Slides from May 21 Face to Face:

http://spl-work-group.wikispaces.com/file/view/spl_r4_may_21_2009_training_session.pdf
http://spl-work-group.wikispaces.com/file/view/DB_FDA+SPL+Session+5_21_09+%282%29.pdf
http://spl-work-group.wikispaces.com/file/view/Pillbox_NLM.pdf

Drug Listing Examples:
http://spl-work-group.wikispaces.com/More+Examples+Here

Do's and Don'ts from the May 21 Face-to-Face

Establishment Registrations & Labeler Code Requests

DUNS Numbers and Establishment Names

- Do not put hyphens in the DUNS number
- DUNS number must be 9 digits
- Registrant name & address: FDA will contact this person for any information about the Establishments in the file.
- The address of the registrant is not validated against the DUNS number.
- Always use the exact same name, including presentation of abbreviations etc.
- Do not make up DUNS numbers – the FDA is checking them!

- Include all the operations performed by the establishment (from the picklist of operations). While this is not being checked right now, it will be checked in the future.
- More types of operations will be added. [Divisions are putting together additional terms for the picklist now] *Establishment Registration requires update of new operators? You can update during the next cycle of updates.*

- Major issue: spaces before or after a telephone number. The spaces will cause a validation error.
- Major issue: spaces before or after an e-mail address. The spaces will cause a validation error.
- If country code is not US, FDA expects a US Agent to be included.
- *Any validation on the phone number against the placement of hyphens? Yes for US numbers. Not yet for foreign numbers. Foreign currently needs to have at least one hyphen.*
- Analytical labs need to register but they don't need to list.

- Company X – when listing – recommendation that they include the analytical lab.
- **Do not register distributors!**
- *If the distributor doesn't manufacture, and they choose to list. Manufacturer would ER. Distributor would submit Labeler Code, and Listing.*

- Include postal code for all establishments unless one does not exist. This is now a Validation Issue. So far, the only country we know of w/out a postal code is Ireland
- Entering provinces – The province (for Canada) goes in the State tag.
- No limit to the amount of importers
- No limit to the number of establishments in on SPL
- Use ISO-3166 three digit Country Code standard.
- Use 'USA' as Country for Puerto Rico.
- Approx 50% Third Party Orgs don't have DUNS number (per D&B) yet. Leave them out until you get the DUNS #.

When to File Registrations

- Timing: Update anytime during year OR for annual registration. Recommendation that you update anytime there is a change.
- Establishment Registration has to be done electronically first before a NO CHANGE notification can be filed electronically.
- The NO CHANGE notification should not include all the details for all the Establishments. Xforms now has a separate SPL file for NO CHANGE.
- If you are acquired by another company, and you want to de-associate all the establishments from your setid so the new company can register them under their setid, you can use the OUT OF BUSINESS notification.

- US Agent: Company Name, DUNS number, Telephone number, email address
- This information replaces the paper US agent letter.

- Should I include the import broker? Import staff said 'yes'. Company purchases the product from a foreign establishment and then resells to many others.
- Collecting IMPORT information is new to the FDA.
- Importer: Company Name, DUNS number, Telephone number, email address
- May or may not be an importer for each establishment.

- Only a recommendation that API supplier be included in the drug listing. If you don't have a DUNS number for the API supplier, leave the API supplier out of the Drug Listing for now.

Listing and Content of Labeling

Kit = more than one part. (Combination Product)
Marketing status
Include NDCs at each part package level if available
1 Kit in 1 Carton/Package/Unit

If the same NDC code is shown at two levels (on vial, on carton of 10) – put the NDC code at the outer level.

End marketing date – is for the purposes of drug listing, more than publishing on NLM. Possible that NLM wants to keep a labeling history.

DEVICE:
Combination Products listing w/ Medical Device Lead
Document Type: Medical Device …. Only when the medical device is the 'lead' product
Marketing Categories & Numbers:
Exempt device = id extension of 3 letters
Humanitarian Device Exemption = H +6 digits,
Premarket Application = P or BP followed by 6 digits,
Premarket Notification = K or BK followed by 6 digits
Specific information on the device is not included
Only include information about the drugs
With combination products – all the content of labeling for all the components in a single SPL.

APIs / Bulk Ingredients
Listing an API separately
Content of labeling sections – container/carton label jpeg file; text from principal display panel
Packaging 'as ordered' – pick one NDC, and the average amount
Route of administration is 'not applicable'
Dosage form is 'powder'
DMF numbers are not used as application numbers for APIs – use BULK INGREDIENT as the marketing category; no application number
The company that manufactures the API should provide NDC code.

- You can list API with Finished Dosage Form Product {if the company owns the API and the finished product}
- Inclusion of the establishment for the API in the SPL files for the finished dosage form product.
- Importation of API: NDC for finished product could be used for import purposes

Repackaged and Relabeled Drug Products

- Manufacturer unknown? Use source NDC. Can only provide 1 source NDC code. If you have multiple sources of different components … need to have multiple product tables.
- Include content of labeling for products which are repackaged or relabeled
- Acquire content of labeling of manufacturers from Daily Med, if available. GUIDs will need to change if you've copied the text from a Daily Med version.

ESG – Elist – Submission Do's and Don'ts

Transition period to Implementation
Combination of e-mail and Gateway notification.

Implementation Period
Gateway notification only.

Either way, you should get an error message back within 24-72 hours.

- For folder name – doesn't seem to like hyphens
- NDC Labeler Request and Establishment Registration SPL must be submitted before CoL/Listing SPL. Validation temporarily turned off on the comparison against the ER.
- Validation procedure checks DUNS number first (Listing vs LCR).
  If those match, then Labeler codes are checked (Listings v LCR)
  Then a check is dones of Establishment DUNS (ER) vs Listings.
  Then a check of Operation Type (ER) vs Listings.
  Contact Name is only linked via the DUNS number & Labeler Code (it's stored in the LCR)

- Do not include thumbs.db file in your submission

Recommendation from Craig: Set up a group mailbox (takes care of vacation or backups)

Error messages will contain a number – that is the reference location in the validation procedure.

AOB

Still working on the SPL-2-Word conversion.