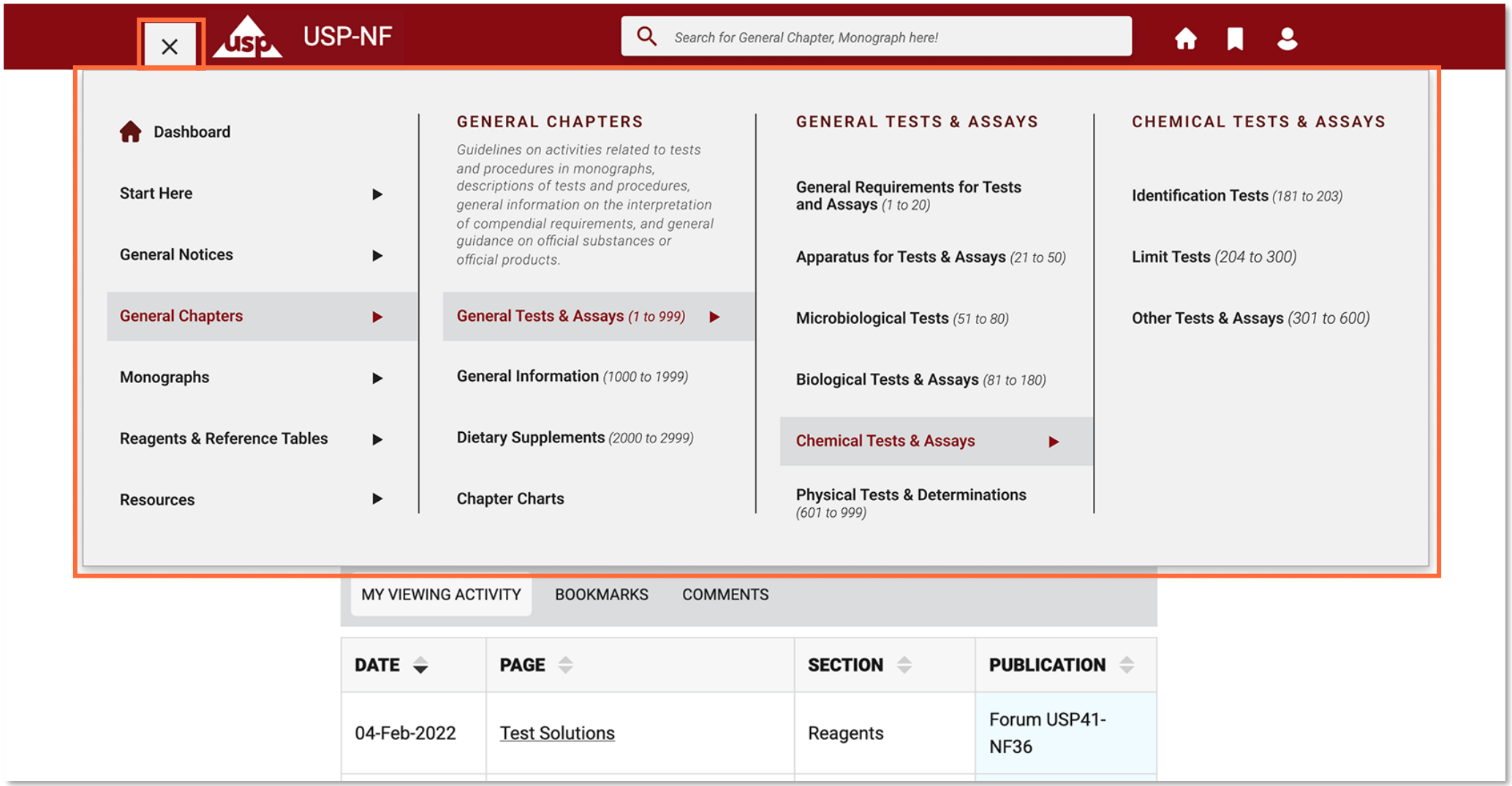
Dashboard View: A Closer Look



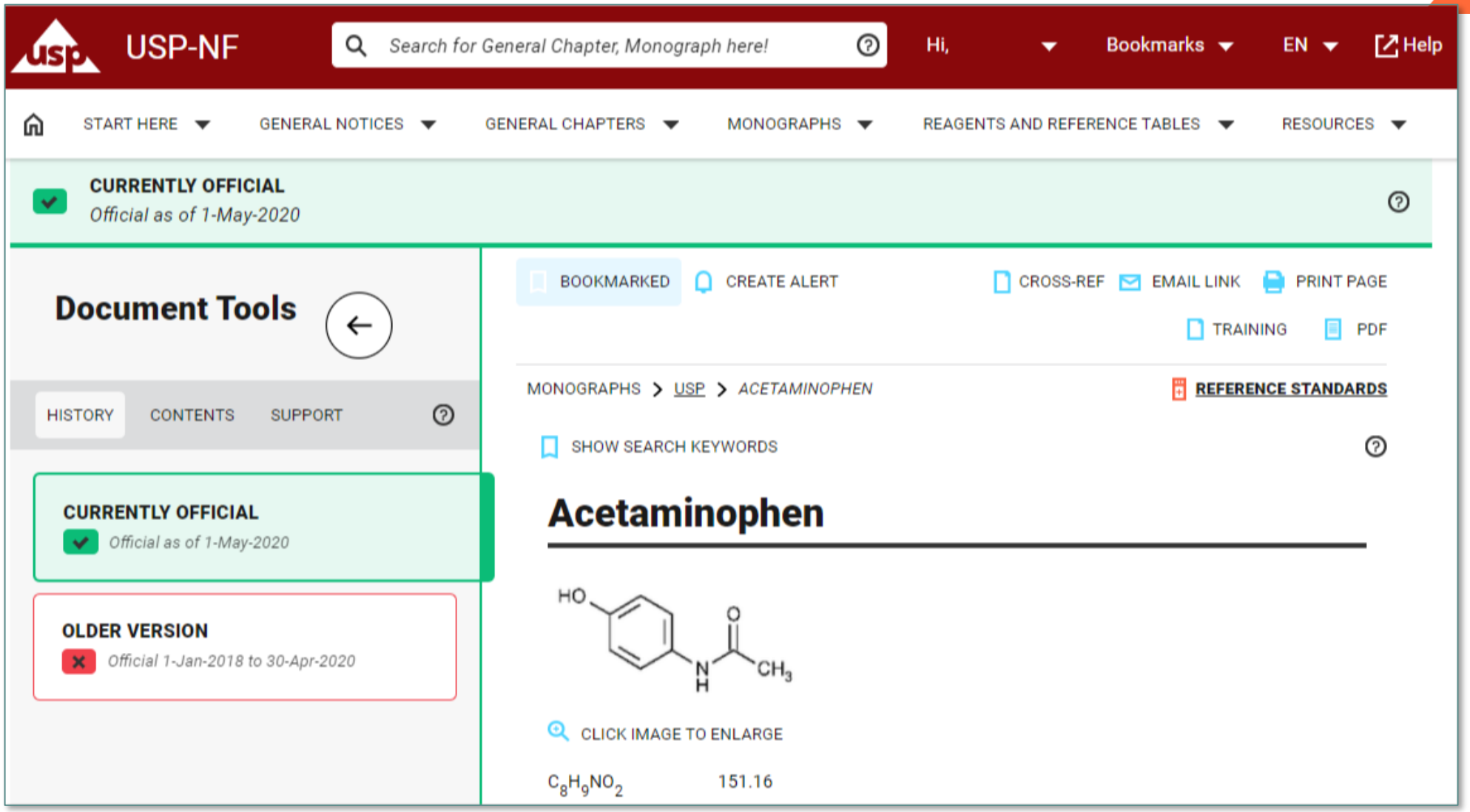
Dashboard View: Bookmarks



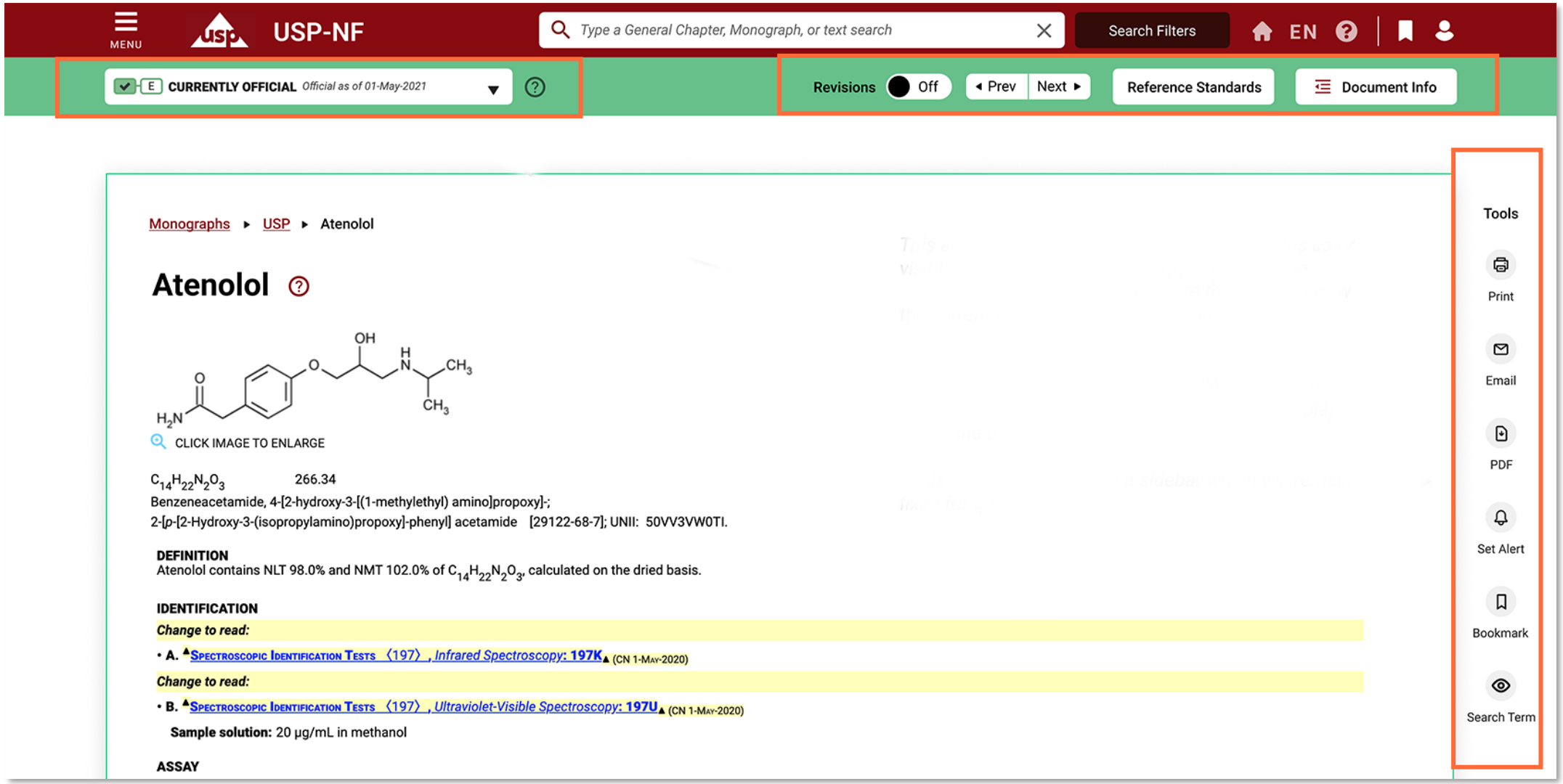
Dashboard View: New Look for Navigation



Document View - Current

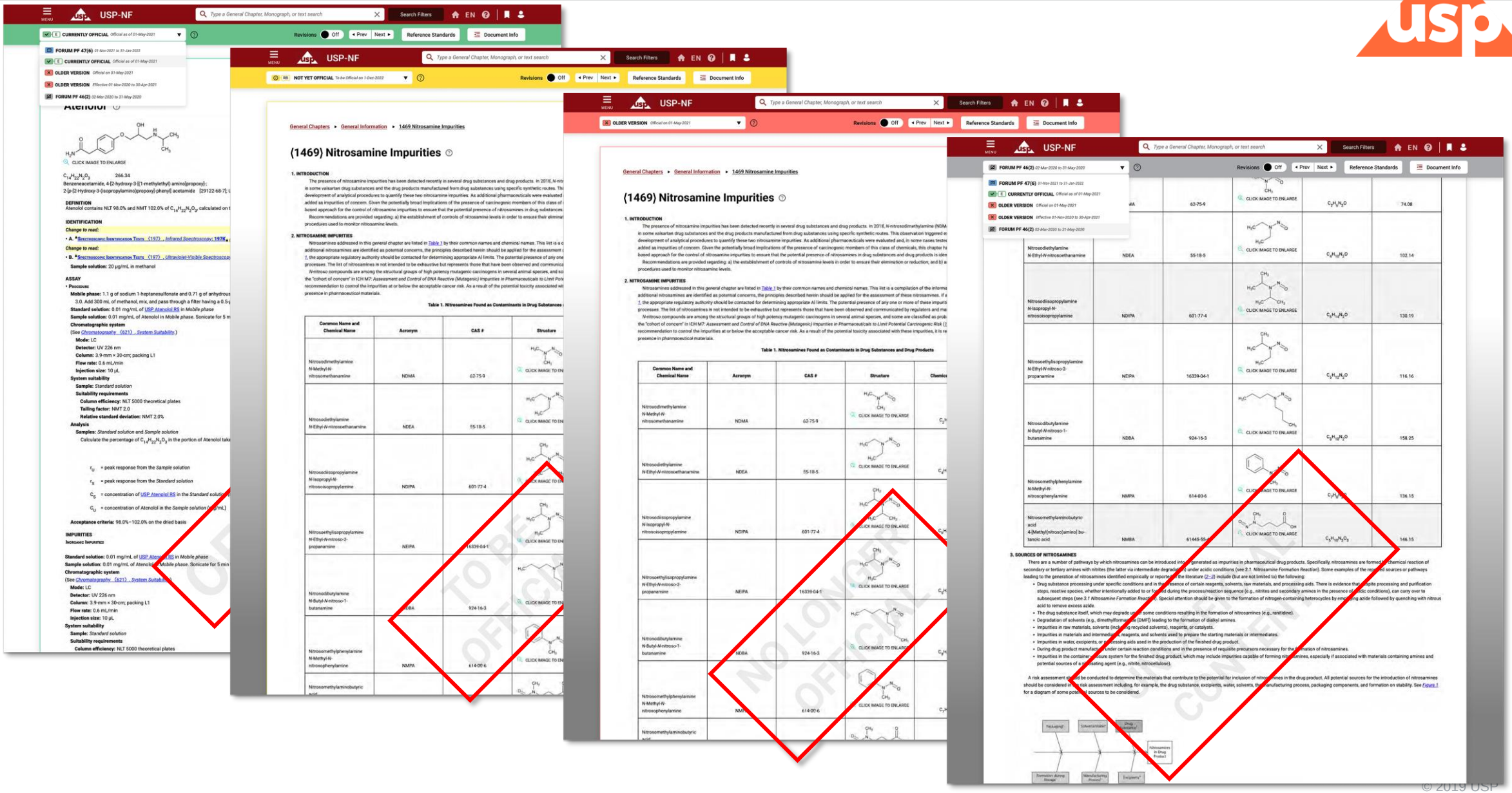


Document View: Currently Official

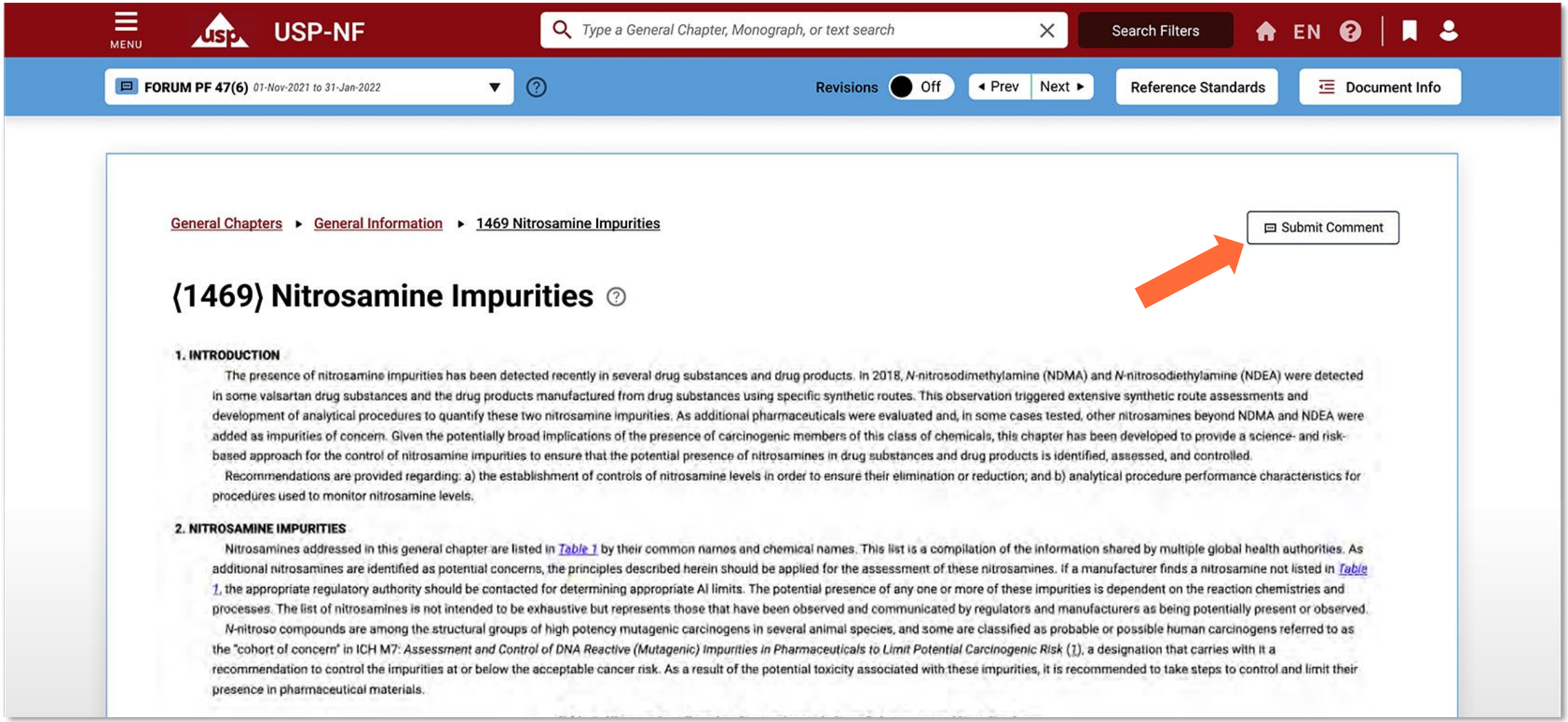


Document View: Status Comparisons

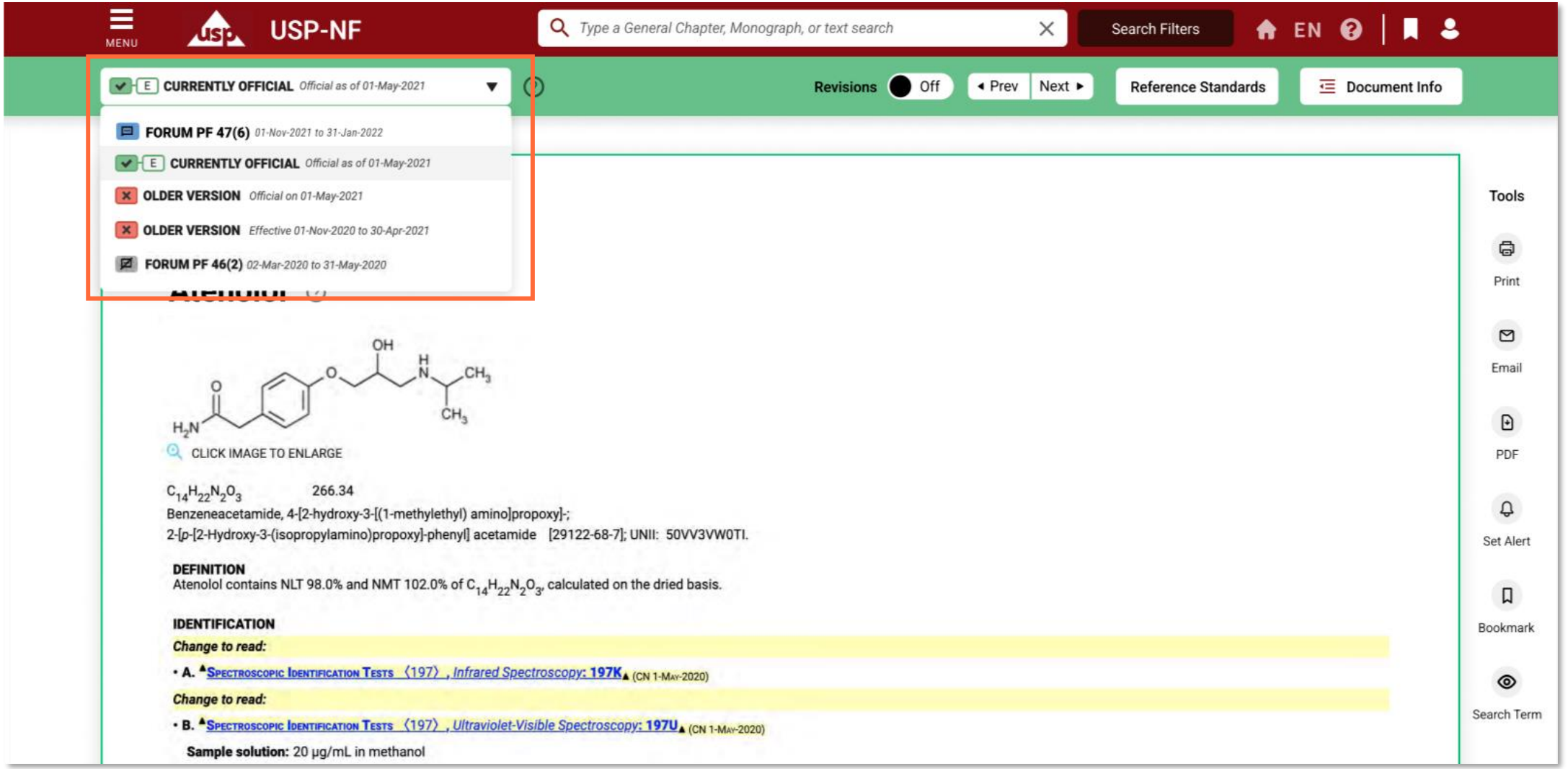
Full Documents with Watermarks



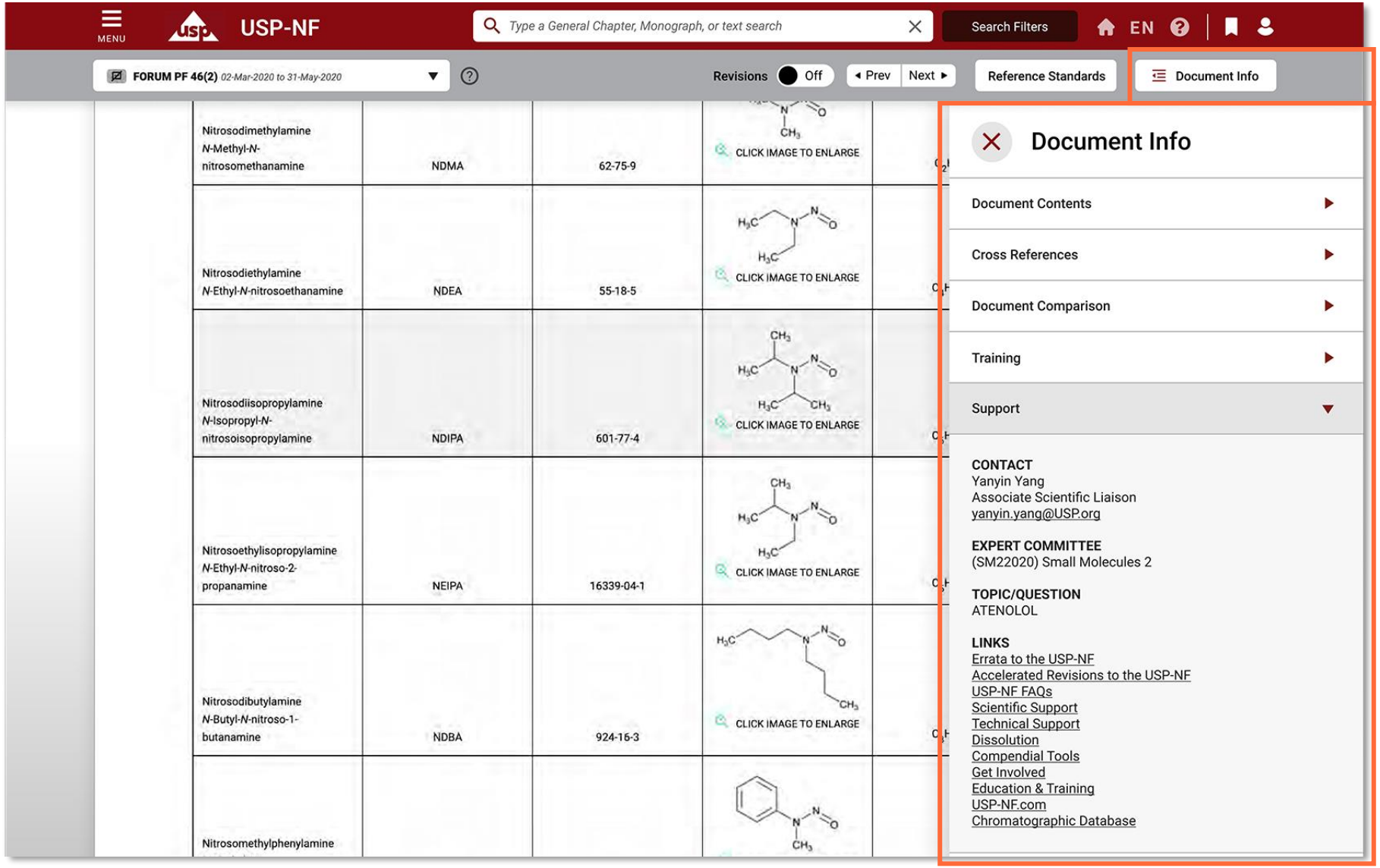
Document View: Pharmacopeial Forum (PF) Document



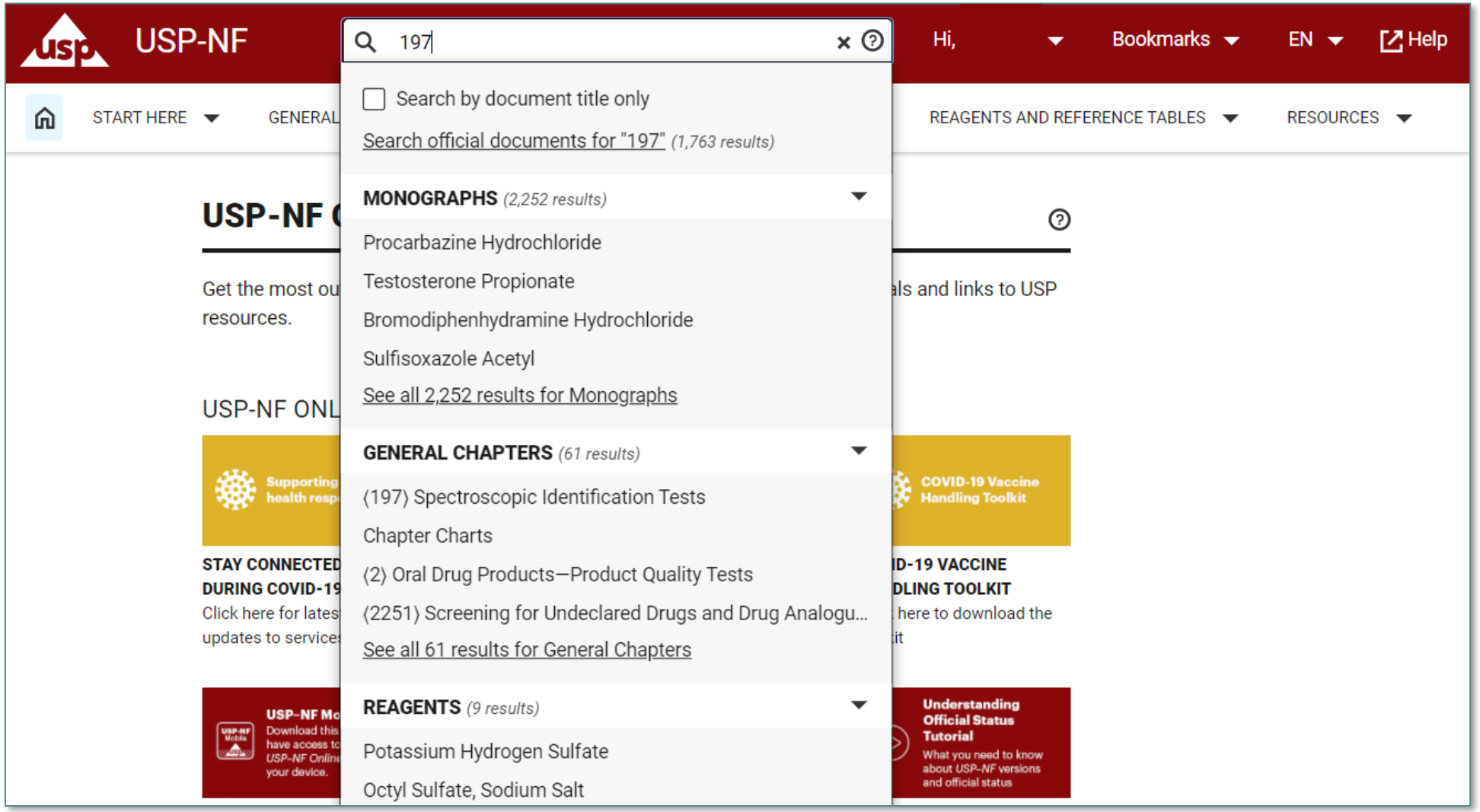
Document View: Document Versions Drop-Down



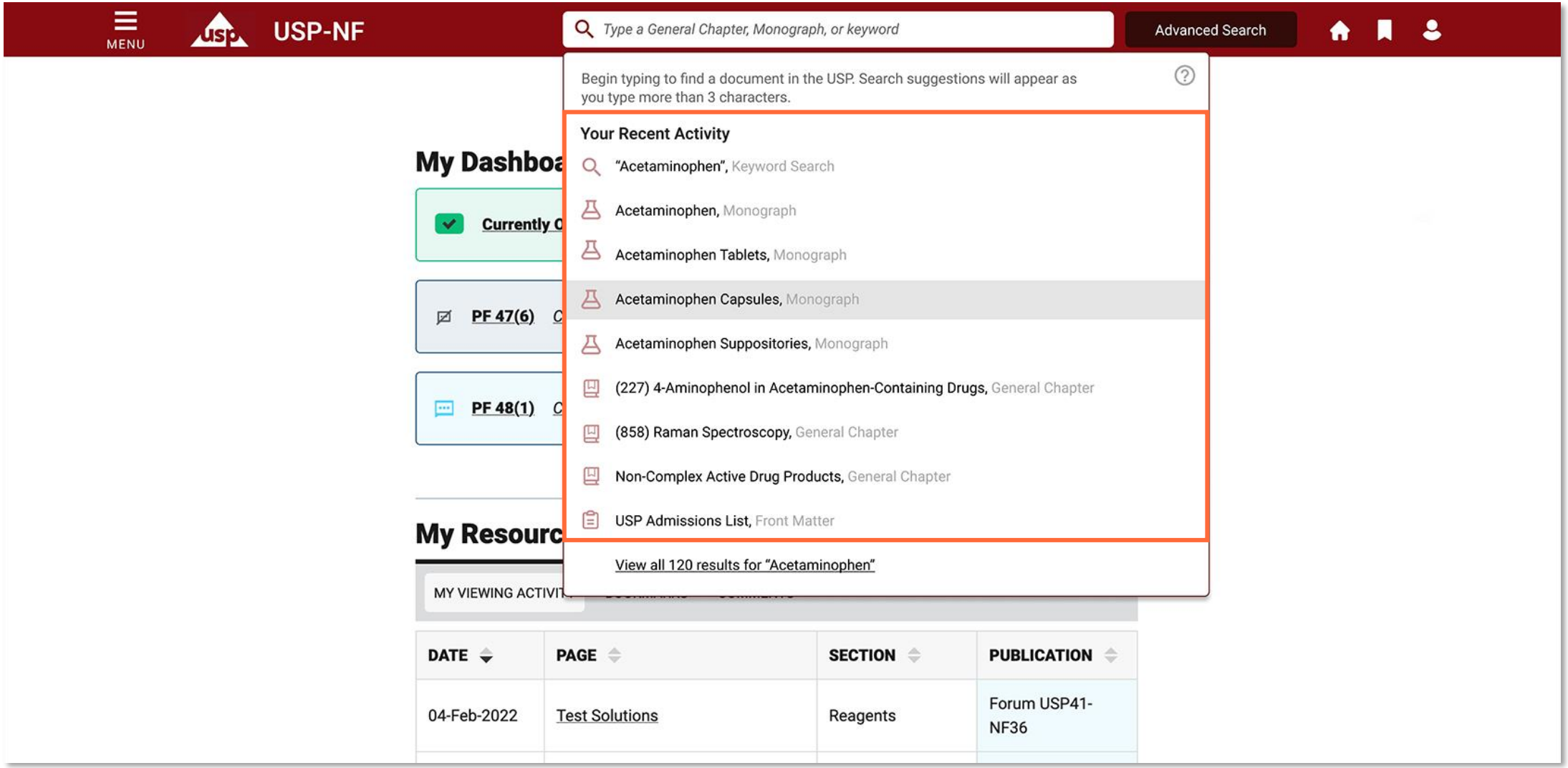
Document View: Document Info Drop-Down



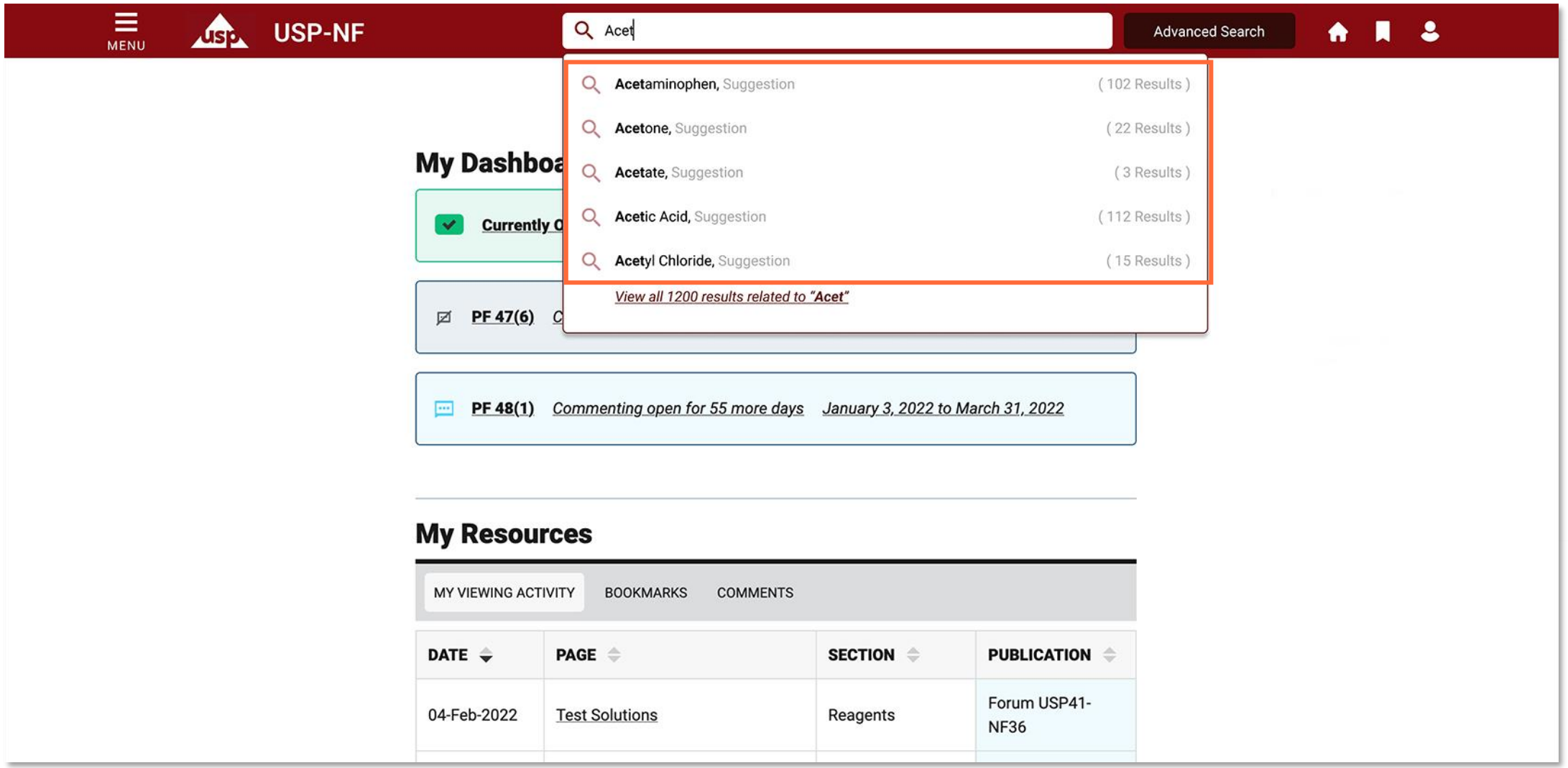
Search Window - Current Format



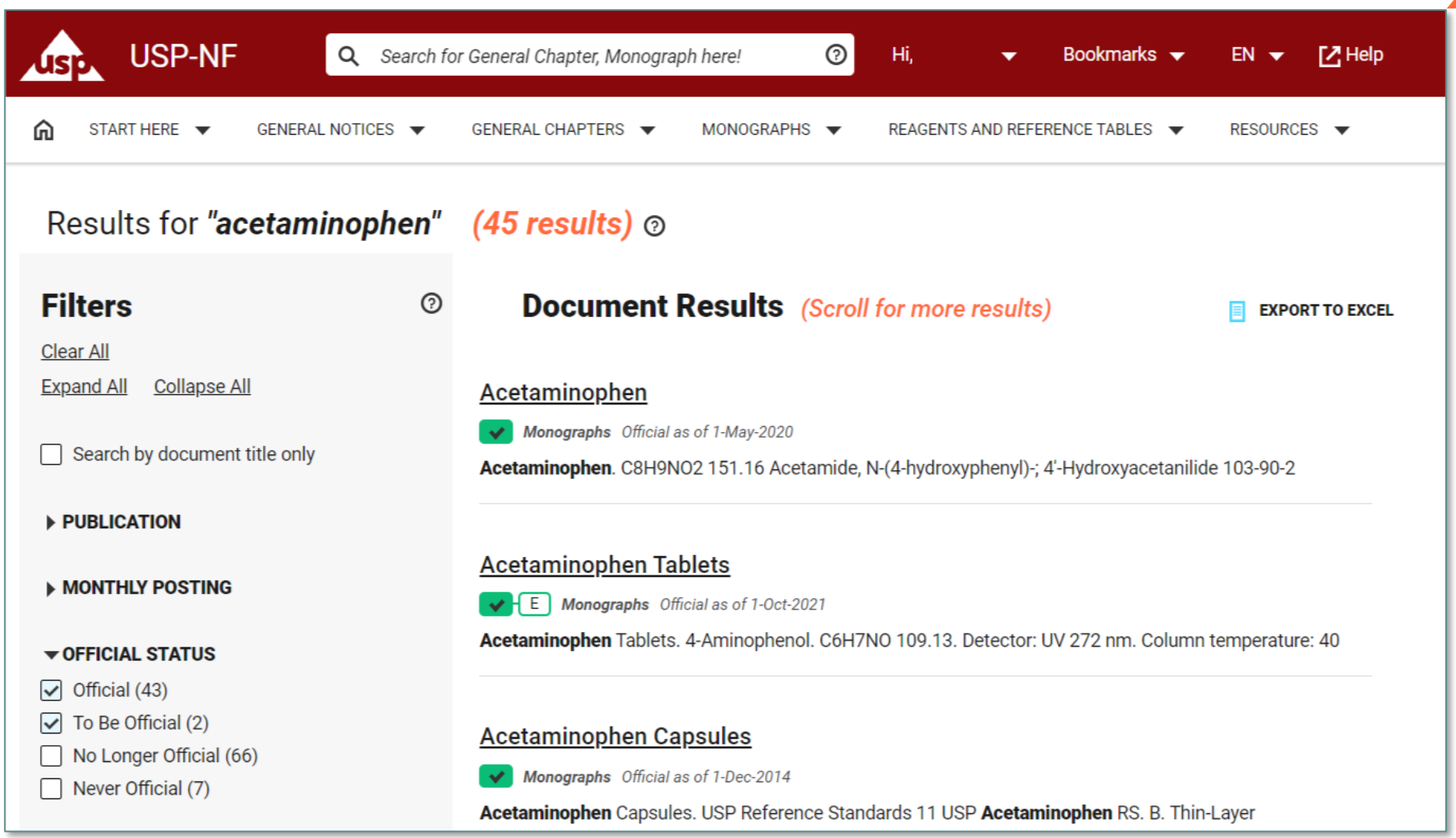
Search Tool: Recent Searches



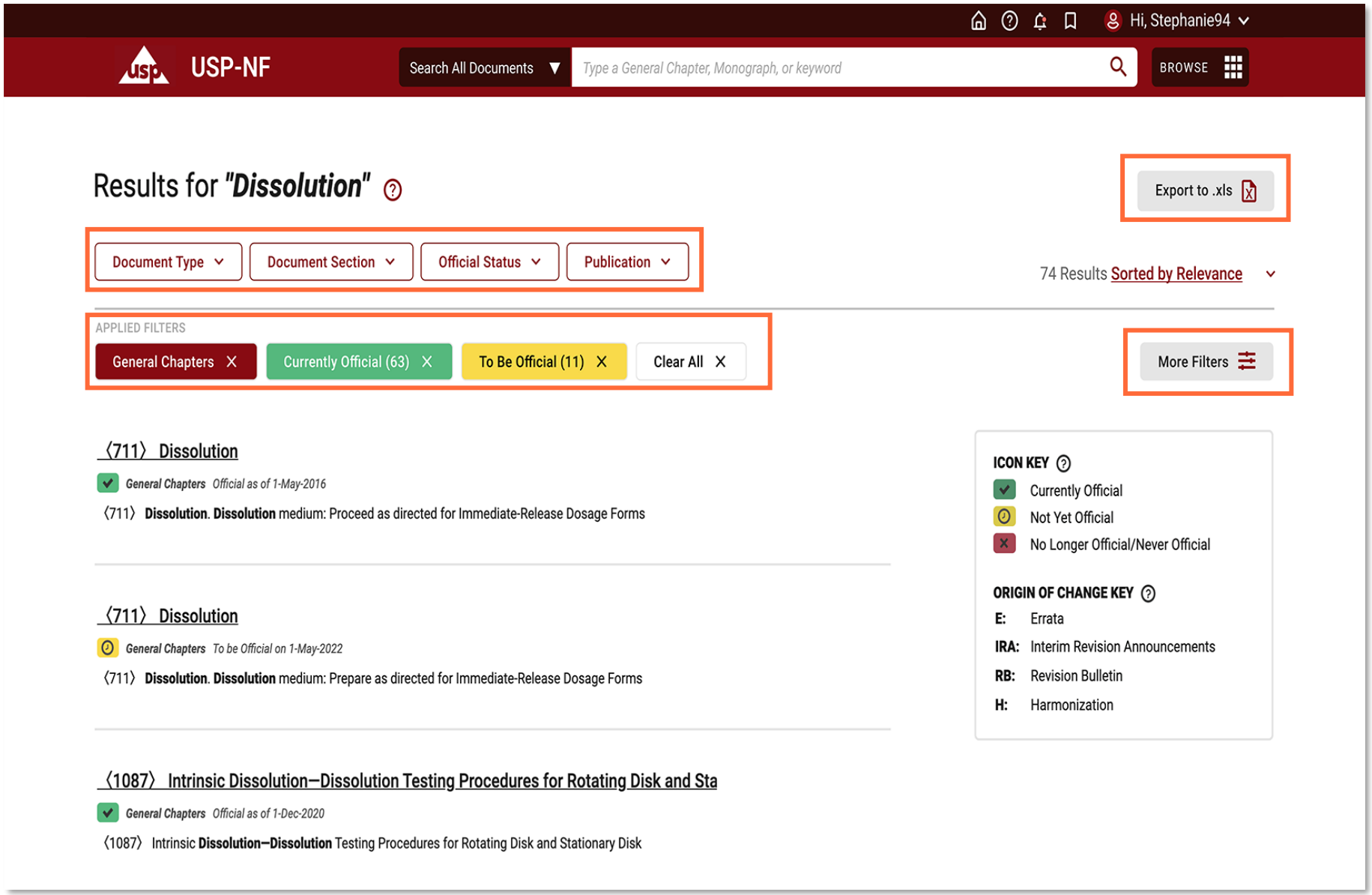
Search Tool: Autosuggest



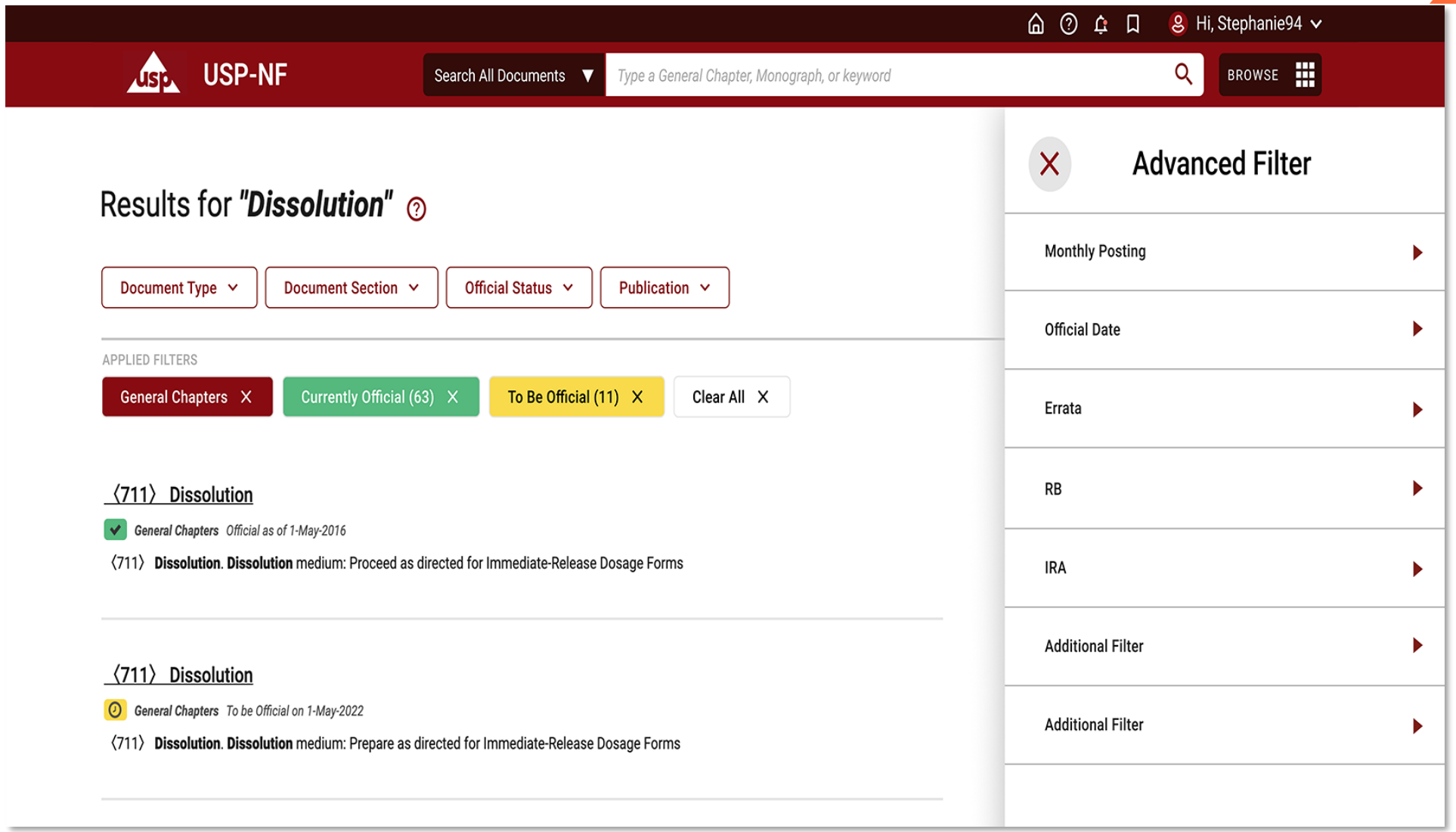
Search Results Page – Current Format



Search Results: View



Search Results: Advanced Filters



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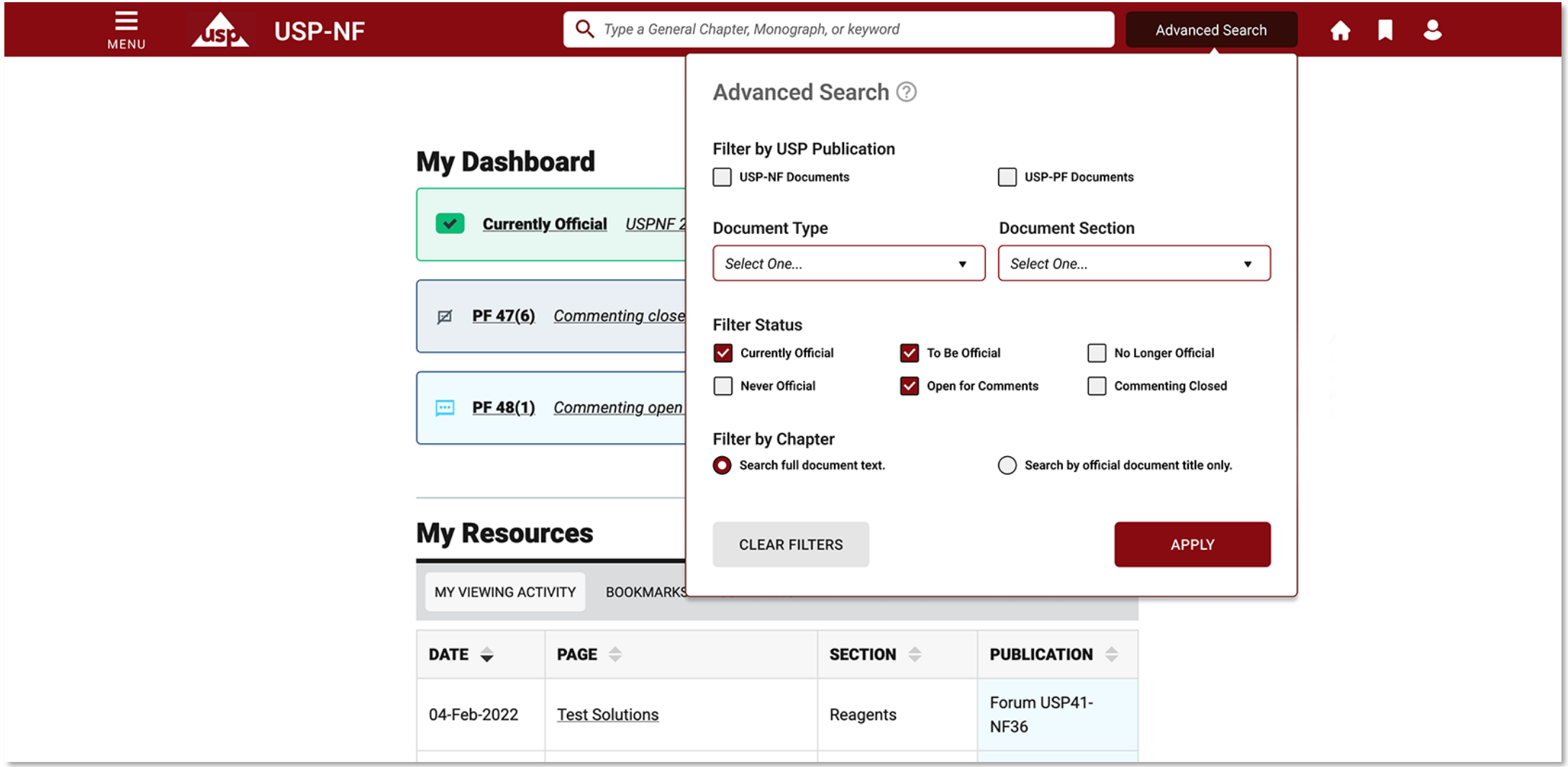

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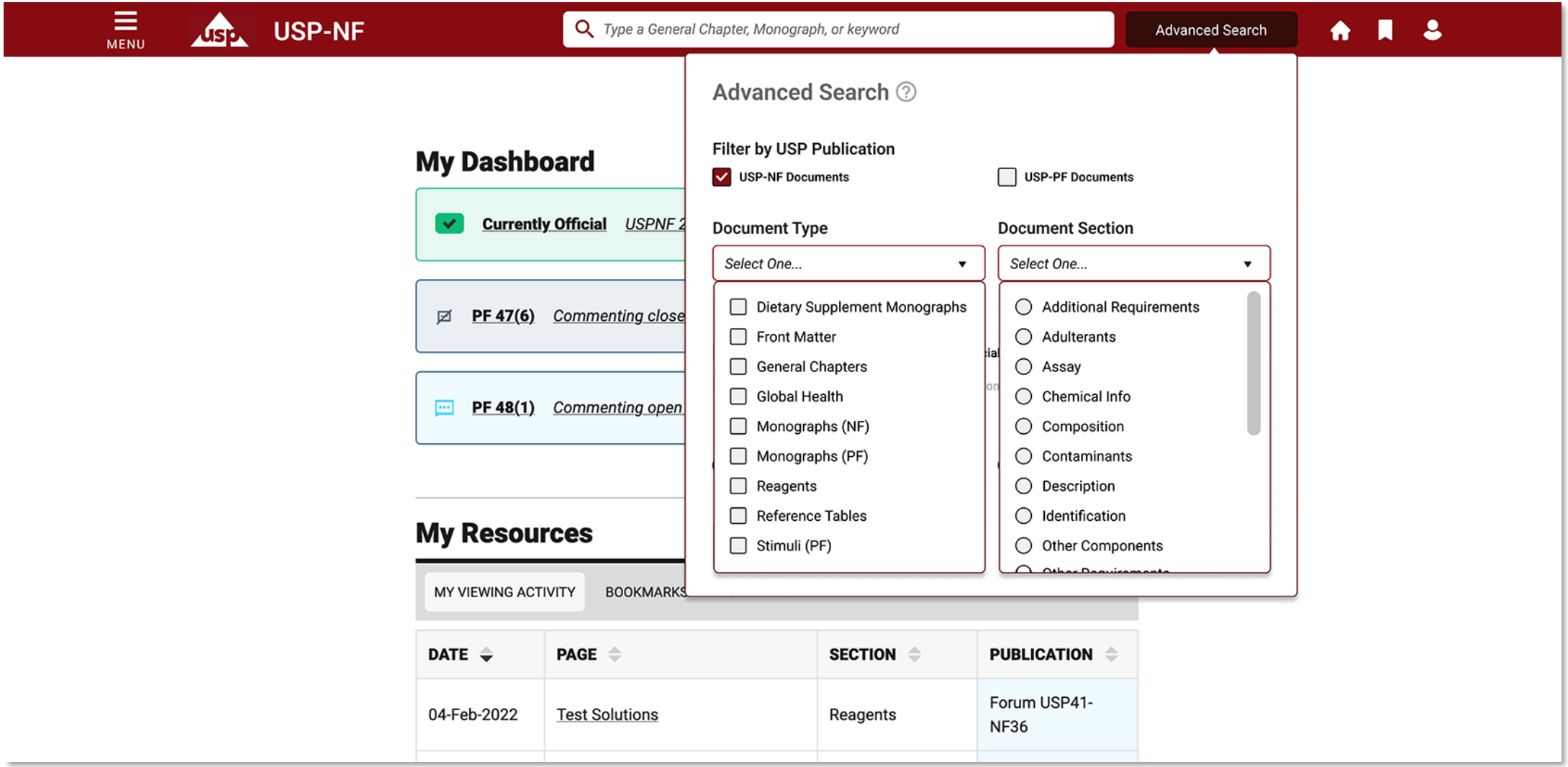

Thank You

Empowering a healthy tomorrow