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Webinar on

CDER Direct - Overview And Helpful Hints

Date : July 14, 2021

Areas Covered

- *Uses*
  - *Features/advantages*
  - *Limitations/disadvantages*
- *SPL submissions available*
- *Browser compatibility*
- *Getting started*
- *Overview of the 3 BASIC SPLs –*
  - *Labeler code request*
  - *Establishment registration*
  - *OTC drug product listing*
- *Helpful hints (throughout and at the end)*

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In this webinar you will learn electronic registration and drug listing requirements and how to implement CDER Direct in their organization and for their specific purpose.

PRESENTED BY:

John Misock - is serving in his fourth career as Senior Consultant with Ceutical Labs, Inc. Flower Mound, TX. John retired from the FDA's Office of Cosmetics and Colors in June 2019 where he served as an SME in the areas of personal care product microbiology and manufacturing Prior to FDA John served in a global capacity with Estee Lauder Companies responsible for regulatory compliance in all manufacturing facilities.

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Date : July 14, 2021

Time : 03: 00 PM EST

Duration : 60Minutes

Price: $179

Webinar Description

The specifications for the electronic drug establishment registration and drug listing information required by FDA are generally defined in the Health Level 7 (HL7) Structured Product Labeling (SPL) document mark-up standard. Further, the HL7 SPL document mark-up standard provides compliance details about minimum requirements for the structure and semantics of the content of authorized published information for drug establishment registration and drug listing information.

SPL format is used for submission of the content of labeling in electronic format as required in New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), Biological License Applications (BLAs), and annual reports on approved drugs. Because the content of labeling required under those provisions can be duplicative in content and format (SPL) of the labeling required to be submitted electronically as part of listing information, FDA encourages applicants to submit this labeling material, and updates, primarily through the drug establishment registration and drug listing system. Rather than make duplicate submissions, applicants are then encouraged to reference the SPL labeling file submitted through the electronic drug registration and listing system in making labeling updates to applications under the content of labeling requirements.

There are numerous “off-the-shelf” software applications available to help the industry maintain compliance with respect to drug establishment registration and drug listing. Many of them can be customized and are customizable specific to the user's needs. Many of them function embedded within software applications with which users may already be familiar. Each method and application has its own strengths and weaknesses.

FDA has provided to industry one of the easier to learn and more user-friendly tools available to satisfy the regulatory requirements related to electronic drug registration and listing process for drug products. The CDER Direct Electronic Submissions Portal offers the basic features and functions necessary in order to create and submit electronic drug establishment registration and drug listing information as required by FDA.

CDER Direct is one of two tools commonly used for drug establishment registration, National Drug Code (NDC) labeler code request, and drug listings. It is intended as an improvement on the Electronic Submissions Gateway (ESG) portal that relies on FDA SPL X-forms (XML) editor. FDA's X-forms, although very successful, can be intimidating to the untrained eye and do not offer a lot of helpful text. Alternatively, CDER Direct offers a more data entry form style of interface. There is more help text available when populating the fields, and many validation error messages have been reworded to be more descriptive. CDER Direct also offers a submission status so you know when an SPL
has made it through both the ESG and SPL Validation.

This CDER Direct training is intended to educate and assist drug firms on the basic use of The CDER Direct Electronic Submissions Portal to satisfy the regulatory requirements related to the electronic drug registration and listing process for drug products regulated by the FDA Center for Drug Evaluation and Research. Upon completion of this training, the attendee will be familiar with the electronic registration and drug listing requirements and how to implement CDER Direct in their organization and for their specific purpose.

Topic Background

Requirements for drug establishment registration and drug listing are set forth in section 510 of the Federal Food, Drug, and Cosmetic Act (the Act) and section 351 of the Public Health Service Act (the PHS Act), and 21 CFR Part 207.3. These requirements specify that (1) owners and/or operators of drug manufacturing establishments are required to annually register their establishments with FDA, and (2) registrants are also required to list each drug manufactured at their establishment(s) and intended for commercial distribution in the United States Specifically, initial drug listings should be submitted within three days after initial registration of the establishment and any updates to listing data are required to be made no later than June or December following a change in the information. However, FDA requests that updates be made as soon as possible.

Changes to the Act resulting from the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85) (FDAAA) Section 224 of FDAAA, which amends section 510(p) of the Act, now expressly require drug establishment registration and drug listing information be submitted electronically unless a waiver is granted. The regulations further specify that the content of labeling must be submitted electronically in a form that FDA can process, review, and archive. The regulations also state that FDA will periodically issue guidance on how to provide the electronic submission. That guidance provides information on how to submit the content of labeling in electronic format. The primary clearinghouse for this data is the FDA Electronic Drug Registration and Listing System (eDRLS).

Submission of complete, accurate, and up-to-date establishment registration and drug listing information into eDRLS provides the agency with a list of all drug manufacturers currently producing drugs for sale in the U.S. and a current inventory of all drugs in the U.S. supply chain. Parts of the data are published in the FDA National Drug Code Directory, FDA label repository, FDA drug establishment current registration site, and the National Institute of Health's DailyMed.

Registration and listing information is also widely used outside FDA for several purposes. This data supports the electronic prescribing and electronic health records, reimbursement, and patient education. Correct and up-to-date information in FDA's NDC Directory and other public drug listing databases is essential to protecting public health.

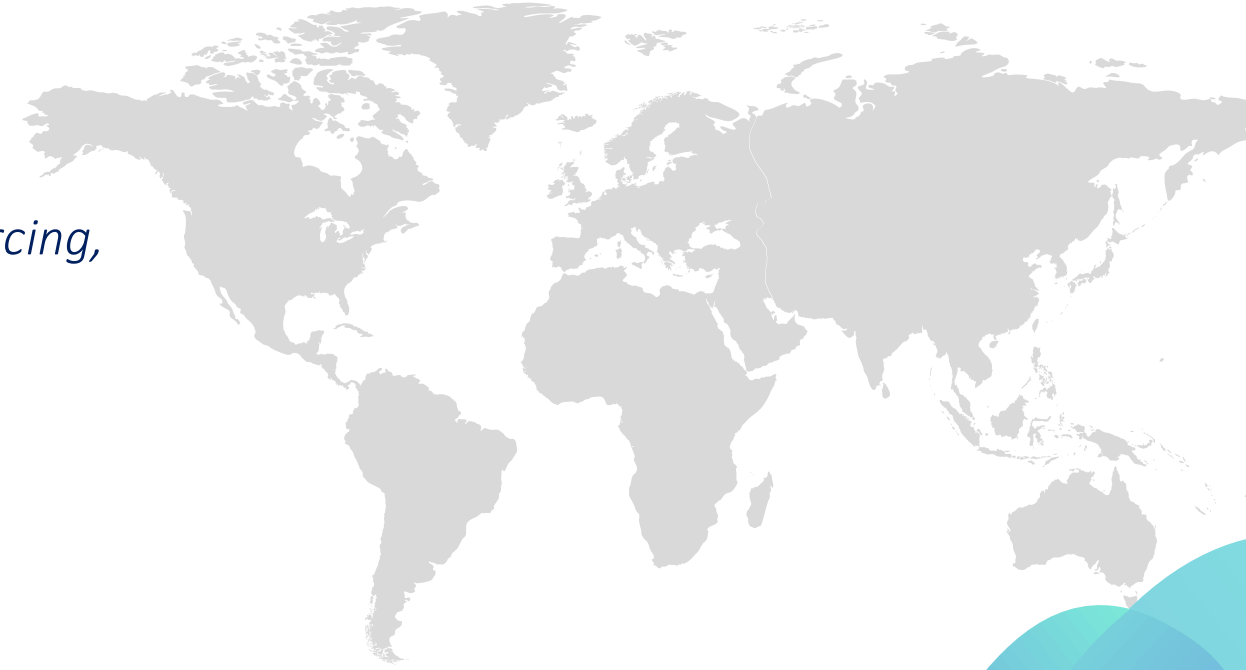
Establishment registration and drug listing data are submitted electronically into eDRLS using Structured Product Labeling (SPL)format. The SPL is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product and facility information. FDA selected SPL in XML (extensible mark-up language) as the appropriate format for the processing, reviewing, and archiving of this data. With the use of SPL, FDA employs automated validation rules which help to prevent inaccurate and incomplete data submission.

FDA monitors the registration and listing of data through surveillance methods, has manufacturers correct any data inaccuracies, and ultimately removes inaccurate data from the public sites if corrections are not made as required. Certain violations of federal law related to inaccuracies in registration and listing data can result in further actions such as data inactivation and/or a warning letter. In June of 2009, FDA began using the electronic drug establishment registration and the listing system as the source of SPL to provide post-approval content of labeling for public access on the Web, making that system the key repository of this information. Clearly, registration and listing information submitted into the FDA Electronic Drug Registration Listing System (eDRLS) is an integral part of the drug regulatory framework.

Fortunately, owners and operators can choose from an array of tools and methods to address these drug manufacturing requirements. One option, the CDER Direct Electronic Submissions Portal, was made available to the industry by FDA, at no charge, for the creation and submission of electronic drug establishment registration and drug listing information to the FDA in the appropriate format. The CDER Direct Electronic Submissions Portal can be used to satisfy the regulatory requirements applicable to the electronic drug establishment registration and listing process for drug products regulated by the FDA's Center for Drug Evaluation and Research.

Who Should Attend ?

Quality Assurance, External Manufacturing/Outsourcing, Regulatory Affairs, Compliance, Purchasing



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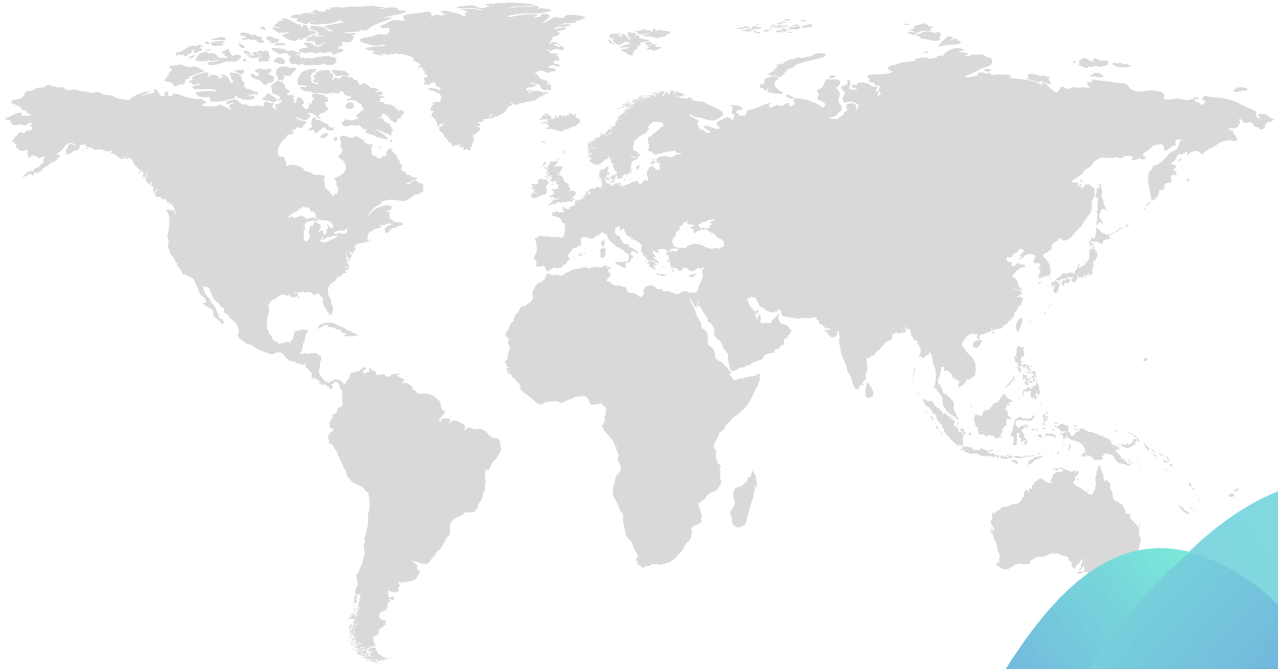
Why Should You Attend ?

- *Registration and listing information submitted into the FDA Electronic Drug Registration Listing System (eDRLS) is an integral part of the drug regulatory framework*

- *Manufacturers who fail to correctly register and list their drug products will not have a recognized National Drug Code (NDC). Medication reimbursement programs will not typically include reimbursement provisions for unlisted drug products. This is experienced directly by the manufacturer/owner of the drug product as a decrease in demand for the drug product*



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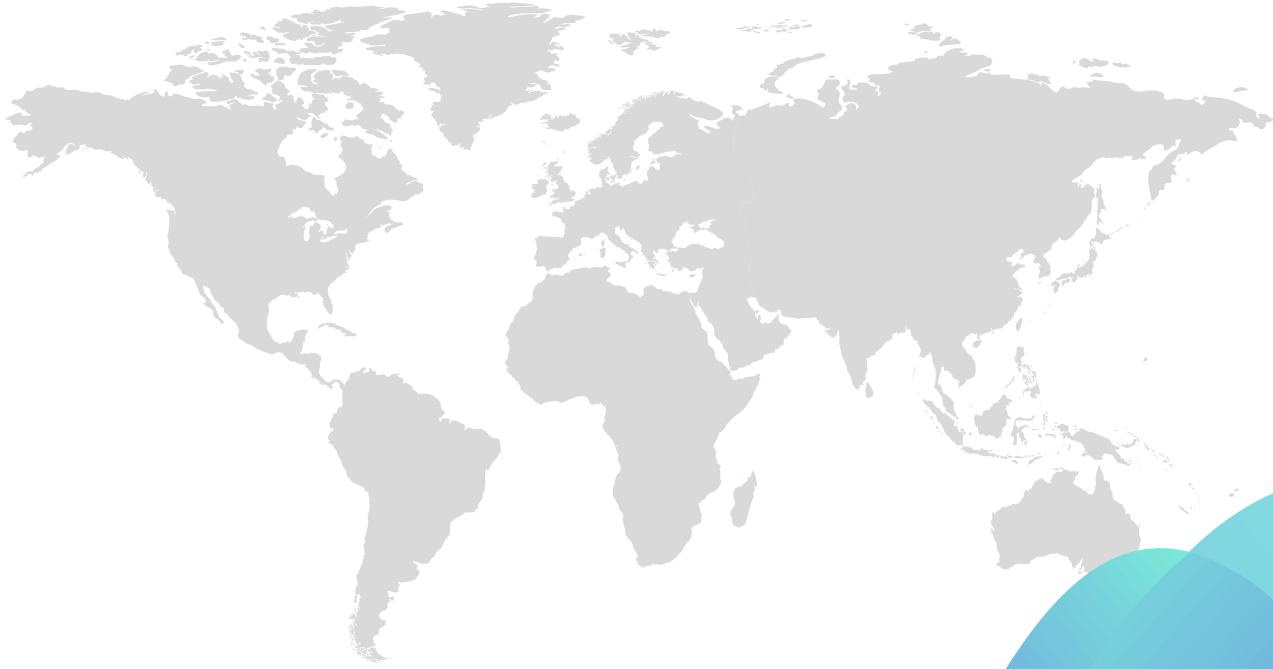
- *Some violations of federal law related to inaccuracies in registration and listing data can result in further actions such as data inactivation and/or a warning letter*

- *Customized and customizable software applications for creating submissions compliant with the HL7 SPL standard can be expensive. And of course, in today's fast-paced world, you will want your customized software to be user-friendly and have a low learning curve. And 24-7 support. You better be ready to hand over a small fortune*



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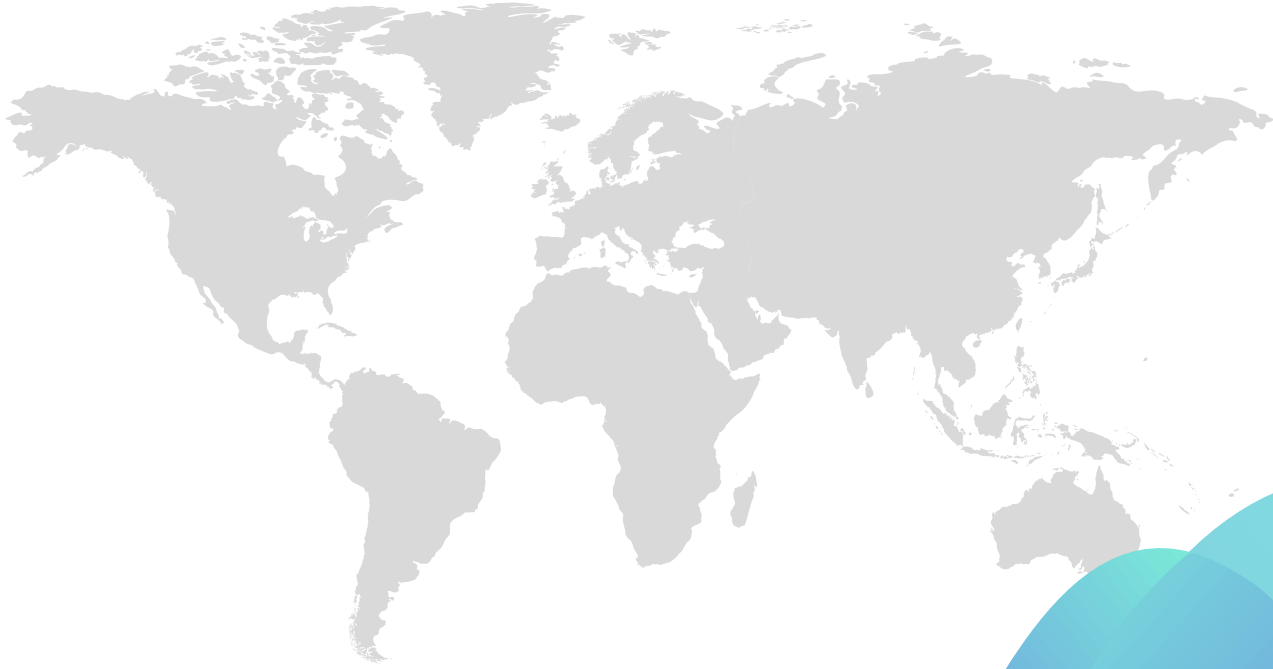
- *Often implementing more software packages in an effort to simplify, can lead to an unnecessary and self-imposed additional layer of digital infrastructure complexities, regulatory compliance requirements, and security risks. This can be especially true in the industries regulated by FDA*

- *And updates. Who doesn't enjoy a good software update that resets everything on your local machine? CDER Direct is highly compatible with most user environments and is housed and maintained by FDA. There are no software updates because the portal is not housed on your computer or server*



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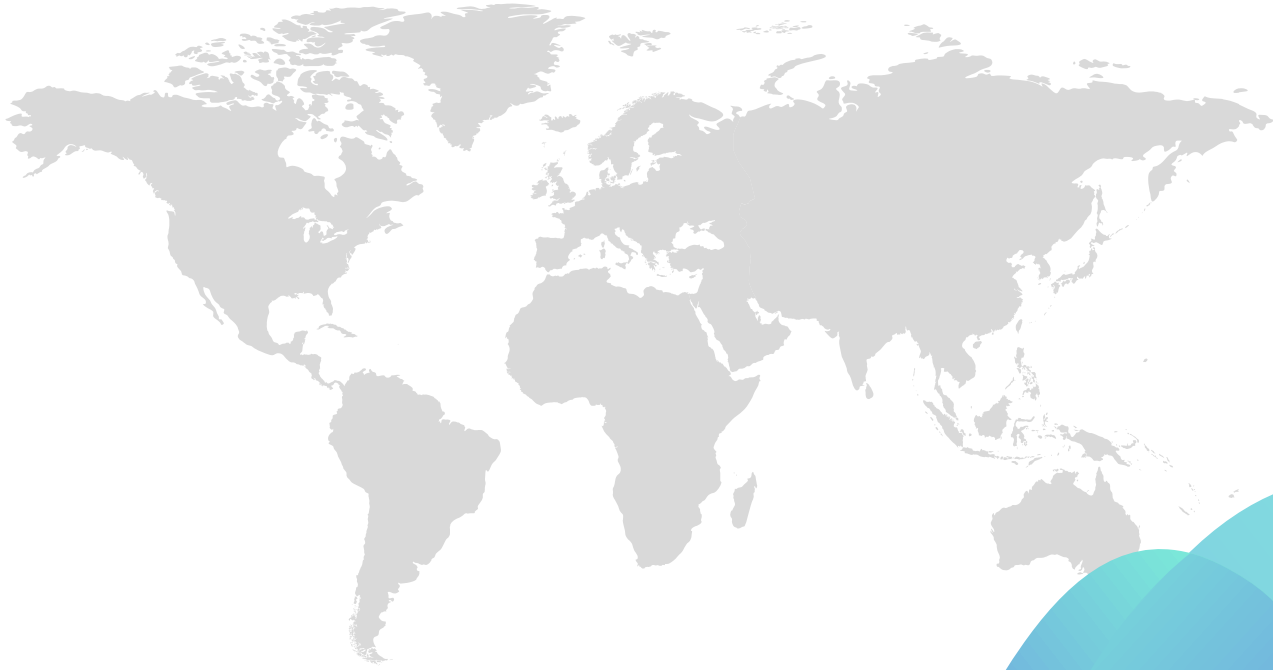
- *And changes to the regulations. When a new requirement is imposed by the regulations applicable to your product, any subsequent updates to the CDER Direct platform are performed by FDA. As a result, the user can be sure that CDER Direct will always support the creation of submissions compliant with the most current regulations*



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