



Supporting Innovation with DFL Standards

June 9th, 2021

FDA DFL Workshop

Presenter: Stephen Konya

Senior Advisor to the Deputy National Coordinator
for Health IT and Innovation Portfolio Lead

The Office of the National Coordinator for
Health Information Technology



National Strategic Priorities for Health IT

- 1) ONC is focused on connecting healthcare and health data through a national interoperable Health IT infrastructure.
- 2) ONC is working to reduce the regulatory and administrative burden related to the use of health IT, including EHRs.
- 3) ONC is working on ways to give clinicians more time to focus on what matters – caring for their patients.

Supporting Documents;

- [ONC's Cures Act Final Rule](#)
- [Strategy on Reducing Burden Relating to the Use of Health IT and EHRs](#)
- [2020-2025 Federal Health IT Strategic Plan](#)

(all can be found at www.HealthIT.gov)



ONC's 21st Century Cures Act Final Rule

Putting the patient first in health technology enables the health care system to deliver:

- Transparency into the cost and outcomes of their care
- Competitive options in getting medical care
- Modern smartphone apps to provide them convenient access to their records
- An app economy that provides patients, physicians, hospitals, payers, and employers with innovation and choice

Direct Links;

- [Fact Sheets](#)
- [Webinars](#)
- [Media/Press](#)
- [Blog Post](#)
- [Download Final Rule](#)

Main Landing Page;

<https://www.healthit.gov/curesrule/>

Step #1 – Define Your Innovation Community

For ONC, we've defined the health IT innovation community as follows;

1. **Early adopters** who implement and test emerging technology and novel approaches
2. **Entrepreneurs** and **developers** who build new technology and bring it to market
3. **Investors** who financially support the builders and implementers of new technology and novel approaches
4. **Incubators, accelerators, bootcamps, associations and membership networks** that support any of the above 3 types of innovation stakeholder categories

Innovation Spectrum Support Stages

• Ideation Support (stage 1)

Purposes:

- Exploration / discovery research
- Calls to action / raise awareness
- Signal priorities
- Address pain points / areas of need

Examples:

- Research grants
- White paper solicitations
- Workshops / meetups
- Challenge competitions
- Hackathons / code-a-thons
- Think tanks

• Development Support (stage 2)

Purposes:

- Build
- Test
- Evaluate
- Iterate
- Validate

Examples:

- Bootcamps
- Accelerator programs
- Pilots
- Mentorship
- Resources / toolkits
- Challenge competitions

• Deployment Support (stage 3)

Purposes:

- Commercialization
- Market penetration
- Implementation / utilization

Examples:

- Public / private partnerships
- Connections to capital / investment
- Matchmaking / surfacing promising solutions
- Alignment with contracting opportunities
- Policy levers / incentives



Opportunities for Greater Innovation and Use of Modern Technologies and Approaches

#1 - Use of embedded QR codes

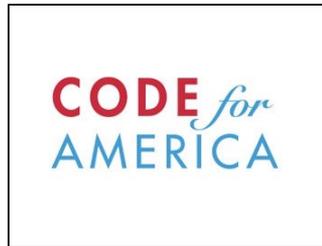
- Greater consumer engagement (for pharmacovigilance, proper use, etc.)
- Translation services / engagement
- Additional Education (informational websites, interactive media, links to peer to peer community forums, etc.)
- Obtaining consumer feedback (surveys, adverse interactions reporting, etc.)

#2 - Realize full potential of open data opportunities

- Partner with industry to use DFL standards in the online / digital marketplace
- Work with civic coders and “big tech” companies on feedback for future development off standards and releases of API accessible/machine readable open data on DFLs/OTCs

Public Health - Restaurant Inspection Data

Local Inspector Value-Entry Specification (LIVES)



Public Health - Restaurant Inspection Data

yelp Find tacos, cheap dinner, Max's Near San Francisco, CA

Home About Me Write a Review Find Friends Messages Talk Events Sign Up Log In

The Topsy Pig

994 reviews & Details

Write a Review Add Photo Share Bookmark

2231 Chestnut St San Francisco, CA 94123

Get Directions (415) 292-2300 thetopspigst.com

"Loud but engaging ... the food was great" in 118 reviews
Noise Level: Loud

"Especially delicious are the ahi tuna burger, mac and cheese, and sweet potato fries." in 105 reviews

"Beer is the way to go here eventhough they do have a full bar." in 139 reviews
Alcohol: Full Bar

Chinese Food San Francisco SP Welcomes the Chinese Chef Han, SF, served President Deng Xiaoping www.zandyrestaurant.com

Print Restaurant Coupons (free) Restaurant Coupons Online. Print Free Coupons Now. savingmore.com/coupons

Ads by Google

Make a Reservation

Thursday, May 1, 2014

9:30 pm 2 people

Find a table

Today 11:30 am - 2:00 am Open now

Menu

Price range: \$11-30

89 Health score 89 out of 100

Recommended Reviews

yelp Find tacos, cheap dinner, Max's Near San Francisco, CA

Home About Me Write a Review Find Friends Messages Talk Events Sign Up Log In

The Topsy Pig - Health Inspections

The Topsy Pig

January 24, 2014 — Routine Inspection

Health Score
89
out of 100

Violations

- High risk food holding temperature [date violation corrected: 1/24/2014]
- Foods not protected from contamination [date violation corrected: 1/27/2014]

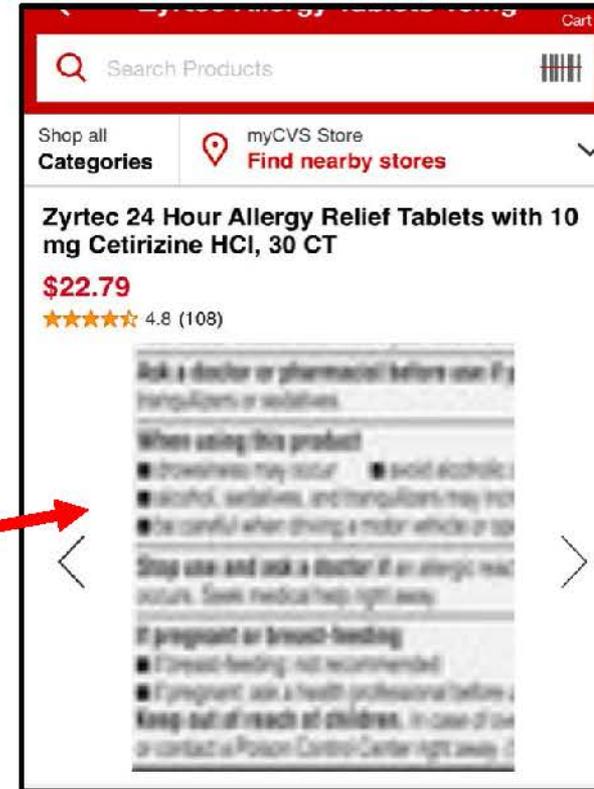
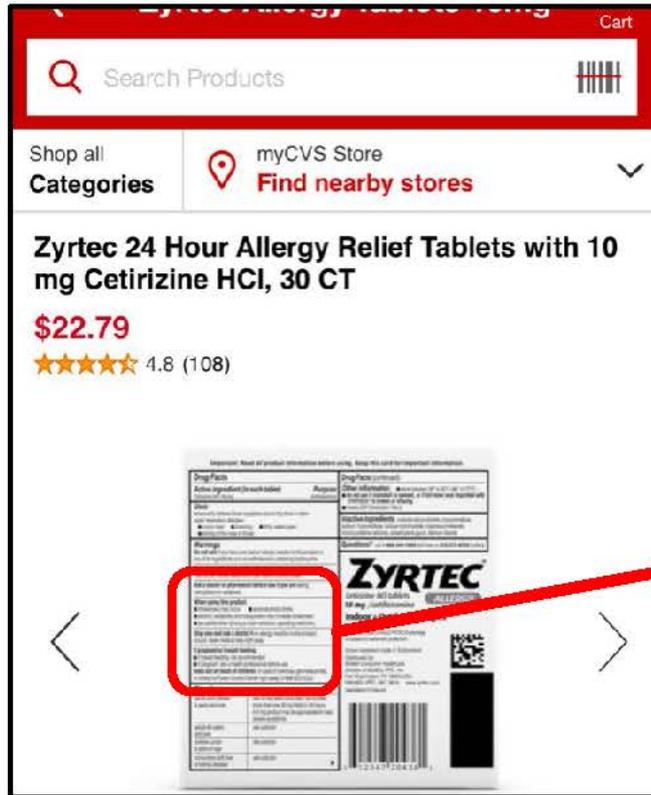
Previous Inspections

Date	Inspection Type	Violations	Score
July 17, 2013	Routine		100
August 17, 2012	Routine		100
January 24, 2012	Routine		95
July 14, 2011	Routine	Violations: July 14, 2011 - Moderate risk food holding temperature [date violation corrected: 7/14/2011]	95

About Yelp Health Scores

We collect public inspection data directly from your local health department. Due to the local health department's inspection schedule as well as other factors, information on this page may not display the most recent information available. Please report any inaccuracies to us via their website or contact us.

CVS Mobile App



CVS Mobile App

Prices may vary from online to in store.

Ships **Free** With **CarePass™**   

Members enjoy free shipping on entire order when it contains at least one CarePass-eligible item.

Eligible for 1 to 4 day shipping 

Free shipping on \$35+ orders

Details 

Ingredients 

Directions 

Warnings 

Reviews 

 **Directions**

Adults and children 6 years and over: one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg product may be appropriate for less severe symptoms. Adults 65 years and over: ask a doctor Children under 6 years of age: ask a doctor Consumers with liver or kidney disease: ask a doctor Other information: Store between 20-25°C (68-77°F) Meets USP Dissolution Test 2 Questions? call 1-800-343-7805 (toll-free) or 215-273-8755 (collect)

Walgreens Mobile App

Zyrtec Allergy Dissolve Tablets
Citrus Flavor 24.0ea

FSA

\$19.99 (\$0.83/ea)

Online and in-store prices may vary

★★★★★ 180

Rebate Available [View](#)



 Pickup
In stock

 Same Day Delivery
In stock

 Shipping
In stock

[Pickup FAQs](#)

Drug Facts

Active ingredient (in each tablet)	Purpose
Cetirizine HCl 10 mg	Antihistamine

Uses
temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

Warnings
Do not use if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

When using this product

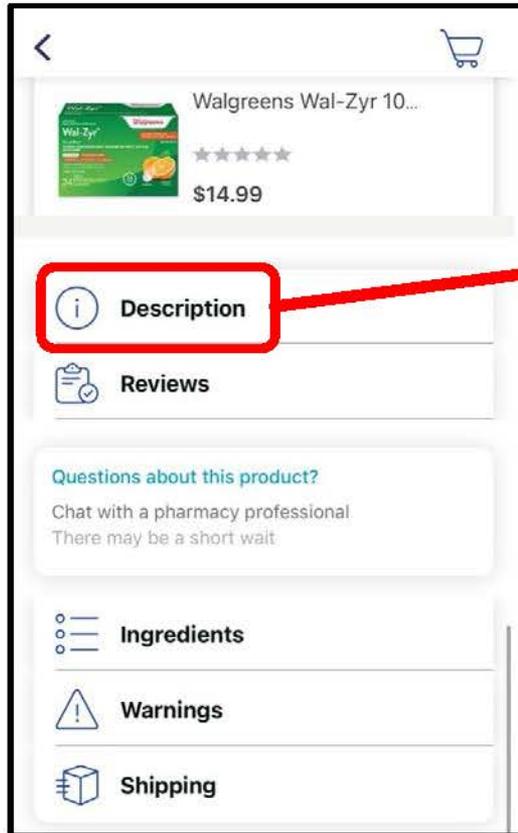
- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.

If pregnant or breast-feeding:

- if breast-feeding: not recommended
- if pregnant: ask a health professional before use.

Walgreens Mobile App



← Description

- 24 hour Zyrtec Allergy Relief Dissolve Tablets for all-day relief of allergy symptoms
 - Tablets help treat symptoms such as runny nose, sneezing, itchy, watery eyes, and itchy nose and throat
 - Get all-day allergy relief from this anti-allergy medicine that starts working hard at hour one
 - This allergy medicine works twice as hard when you take it again the next day
 - Each allergy dissolving tablet contains 10 mg of powerful cetirizine hydrochloride antihistamine
 - These prescription-strength allergy relief tablets melt in your mouth with a tangy citrus flavor
 - Get effective symptom relief from the #1 allergist-recommended brand among OTC oral antihistamines
 - Suitable those 6 years of age and older, this allergy medicine provides relief for a full 24 hours

Get effective relief from allergy symptoms caused by hay fever and other upper respiratory allergies with easy-to-take Zyrtec Allergy Relief Dissolve Tablets. This prescription-strength allergy medicine starts working hard at hour 1 and works twice as hard when you take it again the next day. From the #1 allergist-recommended brand among OTC oral antihistamines, this seasonal allergy medicine contains 10 milligrams of cetirizine hydrochloride in each tablet and helps treat symptoms caused by both



Leveraging Open Data ([open.FDA.gov](https://open.fda.gov))



U.S. Department of Health and Human Services
Food and Drug Administration

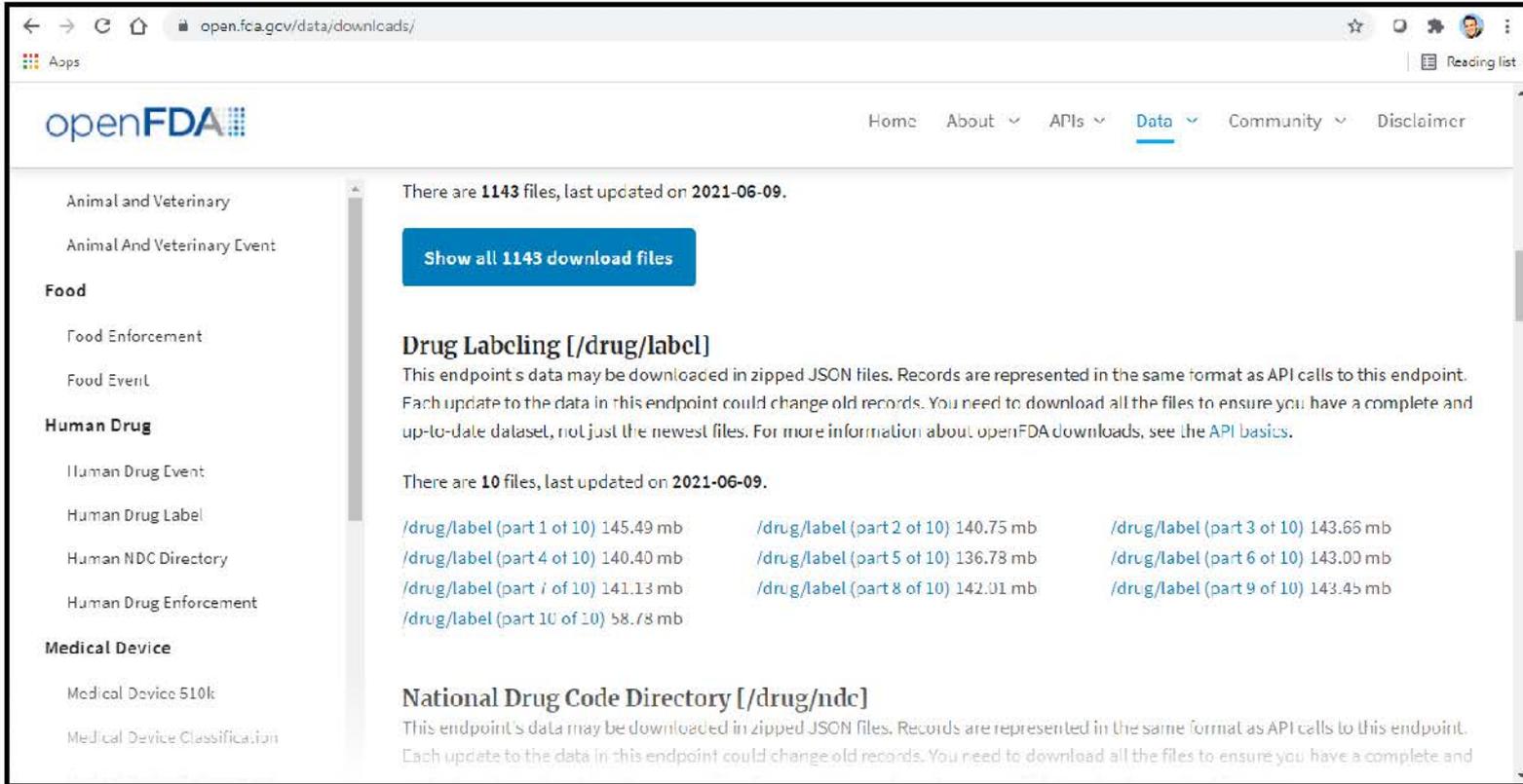
openFDA

[Home](#) [About](#) [APIs](#) [Data](#) [Community](#) [Disclaimer](#)



<https://open.fda.gov/apis/>

Leveraging Open Data ([open.FDA.gov](https://open.fda.gov))



The screenshot shows the openFDA website interface. The browser address bar displays `open.fda.gov/data/downloads/`. The navigation menu includes Home, About, APIs, Data (highlighted), Community, and Disclaimer. The main content area is titled "Data" and lists several categories of data available for download:

- Animal and Veterinary**
 - Animal And Veterinary Event
- Food**
 - Food Enforcement
 - Food EventL
- Human Drug**
 - Human Drug Event
 - Human Drug Label
 - Human NDC Directory
 - Human Drug Enforcement
- Medical Device**
 - Medical Device 510k
 - Medical Device Classification

The "Human Drug Label" section is expanded, showing a summary of 1143 files last updated on 2021-06-09, with a button to "Show all 1143 download files". Below this, the "Drug Labeling [/drug/label]" endpoint is detailed, stating that data can be downloaded in zipped JSON files and that each update could change old records. It lists 10 files available for download, each representing a part of the 10-part dataset:

File Name	Size
/drug/label (part 1 of 10)	145.49 mb
/drug/label (part 2 of 10)	140.75 mb
/drug/label (part 3 of 10)	143.66 mb
/drug/label (part 4 of 10)	140.40 mb
/drug/label (part 5 of 10)	136.78 mb
/drug/label (part 6 of 10)	143.00 mb
/drug/label (part 7 of 10)	141.13 mb
/drug/label (part 8 of 10)	142.01 mb
/drug/label (part 9 of 10)	143.45 mb
/drug/label (part 10 of 10)	58.78 mb

The "National Drug Code Directory [/drug/ndc]" section is also visible, indicating that its data can be downloaded in zipped JSON files and that updates could change old records.



Standards Version Advancement Process (SVAP)



★ **NEW:** Health IT Feedback Portal

Official Website of The Office of the National Coordinator for Health Information Technology (ONC)

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HealthIT.gov > Topics > Certification of Health IT > Certification Criteria > Standards Version Advancement Process (SVAP)

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[Certification Process](#) +

Certification Criteria -

[2015 Edition Cures Update](#)

[2015 Edition](#)

[\(Retired\) 2014 Edition](#)

[2015 Edition Cures Update - Base Electronic Health Record \(EHR\) Definition](#)

[Standards Version Advancement Process \(SVAP\)](#)

[Conditions & Maintenance of Certification](#)

Standards Version Advancement Process (SVAP)

The Standards Version Advancement Process (SVAP) permits health IT developers to voluntarily update health IT products certified under the ONC Health IT Certification Program to newer versions of adopted standards as part of the “Real World Testing” Condition and Maintenance of Certification requirement (§ 170.405) of the 21st Century Cures Act.

Using SVAP, certified health IT developers are permitted to voluntarily use a newer approved version of a standard than is adopted in regulation. Currently, this flexibility is limited to standards that are adopted in the certification criteria required to meet the “Real World Testing” Condition of Certification, which include § 170.315(b), (c)(1) through (c)(3), (e)(1), (f), (g)(7) through (g)(10), and (h).

Health IT developers taking advantage of the SVAP flexibility must ensure that their Real World Testing plans and results of the certified health modules address these updated standards. Additionally, health IT developers updating their already certified health IT modules are required to provide advance notice to their clients and ONC-Authorized Certification Body (ONC-ACB) before adopting a newer approved version of a standard.

Working with industry stakeholders, ONC has developed a collaborative public comment process to identify newer versions of standards that are ready for use in the Program. For additional information on the annual process, including the list of standards and versions eligible for consideration, please visit the [SVAP Process Page](#).

Approved SVAP Versions

The approved SVAP versions for 2020 went into effect in the ONC Health IT Certification Program beginning March 12, 2021. The following newer versions of adopted standards have been approved for use:

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Approved Standards for 2020

Certification Criteria	SVAP Version(s) Approved	Current Standard Version(s)	Regulatory Text Citation
§ 170.315(c)(3) - Clinical quality measures (CQMs) — report	 New version available CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2021 (Available 3/12/2021)	CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2019	§ 170.205(h)(3)
	 New version available CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2021 (Available 3/12/2021)	CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2019	§ 170.205(k)(3)
§ 170.315(e)(1) - View, download, and transmit to 3rd party	 New version available Web Content Accessibility Guidelines (WCAG) 2.1, June 05, 2018 (Available 3/12/2021) ^{ff}	Web Content Accessibility Guidelines (WCAG) 2.0, December 11, 2008 ^{ff}	§ 170.204(a)(1)
	 New version available Web Content Accessibility Guidelines (WCAG) 2.1, June 05, 2018 (Available 3/12/2021) ^{ff}	Web Content Accessibility Guidelines (WCAG) 2.0, December 11, 2008 ^{ff}	§ 170.204(a)(2)
§ 170.315(f)(7) - Transmission to	 New version available HL7 CDA [®] R2 Implementation	HL7 Implementation Guide for CDA [®] Release 2: National Health Care Surveys (NHCS), Release 1 -	

ONC's Standards Version Advancement Process (SVAP)

Setting a New Vision for the Future



To Participate:

- 1) Go to www.HealthIT.gov/HealthInterop2030
- 2) Chat us up on Twitter @ONC_HealthIT with #HealthInterop2030 to send your response

(Submissions will be accepted through July 30, 2021!!!)

Contact Information:

Stephen Konya

Senior Advisor and Innovation Portfolio Lead
U.S. Department of Health and Human Services (HHS),
Office of the National Coordinator for Health IT (ONC)

[Email: Stephen.Konya@hhs.gov](mailto:Stephen.Konya@hhs.gov)

www.HealthIT.gov