UDI Expansion & Progress: FDA Perspective

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How does UDI impact clinical workflow?

- UDI Drives
- (EMR) documentation
- Product consumption
- Inventory replenishment
- Patient charging
- Complete cost accounting

Clinically Relevant Size in the GUDID database
Are we there yet?

Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company’s announcement as a public service. FDA does not endorse either the product or the company.

Pepperidge Farm® Announces Voluntary Recall of Four Varieties of Goldfish® Crackers

For Immediate Release

July 23, 2018

Contact

Consumers
Customer Service
800-579-1791

Media
Bethridge Toovey
Bethridge.Toovey@PepperidgeFarm.com
203-845-7136

Cell Phone Email Alert

From: Walmart.com Recalls <WMRecalls1@walmart.com>
Date: Wed, Jul 25, 2018 at 12:19 AM
Subject: Pepperidge Farm® Announces Voluntary Recall of Four Varieties of Goldfish Crackers

Dear Valued Walmart Customer:

Pepperidge Farm has been notified by one of its ingredient suppliers that whey powder in a seasoning that is applied to some varieties of crackers has been the subject of a recall by the whey powder manufacturer due to the potential presence of Salmonella. Pepperidge Farm initiated an investigation and, out of an abundance of caution, is voluntarily recalling select varieties of Goldfish crackers.

Pepperidge Farm has asked us to recall the products listed below with the corresponding Best by Dates. Our records reflect that you may have purchased one or more of the items listed below.

<table>
<thead>
<tr>
<th>Description</th>
<th>UPC</th>
<th>Sell By Dates</th>
<th>Product Images</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pepperidge Farm® Goldfish® Flavor Blasted® Kara Cheddar Crackers, 6.6 oz. Bag</td>
<td>1410008548</td>
<td>WO 11/25/18, WO 12/2/18, WO 12/9/18, WO 12/16/18, WO 1/20/19</td>
<td></td>
</tr>
</tbody>
</table>
Unique Device Identification System

Adequate identification... Distribution and use

GUDID as reference data source of quality master data

UDI in supply chain

UDI in Regulatory data (annual reports, MDRs, recalls, etc.)

UDI in healthcare data (EHRs, registries, claims, etc.)
It always seems impossible until it’s done

-Nelson Mandela
<table>
<thead>
<tr>
<th>Compliance Date</th>
<th>Must bear a UDI and Submit data to GUDID</th>
<th>Direct Marking (for certain intended uses)</th>
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</thead>
<tbody>
<tr>
<td>Sep 24, 2014</td>
<td>Class III devices</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Devices licensed under the PHS Act</td>
<td></td>
</tr>
<tr>
<td>Sep 24, 2015</td>
<td>Implantable, life-supporting and life-sustaining (I/LS/LS) devices</td>
<td>LS/LS devices</td>
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<tr>
<td>Sep 24, 2016</td>
<td>Class II devices</td>
<td>Class III devices and devices licensed under the PHS Act</td>
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<tr>
<td>Sep 24, 2018</td>
<td>Class I devices</td>
<td>Class II devices</td>
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<tr>
<td></td>
<td>Unclassified devices</td>
<td></td>
</tr>
<tr>
<td>Sep 24, 2020</td>
<td>Class I devices</td>
<td>Class I devices</td>
</tr>
<tr>
<td></td>
<td>Unclassified devices</td>
<td>Unclassified devices</td>
</tr>
<tr>
<td>Sep 24, 2022</td>
<td>Class I devices</td>
<td>Class I devices</td>
</tr>
</tbody>
</table>
|                 | Unclassified devices                    | Unclassified devices                     | Extended via ED guidance
GUDID Records and Submission Compliance Dates

Data Current as of June 3, 2019

Compliance Dates

- Sep-2013
- Sep-2014
- Sep-2015
- Sep-2016
- Sep-2017
- Sep-2018
- Sep-2019
- Sep-2020
4,900+ Companies Have Published Records to GUDID

Data Current as of June 3, 2019

- 1,000-9,999 Records
- 100-999 Records
- 10-99 Records
- 1-9 Records
- 10,000+ Records
GUDID Labeler Locations by Country

Data Current as of June 3, 2019

- Canada: 165
- England: 164
- USA: 3,460
- France: 130
- Germany: 303
- Italy: 120
- Japan: 103
- South Korea: 151
- China: 228
- Israel: 135

All Other Countries in Blue < 100
New Companies in GUDID Each Month

Data Current as of June 3, 2019
AccessGUDID Views

May 2019
UDI Conference 2019

UDI Webpage Views

January-March 2019
UDI Webpage Revisions: Simplicity

Unique Device Identification System (UDI System)

The FDA established the unique device identification system to adequately identify medical devices sold in the United States from manufacturing through distribution to patient use.

When fully implemented, the label of most devices will include a unique device identifier (UDI) in human- and machine-readable form, which will ultimately improve patient safety, modernize device postmarket surveillance, and facilitate medical device innovation.

Device Labelers: Comply with UDI Requirements

In general, the UDI final rule requires device labelers (typically, the manufacturer) to:

1. Include a unique device identifier (UDI), issued under an FDA-accredited issuing agency’s UDI system, on device labels, device packages, and in some instances, directly on the device.
2. Submit device information in the Global Unique Device Identification Database (GUDID).

Search the AccessGUDID Database

AccessGUDID is a searchable database of device identification information, such as the device identifier on the label, device name, company name, UDI safety status, and presentation submission information. AccessGUDID is available for anyone, including patients, care givers, health care providers, hospitals, and industries.

Device Labelers: Submit Data to GUDID

The FDA provides device labelers with two systems for submitting data to GUDID: manual data entry using the GUDID web application (for entering data for one device at a time) and XML SFD submission via FDA Electronic Submissions Gateway (for bulk uploads). For details on each option, see Submit Data to GUDID.
# UDI Regulatory /Resources

<table>
<thead>
<tr>
<th>Type of Resource</th>
<th>Count</th>
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<tbody>
<tr>
<td>FDA UDI Guidance Documents</td>
<td>8 (final) 1 (draft)</td>
</tr>
<tr>
<td>Webinars/Training videos</td>
<td>9</td>
</tr>
<tr>
<td>Technical Documents</td>
<td>5</td>
</tr>
<tr>
<td>UDI Dockets</td>
<td>1</td>
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</tbody>
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As of June 1, 2019
Community Conversations

“The problem before us is to exchange information and so to educate ... that there shall develop a final, cosmopolitan system of medicine which will combine the best elements to be found in all countries.”

-Charles H. Mayo, M.D (1936)
UDI Strategic Partnerships

Developing Infrastructure
• ISO, HL7, NCPDP, X12
• 4 UDI Data Exchange documents

Aligning Infrastructure to Policy
• Office of National Coordinator for Health IT (ONC)
• Center for Medicare and Medicaid Services (CMS)

Testing it out: Pilots and Implementations
• Patient Centered Outcomes Research – Trust Fund Women’s Health Technology
• Medical Device Epidemiology Network – BUILD, RAPID, ...
• CDC – 2 Pilots – Lab and NHSN
• VA VISN Implementations

Identifying Opportunities for improvement
• 560+ members of AHRMM Learning UDI Community
  – 11 Workgroups/Issues
UDI in Real World Data

- **Electronic Health Records** – over 190 include standard functionality for capturing UDI
- **Health Systems** – over 200 implementing UDI by scanning products, linking to GUDID; creating implantable device lists; transmitting to other systems
- **Registries** - Demonstration Projects in 5+ device areas – Cardiovascular, Gastrointestinal, Prostate, Peripheral Artery, Women’s Health Technology
- **Claims** – UDI2Claims pilot; Business Requirements
IMDRF UDI Application Guide

IMDRF/UDI WG/N48 FINAL: 2019
UDI system application guide

IMDRF/UDI WG/N53 FINAL: 2019
UDI data elements across different jurisdictions

IMDRF/UDI WG/N54 FINAL: 2019
Systems requirements related to use of UDI in health care including special use cases

Available to Public on 5/24/2019
http://imdrf.org/ Documents
Improving DI records

1,659 companies (36,311 DIs) have used the Unlock process

82 companies (19,316 DIs) populated the catalog number field which were previously null

72 companies (4,660 DIs) populated the Description field which were previously null

Always room for improvement----
Example: Customer Contact info missing/Null:
37% for all DI
30% for Implants
FDA announced intention to end the temporary extension of the GUDID grace period and requested public comments on December 18, 2018.

Comment period closed January 18, 2019.

Public comments supported reverting grace period back to 7 calendar days from 30 calendar days.

GUDID grace period reverted back to 7 calendar days on March 11, 2019.
FDA Premarket Submission Numbers

• Release of “FDA Premarket Submission Number” and “Supplement Number” fields (premarket numbers) in AccessGUDID and OpenFDA

• Submission of CDER approved FDA Premarket Submission Numbers
The goal is to have the UDI system not only up and running—but actually used as the key to unlock important data that can help patients.

- Dr. Jeff Shuren, FDA CDRH Center Director
Community Conversations - Day 1

• Crowley and Reed: Global use cases rely on proper initial development, maintenance and re-use of data
• Lupinetti, Tcheng and Drozda: Extending the value of UDI to clinicians
• Roan, Black and Fowler: The case for UDI as an ongoing process
• Cordie: Global Supply chain issues
• Networking: 3:30-5:00pm
Community Conversations – Day 2

• Crowley: Comparing EU to US regulations
• LeMaster, Pierce, Watson, Rapp: Voices from the front lines
• Schiller, Steger, Rapp, Erlinger and Pistor: Recording implant data in the sterile field
• Tcheng, Henry, Skau, Reed: UDI in research
• Community Conversation – Set the Future direction of UDI activities
Thank you for helping us move forward!