SPL Process ER/DL Meeting
Meeting Minutes
Jan 14, 2015

Chair of today's meeting: Pat Cowall-Hanover

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

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

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Agenda:

1. **Paperless labeling – Proposed rule: Awareness.** Comment period is until March 18, 2015. Open discussion of what do you think, in particular meeting the implementation timing of SPL submission (2 days for supplement approvals).
   https://www.federalregister.gov/articles/2014/12/18/2014-29522/electronic-distribution-of-prescribing-information-for-human-prescription-drugs-including-biological

   Some of the key points in the proposed rule:
   - **This is a major step forward that people have been working on for 15 years!!!!**
   - Labeling will be submitted electronically in SPL format.
     The proposed rule would require manufacturers and applicants to distribute electronically prescribing information by submitting
     the labeling in an electronic format that FDA can process, review, and archive (currently SPL format) to FDA each time the labeling content is changed. The submitted labeling would be distributed via FDA's labeling repository Web site (labels.fda.gov), which is a publicly available Web site.
   - Patient labeling not in scope
   - Product's Immediate Container Label and Outside package to bear a statement directing HCPs to FDA's labeling repository
   - Manufacturers have to review the label repository to make sure labeling is correct in the repository.
   - Planning for approval within 6 months. Implementation within 2 years.
   - SPL needs to be submitted within 2 days of a change to the USPI.
     - For newly approved drugs, proposed § 201.100(c)(4) would require that applicants, including NDA, BLA, and ANDA applicants, submit prescribing information in this format

in time for the prescribing information to be posted in the labeling repository before the drug enters interstate commerce.
    - For drugs already approved under section 505 of the Federal Food, Drug, and Cosmetic Act or biological products licensed under section 351 of 75 the Public Health Service Act, applicants must submit labeling containing prescribing information within 2 business days of a change to the prescribing information.
    - Under the proposed regulation, labeling should be submitted to FDA for distribution on the same day that a CBE supplement is submitted to the Agency under § 314.70(c)(6).
    - Manufacturers who are not applicants, for example, repackers, would be required to submit the prescribing information within 2 business days of the posting of the applicant's updated labeling.
    - Unapproved drugs: within 2 days of a change of labeling.
      What is an upapproved drug? See link to FDA site:
      http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/enforcementactivitiesbyfda/selectedenforcementactionsonunapproveddrugs/default.htm

- Mfgs would have to notify FDA if labeling is not correct within 4 days. If not correct, the product is considered to be misbranded.
- Paper labeling would still need to be provided with promotional materials. As it today, these will probably be consistent with the current labeling.
- Other initiatives going on with patient labeling. What are they
- Comment requested by FDA on -- dual system for delivering labeling – in case of power outages and system failures.
    - Allowing purchasers to request copies, as needed
    - Paper, fax, email, etc.
    - What format needs to be provided -- current artwork? MSWord to pdf?

Other Discussion:

- What do people think about the 2 day submission timing after approval?
    - Comments: 2 days – from what date? Need to tighten up communication of approval to sponsors - sometimes email, sometimes fax, sometimes snail mail. Or if approval is sent to one individual within the company. Sponsors don't always get it quickly.
    - If send out to vendor, then they will have to meet this timeline.
    - Two days will still be difficult – especially if FDA requests changes in the approval letter.
    - What if immediate launch – ie for generic products.
    - What if validation issue – especially if you have a new manufacturer and you have DUNS issues. Is SPL team willing to do manual overrides very quickly so that we can meet the 2 day guidance.
    - What if something needs to be corrected in the label that FDA sends back.
    - 2 day driver is probably from downstream users who want to see the data quickly.
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- **What issues are you anticipating?**
    - Issue with dual system – still have to print. So where is the savings? And disruptive to business process (ie how fast do you have to ship it)
    - How will generics know when the reference labeling changes.
    - FDA is inviting comments on whether generics need to be held to the same changes as other changes.

- This will potentially result in multiple submissions of the same SPL file -- ie update USPI to meet the 2 day timeline…even though everything else cannot be updated in the 2 days (eg cartons/labels).
- Downstream users are using these files and need this very quickly. They don't realize that this takes time to QC the labeling and update the SPL.
- Generics already have to submit the SPL file to FDA before approval.
- What is the process if the "supplement" relates to a new dosage form that will not be marketed for several months?

- Good opportunity to get comments into the FDA.
- It has taken 7 years to get to this point. Many people think this is a good thing. We need to make sure that we support this initiative and also make sure it is doable.
- See separate powerpoint file with first draft summary of the proposed rule
  - Not an official document. Summary prepared by 1 person for general awareness.
  - There is no proprietary information in it, so you can use it to initiate discussions within your companies.
- We expect that trade organizations will be submitting comments:
  - Phrma's paperless labeling group will probably submit comments.
  - Bio will probably submit comments. There is text related to blood and blood components in the proposed rule.
  - SPL working group is typically silent because FDA participates in the SPL working group, and we don't want to present any conflict of interest.
- Questions:
  - what will FDA be posting on the labels.fda.gov – Rx, OTC, etc.
  - why are the labels being posted in 2 places
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2. **Change to the SPL Stylesheet has been posted today:**
   - display of the Unique Ingredient Identifiers (UNIIs) adjacent to the substance names in the product data elements section.
   - display of data included in recently implemented SPL document types (Human Compounded Drug Product Label, Wholesale Drug Distributor and Third Party Logistics Report, Lot Distribution Data, etc…)

   Discussion:
   - It went live before the meeting: UNII and combination products.
   - It is live on the FDA website but not on Daily Med.
   - If you are having problems, clear cache on IE.

3. **Reminder/Invitation to attend the SPL Tech team meetings, if interested:**
   - REMS: Monday, January 26, FDA will discuss

4. **DUNS issues:** Please send any praises or concerns to Pat Cowall. We are compiling this feedback to send to Lonnie and John Gardner.
   a. We are also planning to send out a survey about DUNS numbers in the near future.

5. **AOB:**

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REMINDERS:

- To accompany publication of the FDA's draft "Guidance for Industry – Electronic Submission of Lot Distribution Reports," an updated version of the SPL Implementation Guide/Validation Procedures document which includes a specific reference to the aforementioned guidance document has been posted: http://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM321876.pdf.

- DER Annual reporting period: Must be submitted for 2015 between October 1 and December 31, 2014. If you haven't submitted yet…you are late.

- SPL tech team on Jan 26, 2015 will discuss SPL and REMS