

# DailyMed & RxNorm

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U.S. Department of Health and Human Services



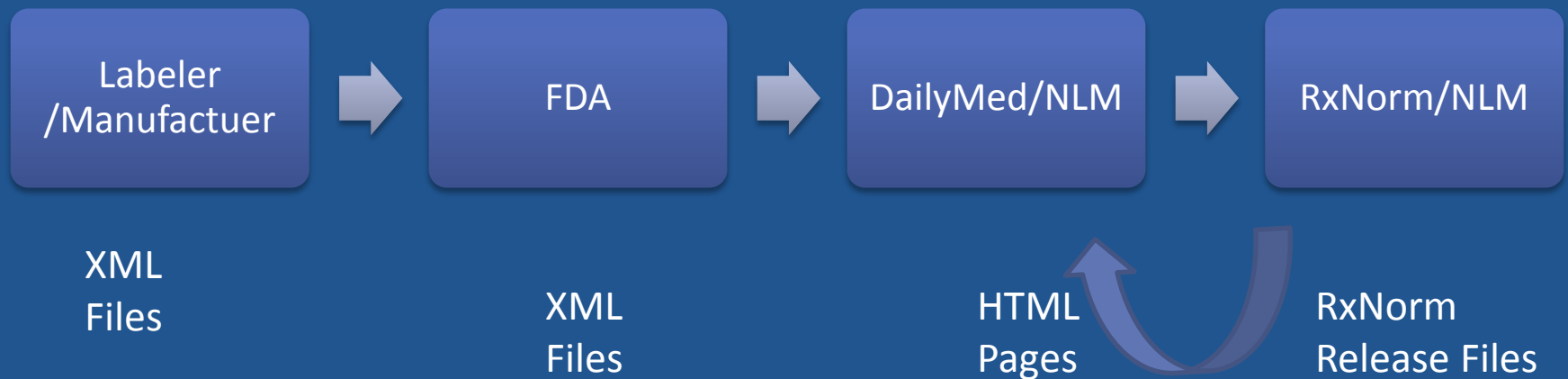
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# DailyMed Basics

- Structured Product Labeling (SPL)
  - HL7 standard in XML format
  - Adopted by FDA as their mechanism for submitting and sharing FDA approved product information and unapproved product information
  - SPL documents contain both package insert for a product and drug listing data elements
- Content validated by the FDA
- Contains prescription, OTCs, homeopathy, veterinarian
- First files November 1, 2005

# DailyMed/RxNorm Workflow

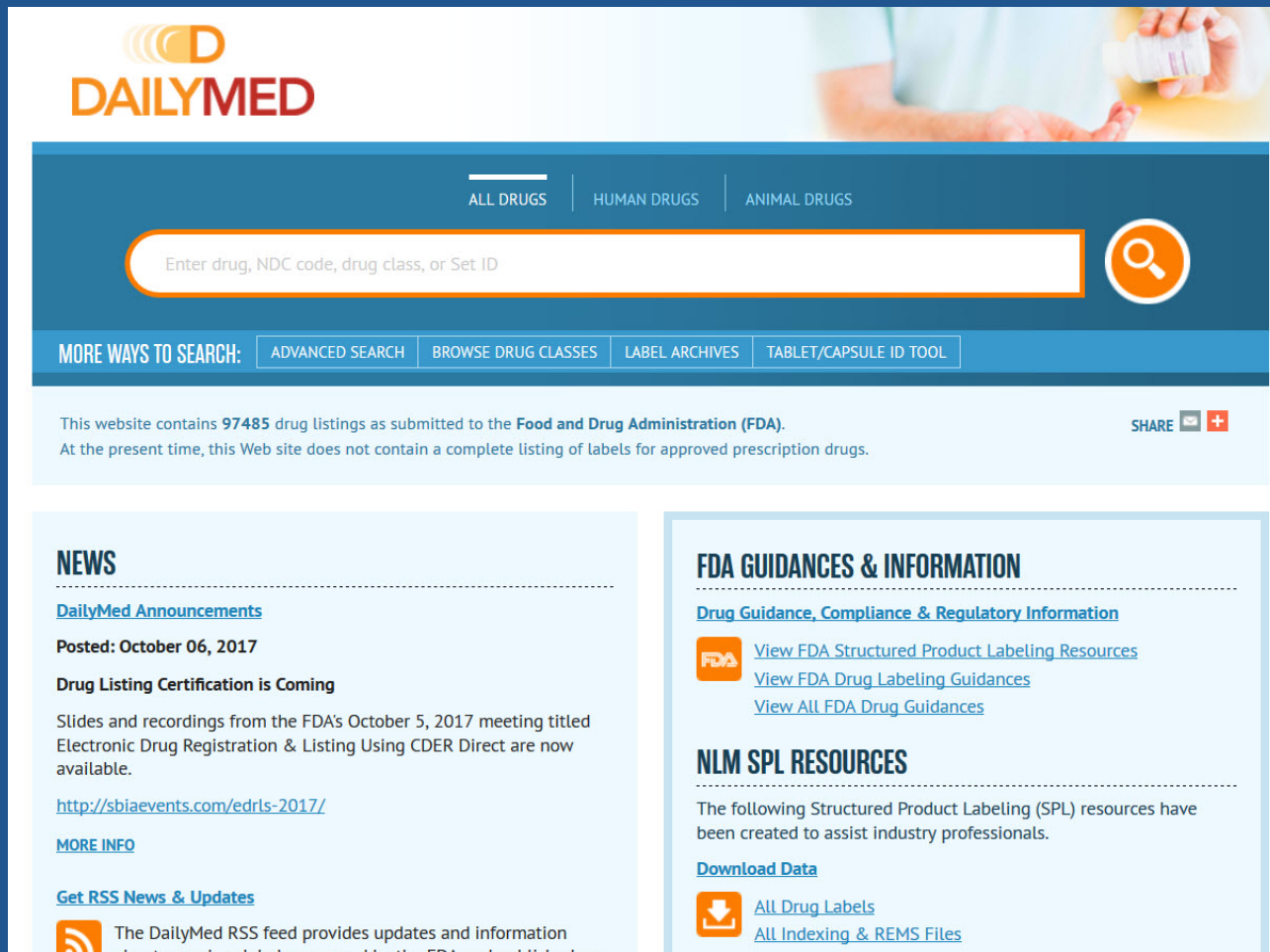


# Why DailyMed?

- Available Online (Section 508 Compliant)
- Advanced search
- Downloadable and printable for reuse
  - PDF
  - XML
- Archive
- Easily and quickly updated

# DailyMed Homepage

## <https://dailymed.nlm.nih.gov/dailymed/>



The screenshot shows the DailyMed homepage with a blue header and a white search bar. The search bar contains the text "Enter drug, NDC code, drug class, or Set ID". Below the search bar are links for "ALL DRUGS", "HUMAN DRUGS", and "ANIMAL DRUGS". A "MORE WAYS TO SEARCH:" section includes links for "ADVANCED SEARCH", "BROWSE DRUG CLASSES", "LABEL ARCHIVES", and "TABLET/CAPSULE ID TOOL". A notice states: "This website contains 97485 drug listings as submitted to the Food and Drug Administration (FDA). At the present time, this Web site does not contain a complete listing of labels for approved prescription drugs." The page is divided into two main sections: "NEWS" and "FDA GUIDANCES & INFORMATION". The "NEWS" section features a "DailyMed Announcements" link, a post dated "October 06, 2017" titled "Drug Listing Certification is Coming", and a link to "http://sbiaevents.com/edrls-2017/". The "FDA GUIDANCES & INFORMATION" section includes a "Drug Guidance, Compliance & Regulatory Information" link and three sub-links: "View FDA Structured Product Labeling Resources", "View FDA Drug Labeling Guidances", and "View All FDA Drug Guidances". The "NLM SPL RESOURCES" section states: "The following Structured Product Labeling (SPL) resources have been created to assist industry professionals." and includes links for "Download Data", "All Drug Labels", and "All Indexing & REMS Files".



**DAILYMED**

ALL DRUGS | HUMAN DRUGS | ANIMAL DRUGS

Enter drug, NDC code, drug class, or Set ID

MORE WAYS TO SEARCH: [ADVANCED SEARCH](#) [BROWSE DRUG CLASSES](#) [LABEL ARCHIVES](#) [TABLET/CAPSULE ID TOOL](#)

This website contains **97485** drug listings as submitted to the **Food and Drug Administration (FDA)**.  
At the present time, this Web site does not contain a complete listing of labels for approved prescription drugs.

SHARE  

### NEWS

[DailyMed Announcements](#)

Posted: October 06, 2017


**Drug Listing Certification is Coming**

Slides and recordings from the FDA's October 5, 2017 meeting titled Electronic Drug Registration & Listing Using CDER Direct are now available.

<http://sbiaevents.com/edrls-2017/>


[MORE INFO](#)

[Get RSS News & Updates](#)

 The DailyMed RSS feed provides updates and information about new drug labels approved by the FDA and published on

### FDA GUIDANCES & INFORMATION


[Drug Guidance, Compliance & Regulatory Information](#)

 [View FDA Structured Product Labeling Resources](#)  
[View FDA Drug Labeling Guidances](#)  
[View All FDA Drug Guidances](#)

### NLM SPL RESOURCES

The following Structured Product Labeling (SPL) resources have been created to assist industry professionals.


[Download Data](#)

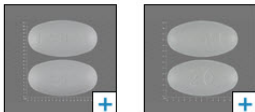
 [All Drug Labels](#)  
[All Indexing & REMS Files](#)

# DailyMed Example

**LABEL: LIPITOR- atorvastatin calcium tablet, film coated**

[LABEL RSS](#) [SHARE](#) [+](#)

**VIEW PACKAGE PHOTOS**  
  
[+ VIEW MORE](#)

**VIEW DRUG PHOTOS**  
**NDC Codes:**  
0071-0158-23    0071-0156-23  
  
[+ VIEW MORE](#)

**SAFETY**  
[Report Adverse Events](#)  
[FDA Safety Recalls](#)  
[Presence in Breast Milk](#)

**RELATED RESOURCES**  
[Medline Plus](#)  
[Clinical Trials](#)

**NDC Code(s):** 0071-0155-10, 0071-0155-23, 0071-0155-34, 0071-0155-40, [view more](#)  
**Packager:** Parke-Davis Div of Pfizer Inc

**Category:** HUMAN PRESCRIPTION DRUG LABEL  
**DEA Schedule:** None  
**Marketing Status:** New Drug Application

**DRUG LABEL INFORMATION** Updated July 6, 2017  
[If you are a consumer or patient please visit this version.](#)

**DOWNLOAD DRUG LABEL INFO:** [PDF](#) | [XML](#) | [+](#)    **OFFICIAL LABEL (PRINTER FRIENDLY)** [+](#)

**VIEW ALL SECTIONS**

[+ HIGHLIGHTS OF PRESCRIBING INFORMATION](#)  
These highlights do not include all the information needed to use LIPITOR safely and effectively. See full prescribing information for LIPITOR. LIPITOR - ® (atorvastatin calcium ...

[+ FULL PRESCRIBING INFORMATION: CONTENTS\\*](#)  
Table of Contents

[+ 1 INDICATIONS AND USAGE](#)  
Therapy with lipid-altering agents should be only one component of multiple risk factor intervention in individuals at significantly increased risk for atherosclerotic vascular disease ...

[+ 2 DOSAGE AND ADMINISTRATION](#)  
2.1 Hyperlipidemia and Mixed Dyslipidemia The recommended starting dose of LIPITOR is 10 or 20 mg once daily. Patients who require a large reduction in LDL-C (more ...

[+ 3 DOSAGE FORMS AND STRENGTHS](#)

# DailyMed Example

| AMBIEN<br>zolpidem tartrate tablet, film coated                   |                         |                    |               |
|---|-------------------------|--------------------|---------------|
| PRODUCT INFORMATION   |                         |                    |               |
| Product Type  | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:0024-5401 |
| Route of Administration   | ORAL                    | DEA Schedule       | CIV           |
| ACTIVE INGREDIENT/ACTIVE MOIETY                                   |                         |                    |               |
| Ingredient Name   |                         | Basis of Strength  | Strength      |
| zolpidem tartrate (UNII: WY6W63843K) (zolpidem - UNII:7K383OQI23) |                         | zolpidem tartrate  | 5 mg          |
| INACTIVE INGREDIENTS  |                         |                    |               |
| Ingredient Name   |                         |                    | Strength      |
| hypromellose, unspecified (UNII: 3NXW29V3WO)                      |                         |                    |               |
| lactose, unspecified form (UNII: J2B2A4N98G)                      |                         |                    |               |
| magnesium stearate (UNII: 70097M6I30)                             |                         |                    |               |
| microcrystalline cellulose (UNII: OP1R32D61U)                     |                         |                    |               |
| polyethylene glycol, unspecified (UNII: 3WJQ0SDW1A)               |                         |                    |               |
| titanium dioxide (UNII: 15FIX9V2JP)                               |                         |                    |               |
| FD&C Red No. 40 (UNII: WZB9127XOA)                                |                         |                    |               |
| polysorbate 80 (UNII: 6OZP39ZG8H)                                 |                         |                    |               |

# Other Features of DailyMed

- Indexing Files
  - Pharmacologic class
  - Billing Unit
  - Product Concept
  - Biologic or Drug Substance
  - Substance
  - Warning Letter Alert
  - REMS
- Mapping Files
  - SPL-RxNorm
  - SPL-Pharmacologic Class
  - SetID-Drug Name
- API
  - RxImage
  - RxNorm Names and Codes
  - RSS feed



# RxNorm

- What is RxNorm?
- How is it Structured?
- Substances in RxNorm
- Accessing RxNorm Data
- BoSS Project

# What is RxNorm?

- Drug terminology produced by NLM
- List of normalized names and unique identifiers for drugs derived from other drug terminologies
- Data from other drug terminologies and sources of drug information

# What is RxNorm?

- Collection of commonly-used public and private drug vocabularies:
  - FDA Structured Product Labels (DailyMed)
  - FDB
  - Gold Standard
  - Micromedix
  - Multum
  - VA National Drug File
  - NDF-RT
  - SNOMED
  - DrugBank
  - Anatomical Therapeutic Chemical Classification System (ATC)
  - MeSH
  - CMS Formulary Reference File

# What is RxNorm used for?

- Center for Medicare and Medicaid Services (CMS)
  - Formulary Reference File
  - Clinical Quality Measures (CQMs), Meaningful Use Value Sets
- Office of the National Coordinator (ONC)
  - Standard for medications and medication allergies
  - Required for Electronic Health Record (EHR) certification
- National Council for Prescription Drug Programs (NCPDP)
  - SCRIPT ePrescribing standard
  - Formulary and Benefit standard
- Veterans Affairs – Department of Defense (VA-DoD)

# Why RxNorm?

- Sample of NDCs from drug vocabularies:

000121-4727-10

603941854

050383-\*051-04

050962-\*203-59

55648069401

472038316

051660-\*851-16

49884-0396-33

68094-0316-58

049856-0351-\*1

55111060216

50962-0203-60

55111-0602-16

121472710

050962-\*203-60

173038354

68094031658

000121-0727-16

# Why RxNorm?

- Sample of drug names from drug vocabularies:

ranitidine 15 mg/mL oral syrup

RANITIDINE HCL 15 mg/mL ORAL SYRUP

RANITIDINE HCL 15 mg/mL ORAL SYRUP

RANITIDINE HCL@15  
mg/mL@ORAL@SYRUP

Ranitidine HCl Syrup 15 MG/ML (75  
MG/5ML)

Ranitidine Hydrochloride 15 MG/ML Oral  
Solution

Ranitidine Hydrochloride 15mg/1mL Oral  
solution

Ranitidine 15 MG/ML Oral Solution

RANITIDINE 15 MG ORAL SYRUP

RANITIDINE HYDROCHLORIDE 15 MG  
ORAL SYRUP

RANITIDINE HYDROCHLORIDE 16.8 MG  
ORAL SYRUP

RANITIDINE HYDROCHLORIDE 75 MG  
ORAL SOLUTION

RANITIDINE HYDROCHLORIDE 15 mg in 1  
mL ORAL SYRUP

RANITIDINE HYDROCHLORIDE 15 MG  
ORAL SYRUP

Ranitidine 15 mg in 1 mL ORAL SOLUTION

RANITIDINE 15 MG ORAL SOLUTION

RANITIDINE HYDROCHLORIDE 16.8 MG  
ORAL SOLUTION

# How is RxNorm structured?

## Group synonymous terms

(RANITIDINE 15 MG ORAL  
SOLUTION,

Ranitidine 75mg/5mL syrup,  
RANITIDINE 15 MG ORAL SYRUP)

Create  
unique  
identifier

(RXCUI=7  
05610)



\*only created for in  
scope content

Create normalized  
name\*

(Ranitidine 15 MG/ML  
Oral Solution)

# Semantic Clinical Drugs (SCD)

- Normalized:
  - Ingredient
  - Strength
  - Dose Form
- Out of Scope: Radiopharmaceuticals, Homeopathics, Medical Foods, Bulk Powders, Supplies, Cosmetics, Suntan Lotion



# How is RxNorm structured?

- Many levels of description - labeled with term types:

| TTY        | Ingredient        | Strength        | Dose Form            | Brand Name      |
|------------|-------------------|-----------------|----------------------|-----------------|
| IN         | Ranitidine        |                 |                      |                 |
| SCDC       | Ranitidine        | 15 MG/ML        |                      |                 |
| SCDF       | Ranitidine        |                 | Oral Solution        |                 |
| <b>SCD</b> | <b>Ranitidine</b> | <b>15 MG/ML</b> | <b>Oral Solution</b> |                 |
| <b>SBD</b> | <b>Ranitidine</b> | <b>15 MG/ML</b> | <b>Oral Solution</b> | <b>[Zantac]</b> |
| SBDF       | Ranitidine        |                 | Oral Solution        | [Zantac]        |
| SBDC       | Ranitidine        | 15 MG/ML        |                      | [Zantac]        |
| BN         |                   |                 |                      | Zantac          |

# How is RxNorm structured?

- Relationships connect TTYs/RXCUIs
  - SCD has tradename SBD
  - BPCCK contains SCD consists of SCDC has ingredient IN
  - SBD has doseform DF
- RXCUIs have associated attributes
  - NDCs
  - Marketing Category
  - Labeler

# Ingredients in RxNorm

- Ingredients (IN) – warfarin, fluoxetine, filgrastim
  - Frequently base ingredient/active moiety
- Precise Ingredients (PIN) – warfarin sodium, fluoxetine hydrochloride, filgrastim-sndz
  - Often the salt, ester, isomer, organism specific form, biosimilar
- A PIN must be related to an IN
- An IN can have 0 to many PINs
- Brand Names (BN)
  - A BN can only have 1 set of ingredients
  - Must be related to an IN or PIN

# Ingredients in RxNorm

- New INs, PINs created when we create normal forms
- SPL/DailyMed Labels
  - Almost all ingredients in a DailyMed label
    - exceptions: water buffalo
  - Includes out of scope content
  - UNIs added as an attribute
  - Not 1:1 with UNIs but close
    - Insulin
    - Biosimilars

# Naming Ingredients

- Use the US names when available (USAN/USP)
- What we see in drug labels
- Synonyms for INs & PINs
  - INN Names
  - When there is a Latin & Common Name

# What is no in RxNorm

- Drug Indications/Pharmacologic Actions created by NLM
- Drugs not found in our sources
  - No normal forms for experimental clinical drugs
  - Foreign content
- Supplies found in pharmacies
- The entire list of UNII

# How Do I Get My Drugs into RxNorm?

- DailyMed Label
- Daily Updates from DailyMed
- Weekly & Monthly Releases

# How do I access RxNorm data?

<http://www.nlm.nih.gov/research/umls/rxnorm/>

- Monthly zip file\*
  - Weekly updates for newly added DailyMed drug labels
- Current Prescribable Content subset zip file
- APIs – RxNorm, prescribable subset

\*Requires a (free) UMLS license to access



ATOMS LIST x FDA Substance R x RxNav x THYMIC FACTOR, x thymulin sequenc x pubmed - Yahoo S x Nonathymulin in r x

https://mor.nlm.nih.gov/RxNav/search?searchBy=String&searchTerm=FILGRASTIM-SNDZ Search

U.S. National Library of Medicine About Disclaimer FAQ

**RxNav**  
Navigating RxNorm Drugs

String FILGRASTIM-SNDZ

**FILGRASTIM-SNDZ** [RxCUI = 1605064]

RxNorm Graph RxNorm Properties NDC RxTerms NDF-RT Pill Images Class View Interaction View Status

Views

- Classic
- Simple
- Table

Filters

☐ H ☐ V ☐ Rx ☐ S

☒ Group ☐ Form

Links

Legend

- MIN
- Pack
- Multi

Download

| IN/MIN | Ingredient (1) | PIN    | Precise Ingredient (1) | BN     | Brand Name (1) |
|--------|----------------|--------|------------------------|--------|----------------|
| H Rx S | Filgrastim     | H Rx S | FILGRASTIM-SNDZ        | H Rx S | Zarxio         |

| SCDC   | Clinical Drug Component (1) | SBDC   | Branded Drug Component (1)         |
|--------|-----------------------------|--------|------------------------------------|
| H Rx S | FILGRASTIM-SNDZ 0.6 MG/ML   | H Rx S | FILGRASTIM-SNDZ 0.6 MG/ML [Zarxio] |

| SCD/GPCK | Clinical Drug or Pack (2)                          | SBD/BPCK | Branded Drug or Pack (2)                  |
|----------|--|----------|---|
| H Rx S   | 0.5 ML FILGRASTIM-SNDZ 0.6 MG/ML Prefilled Syringe | H Rx S   | 0.5 ML Zarxio 0.6 MG/ML Prefilled Syringe |
| H Rx S   | 0.8 ML FILGRASTIM-SNDZ 0.6 MG/ML Prefilled Syringe | H Rx S   | 0.8 ML Zarxio 0.6 MG/ML Prefilled Syringe |

| SCDG   | Clinical Dose Form Group (1)  | DFG    | Dose Form Group (1) | SBDG   | Branded Dose Form Group (1) |
|--------|-------------------------------|--------|---------------------|--------|-----------------------------|
| H Rx S | Filgrastim Injectable Product | HvRx S | Injectable Product  | H Rx S | Zarxio Injectable Product   |

**RxNav**  
Navigating RxNorm Drugs

## Class Browser

- > Anatomical Therapeutic Chemical (ATC1-4)
- > Established Pharmacologic Classes (EPC)
- [from DailyMed]
- > MeSH Pharmacologic Actions (MESHPA)
- > Disease
- > Chemical Structure (Chem) [from DailyMed]
- > Mechanism of Action (MoA) [from DailyMed]
- > Physiologic Effect (PE) [from DailyMed]
- > Pharmacokinetics (PK)
- > VA Classes (VA)

## RxClass

Exploring drug classes and their RxNorm drug members

Adrenergic alpha-Agonists

☒ by class name/id ☐ by RxNorm drug name/id ☒ ingredient drug only Edit Drug Sources

Adrenergic alpha-Agonists

class: **Adrenergic alpha-Agonists** / id: N0000000209 / class type: **MOA** / [show context](#)

12 RxNorm generic drugs for **has\_MoA** in DailyMed / [similar classes](#)

| Type | RXCUI  | RxNorm Name     | Relation | All classes |
|------|--------|-----------------|----------|-------------|
| IN   | 14845  | apraclonidine   | DIRECT   | Show        |
| IN   | 134615 | brimonidine     | DIRECT   | Show        |
| IN   | 2599   | Clonidine       | INDIRECT | Show        |
| IN   | 48937  | Dexmedetomidine | INDIRECT | Show        |

# Basis of Strength Substance (BOSS) Project

- SNOMED CT and IDMP Alignment
- Began Summer 2017; Estimated Release Spring 2018
- Identify components
  - Active Ingredient
  - Active Moiety
  - Basis of strength substance
  - Strength
  - Unit of Measure

# Questions?

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