SPL Process ER/DL Meeting
Meeting Minutes
Mar 9, 2016

Chair of today's meeting: Pat Cowall

Teleconference information:
USA Toll-Free: 866-213-2145
USA Paid/International: 609-454-9913
Access code: 273 8216

Link to the SPL wiki:
http://spl-work-group.wikispaces.com/share/view/51351516

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1. Effective date – to the pack level (Lonnie Smith)?
   Effective Time Package Data Elements – discussion about requesting that companies include this field. For SPL Products that are publicly available, data is available in the Comprehensive NDC SPL Data Elements (NSDE). At present, package marketing start date being derived from the submission date for products. With some companies submitting SPL files long after a product is first marketed, and variability in package marketing start dates. Having the package marketing start date included in the data from the companies will generally more accurate than the derived date (from the submission date).

   - This data element has been in the data elements for a long time.
   - NSDE files has been calculated by the date of SPL submission. This has been deemed problematic recently, because it is not exact.
   - If you include this data element, the package start date in the NSDE will be the actual date in the SPL file.
   - In the future, for CDER products, API, bulk, in process, this date will be expected and the validation rules will be implemented to require this date. `
     - If you don't want to submit this date, or if your software isn't updated, the company can request a manual over- ride. Send an email to spl@fda.hhs.gov stating that you are intentionally not including a market start and end date for the product. Don't have to include a reason.
     - CVM does not want this data down to the pack level.
     - CBER will remain optional.
     - Human compounded drug – market status information is not included.
   - Date of implementation of this validation procedure: soon (eg about the end of March).
   - The IG will be changed to include this mandatory requirement for CDER products - at the next release.
   - Validation procedure is 3.1.8.13
   - This data has not been sent to NSDE in the past, but it will now be sent to the NSDE file.

- Should we leave the pack in the SPL file forever …or should we take it out like we have in the past? This is a usability question – what do you want people to see on Daily Med.
- The SPL is posted based on the product's market start date – not the package market start date? If you have a future date on the package level, the file will still posted on Daily Med based on the market start date of the product.

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2. Business operation qualifiers (Lonnie Smith)?

   Business Operation Qualifiers: Human drug establishment vs Animal drug establishment. FDA is discussing requiring inclusion of business operation qualifiers for Animal establishments, to more consistently identify whether an establishment is for animal or human drug.

   Comments from Charisse Kasser at last meeting

   - Making the business operation qualifiers mandatory because this is useful for inspection purposes – to know what they are inspecting.
   - Pharma quality people sent out an email – "you are registered but we don't see any drug listings". Animal companies got this email too and wondered why they got the email. The qualifier will help identify.
   - Implementation will probably be in Q4 2016 when establishments do their next DER. It might get turned on earlier at time of FDA system update – for updates.

   Lonnie's comments at today's meeting:

   - In future, the business operation qualifiers will be required for DER
     - Can ask for manual override if you don't want to include.
   - These are not needed for the drug listing files.
   - Compounding qualifiers have been required since 2013.
   - What business operations will require a qualifier? Ie Manufacturer only or…do you need to put them on label and pack?
   - Lonnie to send slide to explain this.
   - Implementation Timing: TBD. Will be implemented before Oct, 2016. If you can't do this, you need to request override.

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3. Lonnie Smith announcement: Will start having quick refresher training sessions – 30 minutes – on one topic.
   - SPL document tracking data elements (version number, set ID, doc ID, related document element).
   - Will have to register for the training.
   - See web page for future meetings – quick refresher training -- will be posted on the SPL training web site.
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4. We recently updated only a part of an SPL (AutoInjector IFU). Not all IDs were changed only the ID in the AI IFU was changed. However, we received the attached validation error asking us to fix IDs. My understanding is that IDs are changed when the content changes, so if the content in the other pieces of labeling did not change, then the IDs don't need to change. Have any of you had this issue? If so, is there a way to fix it once and for all? (Smitha Mathew)

   id must not match any other id across all sections, documents, or any id other than the id of the same section previously submitted

   Meeting discussion:
   - Rule: You shouldn't have to change the ID on sections that didn't change.
   - But, any change in the section (spaces, line returns, etc) will require a change to the section ID.
   - And sometimes funny things happen in the file, and you just have to change the section IDs.

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Topics to be postponed to the next meeting:

5. I would be curious to know whether anyone on the call uses the FDA CDER Direct portal and if so for what purpose? (estab registration, labeler code, domestic drug listing, foreign drug listing??). (Mary Beth Kline)

   Since you cannot create a draft SPL file in CDER Direct and my labeling colleagues need to submit the draft SPL prior to a PAS approval, we cannot use CDER Direct for our domestic drug listing. Unfortunately, CDER Direct only enables you to download SPL after the submission is accepted (I had sent their mailbox that question and was told that you cannot download draft SPL). We do use it for our labeler code requests, our foreign establishment registrations, and our foreign drug listing since we do not need a draft SPL.

   Meeting discussion:

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6. Labeler Code requests that were rejected. (Cynthia Turek)
   Can someone from the LT discuss labeler code rejections and how they are handled?

Meeting discussion:

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