



# **Electronic Drug Establishment Registrations, Drug Listings and the FDA Electronic Submissions Gateway**

**Audio Conference  
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# Learning Objectives

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1 – understand the FDA electronic registration / listing Guidance

2 – understand how to accomplish registrations and listings, including how to obtain and use an ESG account

3 – understand the three new electronic file types: electronic labeler code request (eLCR), electronic drug establishment registration (eDR), and electronic drug listing (eDL)

4 – understand key practical aspects of file preparation and submission

# Presentation Contents

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- 1 – the FDA electronic registration / listing Guidance
- 2 – obtaining and using an ESG account
- 3 – electronic file types: electronic labeler code request (eLCR), electronic drug establishment registration (eDR), and electronic drug listing (eDL)
- 4 – eLCR, eDR and eDL challenges
- 5 – helpful resources

# eDRDL – Background

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- ◆ September 2007: Changes to the Food, Drug and Cosmetics Act: mandated electronic registrations and listings of human prescription drugs, OTC products, biologic drugs and animal drugs.
- ◆ May 2009: Final Guidance issued, requiring labeler code requests, drug establishment registrations, and drug listings be submitted electronically, in SPL format, through the FDA Electronic Submissions Gateway (ESG) beginning June 1, 2009.



# The Double Electronic Mandate

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- ◆ Information must be submitted electronically, in an Extensible Markup Language (XML) document, prepared in SPL Release 4 format.
- ◆ The file may not be sent to FDA by physical means (e.g. CD or DVD), nor by e-mail nor by simple file transfer techniques, it must be sent through the FDA ESG.



# eDRDL – June 1, 2009 Reality

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- ◆ Final guidance document issued May 31, 2009:

## **Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing**

states that FDA will no longer accept paper copies of drug establishment registration and drug listing information

- ◆ FDA received 6,000 paper submissions in last 2 weeks of May 2009
  - FDA returned **ALL** 6,000 paper submissions

# eDRDL – Getting It Done

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- ◆ Send a letter of Non-Repudiation for Digital Signatures to FDA
- ◆ Get DUNS numbers
- ◆ Establish an ESG account (test account, then production account)
- ◆ Establish a file creation and editing capability (select and purchase software)
- ◆ Understand file content requirements
- ◆ Prepare, submit and revise files

# eDRDL - Getting It Done - With Help

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- ◆ get DUNS numbers
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# Establishing an ESG Account – Basic Steps

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- ◆ Send a Letter of Non-Repudiation to FDA
- ◆ Purchase a Digital Certificate, export public and private keys
- ◆ Proceed with Test Account steps, test submissions (no load test required for eDRDL only), Production Account steps (including sending your public key file to FDA)

# Establishing an ESG Account – Timeframes and Gotchas

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## Timeframes:

- ◆ Allow adequate time: your team, FDA team
- ◆ Plan for 60-90 days

## Gotchas:

- ◆ You must have the right kind of certificate
- ◆ Your public and private keys must match
- ◆ Your machine should use Internet Explorer 6 or 7

# Real ESG Account Experience

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- ◆ The ESG can have issues
  - not able to receive submissions (Sept. 2009)
  - unusual processing errors
  - files submitted as test may be accidentally sent for processing!
- ◆ Don't Look for Confirmations
  - the system provides “receipt” / “acknowledgement” messages, not confirmations of successful processing
  - DFARS website is useful to confirm eDR processing

# eDRDL File Types and Sequence

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## ◆ Files:

- Labeler Code Request (LCR, eLCR)
- Drug Establishment Registration (DR, eDR)
- Content of Labeling / Listing (CoL/L) or Drug Listing (DL, eDL)

## ◆ Preferred Submission Sequence:

- eLCR
- eDR
- eDL

Note: eLCR must precede eDL!

# eDRDL Files – Labeler Code Request / Registration - 1

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- ◆ The eLCR is a very simple file
  - used to request a new NDC Labeler Code
  - used to register an existing NDC Labeler Code
- ◆ Submit the eLCR once (or twice)
  - submit once: to register your existing Code
  - submit twice: to request a new Code, then resubmit to register your new Code
- ◆ New content requirements
  - more extensive contact information, including e-mail

# eDRDL Files – Labeler Code Request / Registration - 2

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## ◆ Important details

- for eLCR files where a new NDC Labeler Code is being requested, the initially submitted XML file must have the XML coding related to the NDC code removed
- it is also important to have your DUNS number in the eLCR file
  - make sure you use the right DUNS number
- if submitting without a DUNS number, notify FDA immediately before submitting the file

# eDRDL Files – Labeler Code Request / Registration - 3

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## ◆ Timeframes

- processing of files with existing labeler codes is intended to be rapid: validation error messages within 24 hours, files processed within 1-3 days
- action on a request for new NDC labeler code may take **30-60 days!**
- expect questions from FDA regarding your reasons for requesting a new NDC labeler code
- if submitting without a DUNS number, expect longer processing times

# eDRDL Files – Labeler Code Request / Registration - 4

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- ◆ Follow-Up / Annual Updates
  - there is no requirement at this time for annual updates to LCR submissions
  - once your eLCR is processed and the information is in the FDA eLIST system, no further action is required unless the contact information changes

# eDRDL Files – Drug Establishment Registration - 1

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- ◆ The eDR can be a very simple file
  - used to register all the owned/operated establishments of the registrant
  - used to request a new FDA Establishment Identifier (FEI) number when one does not exist
- ◆ Submit the eDR once initially (or twice)
  - submit once: to register your establishments
  - submit twice: to register and to request an FEI#, then resubmit to add FEI# to registration

# eDRDL File Types – Drug Establishment Registration - 2

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- ◆ New content requirements
  - all establishments in one file!
  - there must be importer and U.S. agent information for any foreign establishment in the file
  - the eDR file “registers” the U.S. Agent
- ◆ Important details
  - make sure you use the right DUNS numbers
  - FDA is requesting/requiring “site-specific” DUNS numbers where there are several physical establishments

# eDRDL Files – Drug Establishment Registration - 3

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## ◆ Timeframes

- processing of files is intended to be rapid: validation error messages within 24 hours, files processed within 1-3 days
- action on a request for new FEI# may take **30-60 days!**
- if submitting without a DUNS number, expect longer processing times

# eDRDL Files – Drug Establishment Registration - 4

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- ◆ Follow-Up / Annual Updates
  - FDA presentations specify annual updates (CFR contains a timetable for annual updates for paper submissions)
  - Common sense: update when an establishment needs to be added or removed, or update on anniversary of initial submission
  - There are simple files for “No Change” or “Out of Business”

# eDRDL Files – Drug Listing - 1

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- ◆ The eDL is typically the most complex file
  - used to list the product
  - used to provide information about establishments involved in the manufacturing and processing of the product
  - used to provide information about the active and inactive ingredients in the product
  - for prescription products, the eDL content is posted to DailyMed

# eDRDL File Types – Drug Listing - 2

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- ◆ Some “new” content requirements
  - proprietary name, suffix, and non-proprietary name
  - all establishments involved in the manufacturing, analysis and processing of the final product
  - active ingredients, and active moieties, UNII codes
  - detailed strength information
  - detailed packaging and content of labeling information
  - electronic images of the physical labeling, including the principal display panel

# eDRDL File Types – Drug Listing - 3

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- ◆ Some “new” content requirements - continued
  - Start Marketing Date
  - For OTC products: Application # or Monograph Citation #

# eDRDL Files – Drug Listing - 4

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## ◆ Processing / Timeframes

- it is not unusual to receive additional acknowledgement messages (expect this!)
- messages may direct you to make alterations to your file
- messages may provide validation errors that have “multi-file” context (OTC listings)
- messages may direct you to adjust Non-proprietary Name information

# eDRDL Files – Drug Listing - 5

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## ◆ Processing / Timeframes

- processing of files is intended to be rapid: validation error messages received within 24 hours, files processed within days
- updates uploaded to DailyMed, in some cases very rapidly (only prescription and some OTC products)
- no current mechanism to verify successful processing of all submissions

# eDRDL Files – Drug Listing - 6

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- ◆ Follow-Up / Annual Updates
  - FDA presentations are unclear about update requirements (CFR contains a timetable for annual updates for paper submissions)
  - Common sense: follow your previous paper-based practice, or update on anniversary of initial submission, or update when information changes

# eDRDL Files – Drug Listing – OTC Products

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- ◆ Specific OTC Considerations
  - Drug Facts information is essentially Content of Labeling
  - Evaluate preparation of single SPL file versus multiple SPL files for OTC products using the same NDC product code
  - If multiple OTC products use same NDC product code, non-proprietary names must be the same (including suffix information)

# eDRDL Files – Drug Listing –API & Medical Gases

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## ◆ API Listings:

- use “bulk ingredient” for Document Type and N/A for Route of Administration
- make sure to include bag/drum label images

## ◆ Medical Gas Listings:

- use “Human Prescription Drug Label” for Document Type and “Inhalation for Route of Administration
- make sure to include cylinder label image(s)

# eDRDL – Helpful Resources

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FDA links:

Letters of Non-Repudiation:

<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm113964.htm>

Main ESG Page:

<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/UCM2005551.htm>

ESG Account Setup Checklist:

<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm114831.htm>

ESG User Guide (pdf file):

<http://www.fda.gov/downloads/ForIndustry/ElectronicSubmissionsGateway/ucm114648.pdf>

ESG Page for eDRDL ESG Accounts:

<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm177328.htm>

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# eDRDL – Helpful Resources

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FDA links:

ESG eDRL page:

<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm177328.htm>

Main eDRL page:

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm>

May 2009 Guidance: Drug Registration and Listing

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072339.pdf>

Structured Product Labeling Resources

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

DFARS Webpage to Check Establishment Registration Status:

<http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm>

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# eDRDL – Helpful Resources

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## External links:

Dun and Bradstreet for DUNS numbers (expedited):

[http://www.dnbgov.com/federal\\_compliance/fda/DUNSrequest/](http://www.dnbgov.com/federal_compliance/fda/DUNSrequest/)

Pragmatic Validator Lite:

<http://validator.pragmaticdata.com/validator-lite/>

SPL Work Group:

<http://spl-work-group.wikispaces.com/>

SPL Work Group Training Materials:

<http://spl-work-group.wikispaces.com/Training>

# eDRDL – Getting Help

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- ◆ Service Provider Capabilities / Competencies to Look For:
  1. ESG account and experience
  2. Professional SPL-R4 software and XML experience
  3. Labeling and listing experience (paper and electronic)
  4. Regulatory expertise
  5. Scientific expertise

# eDRDL – Conclusion

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- ◆ The new requirements are complex
- ◆ In many cases, it is learning by trial and error
- ◆ Over time, requirements will become clearer and processes will become more transparent
- ◆ Plan and allow adequate time to complete your submissions
- ◆ If you do not have the time or the resources: get help from an experienced service partner

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# Questions?

# Beckloff Associates would be pleased to assist with your registrations and listings

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[http://www.cardinalhealth.com/beckloff/eDRDL\\_Services.pdf](http://www.cardinalhealth.com/beckloff/eDRDL_Services.pdf)

<http://www.cardinalhealth.com/beckloff/services/publishing/>

<http://www.cardinalhealth.com/beckloff/services/eCTD/>

<http://www.cardinalhealth.com/beckloff/>

or call us at: (913) 451-3955

# Contact Information

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***THANK YOU!***