



Keynote:

The State of Drug Registration and Listing (DRLS)




Paul Loebach



Where did DRLS start?

1972-2009

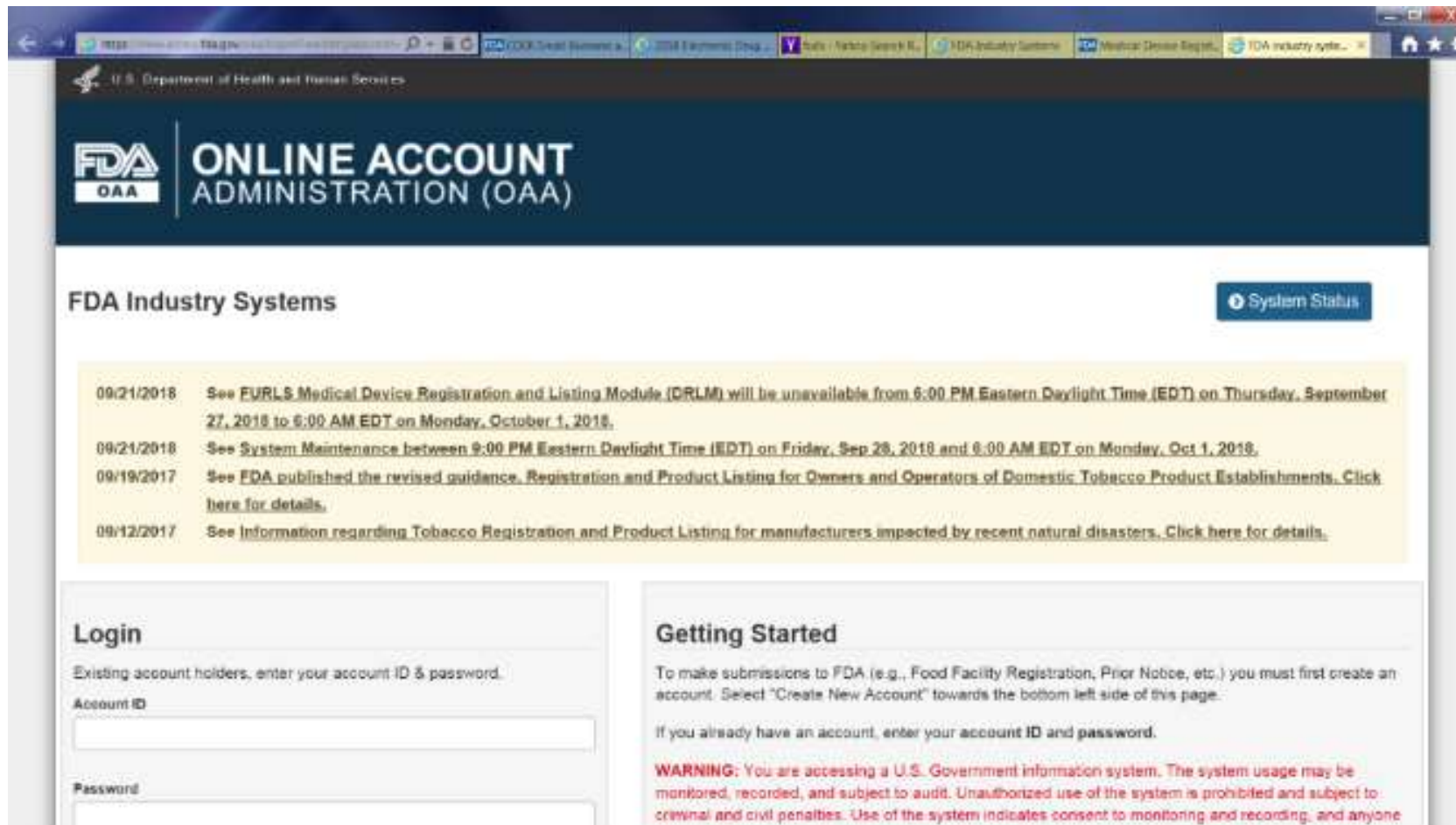
Paper Forms 2656, 2657, and 2658

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION DRUG PRODUCT LISTING <i>(In accordance with Public Law 92-387)</i>										NAME AND ADDRESS OF FIRM Chatten Chemicals, Inc. 3801 St. Elmo Avenue Chattanooga, TN 37409										LABELING REVISION CHANGES: <input type="checkbox"/> TYPE OF CHANGE <input type="checkbox"/> INDICATION <input type="checkbox"/> NAME/ADDRESS/TYPE OF FIRM <input type="checkbox"/> OTHER (Specify)										FOR FDA USE										 L10042398																			
SEC 5 U 01										PRODUCT TRADE NAME OR CATALOG NAME THEOPHYLLINE SODIUM GLYKINATE										DATE JUN 24 1995										LABELER PRODUCT																													
FDA APPLICATION NO. 01										REPORT DATE 06/26/95										TYPES OF BUSINESS OTHER (Specify)										PRODUCT TYPE OTHER (Specify)										PRODUCT DISCONTINUED OTHER (Specify)										BASIS OF CONCENTRATION WHOLE NUMBERS DECIMAL UNIT 100 100 100 100 100 100									
DOSAGE FORM 03										ROUTES OF ADMINISTRATION 03										PACKAGE SIZE 03										PACKAGE TYPE 03										NOTICE: This report is required by law (21 C.F.R. 302.20). Failure to report can result in imprisonment for not more than one year or a fine of not more than \$1,000, or both, (F.D.C. Act Section 703).																			
INITIAL MARKETING DATA 03										FIRST RECEIVED MARKETING DATA 03										DISCONTINUED DATA 03										YEAR 03										MONTH 03										DAY 03									
SEC 5 U 05										TYPE A										ESTABLISHED NAME OF PRODUCT AND/OR INGREDIENTS OR BIOLOGIC PROPER NAME, TEST OBJECTIVE/EQUIPMENT/REAGENT NAME, ETC. THEOPHYLLINE SODIUM GLYKINATE										FOR FDA USE ONLY AMOUNT 100 100 100 100 100 100										UNIT 100 100 100 100 100 100																			
SEC 5 U 07										ACTUAL MANUFACTURING SITE OF THE ABOVE DRUG PRODUCT CHATTEN CHEMICALS, INC.										DATE JUN 24 1995										FOREIGN COUNTRY TN										AUC 61966										SHORT NAME CHATTEN CHEMICALS									

Where did DRLS start?

2004-2009 (Registration only)

FDA Industry Systems



The screenshot shows the FDA Industry Systems website. At the top, there's a navigation bar with the FDA logo and the text "U.S. Department of Health and Human Services". Below this is a dark blue header with the text "ONLINE ACCOUNT ADMINISTRATION (OAA)".

The main content area is titled "FDA Industry Systems" and includes a "System Status" button. Below this, there's a list of announcements:

- 09/21/2018 See [FURLS Medical Device Registration and Listing Module \(DRLM\)](#) will be unavailable from 6:00 PM Eastern Daylight Time (EDT) on Thursday, September 27, 2018 to 6:00 AM EDT on Monday, October 1, 2018.
- 09/21/2018 See [System Maintenance](#) between 9:00 PM Eastern Daylight Time (EDT) on Friday, Sep 28, 2018 and 6:00 AM EDT on Monday, Oct 1, 2018.
- 09/19/2017 See [FDA published the revised guidance, Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments. Click here for details.](#)
- 09/12/2017 See [Information regarding Tobacco Registration and Product Listing for manufacturers impacted by recent natural disasters. Click here for details.](#)

Below the announcements, there are two main sections:

- Login**: Existing account holders, enter your account ID & password. It includes input fields for "Account ID" and "Password".
- Getting Started**: To make submissions to FDA (e.g., Food Facility Registration, Prior Notice, etc.) you must first create an account. Select "Create New Account" towards the bottom left side of this page. It also includes a note: "If you already have an account, enter your account ID and password."

A red warning box at the bottom states: "WARNING: You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording, and anyone".

Where did DRLS start?

2009 – Present

Structured Product Labeling (SPL)

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ESTABLISHMENT REGISTRATION			
Registrant - Synergy Health ABT, LLC (170088440)			
Contact	Address	Telephone Number	Email Address
Drug Mgrs	Address: 6759 E 46th Ave, Dr Suite 100 City, State, Zip: Denver, CO, 80236 Country: USA	+720.332.1101	drug.mgrs@synergyhealthllc.com
Establishment			
Name	Address	ID/FEI	Business Operations
Synergy Health Division AG	Address: Hugenstrasse 6 City, State, Zip: Dusseldorf, 40210 Country: CHE	05107038	ant(Syn)Man die tere human perscription drug products
Contact	Address	Telephone Number	Email Address
Drug Mgrs	Address: 6759 E 46th Ave, Dr Suite 100 City, State, Zip: Denver, CO, 80236 Country: USA	+720.332.1065	drug.mgrs@synergyhealthllc.com
US Agent (ID)	Address	Telephone Number	Email Address
Drug Mgrs (170088440)		+720.332.3285	drug.mgrs@synergyhealthllc.com
Establishment			
Name	Address	ID/FEI	Business Operations
Synergy Health ABT, LLC	Address: 180 W 1st St, Suite 1 City, State, Zip: Lima, OH, 41834 Country: USA	07420861.106511342	ant(Syn)Man die tere human perscription drug products
Contact	Address	Telephone Number	Email Address

In 2009 SPL was new for DRLS, too!

- Some data entry staff transitioned to regulatory experts
- Some data entry staff transitioned into SPL /process experts
- Many of us are both!
- Similar to those in industry, everyone here had to learn a new way of thinking regarding the entry and retrieval of data.
- Once we learned, we had to start teaching others.



Vision: *A complete and accurate Drug Registration and Listing database*

Mission: *To enable industry to submit complete and accurate registration and listing data and to disseminate that data to those who need it.*

Values: *We are a customer service organization. To that end, it is far more efficient and beneficial to the FDA and Office of Compliance missions to spend an hour of time helping a company submit the data to us correctly, than to spend many hours seeking enforcement against those who do not.*

Our customers include:

- *Industry*
- *Other FDA offices*
- *Other government offices (Congress, CMS, DEA VA, etc.)*
- *Healthcare providers*
- *Academia*
- *General public*

*We will be proactive and collaborative in assisting industry with submitting correct data, but **firm in our commitment to ensuring compliance.***

That's Why We're Here Today!

Here's what we're doing to help:

- 2nd Annual SBIA REdI Drug Registration and Listing Workshop
- eDRLS Helpdesk: edrls@fda.hhs.gov
- eDRLS Webpage: www.fda.gov/edrls
- CDER Direct
- NDC Directory
- Drug Establishment Current Registration Site (DECERS)
- The new eDRLS Toolkit!

eDRLS Toolkit

Everything you need in one place

- Brief instructions and explanations of the entire Registration and Listing process, including a glossary of terms
- Helpful hints to get your submissions correct the first time
- Troubleshooting tips when you don't get it right
- Links to all the helpful resources, lookups, SPL applications, data publications
- Email links to more than one help desk to get you the assistance you need

What else is new to eDRLS?

Today you'll hear about:

- NDC Reservation
- Listing Certification
- The latest validations put in place for both Registration and Listing
- The latest enhancements to CDER Direct

Today's Learning Objectives:

1. Describe drug establishment registration and drug listing requirements under food, Drug and Cosmetic Act
2. List all the available free tools through FDA to submit registration and listing information
3. List all the required data for drug establishment registration with FDA
4. List all the required data for drug listing with FDA

***Thanks to all our registrants for attending
In person and online***

***We hope you find today useful, educational,
and time worth spent***



