IPEC Americas –GPhA-FDA-OPQ Face-to-Face Meeting, Inactive Ingredient Database (IID)
September 23, 2016

Attendees

FDA STAFF	ORGANIZATION: DHHS/FDA/	JOB POSITION	e-Mail
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GPhA		**Title**	**e-Mail**
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Meeting Summary

1. Meeting purpose

The purpose was for the IPEC-Americas/GPhA IID EWG to meet with FDA individuals responsible for updating and making revisions to the IID. The meeting was requested by the Industry IID WG to address the many concerns resulting in the quarterly updates made by FDA. The specific timeframe the discussion centered around were updates made between April 2015 and July 2016.

2. Meeting Discussion

Two documents were provided to Susan prior to the meeting so FDA had adequate time to review in preparation for the meeting. The ***first*** document contained EXAMPLES of inconsistencies found in the IID updates between April 2015 and July 2016. The primary areas of concern were:

1. New Records added then deleted or changed in subsequent posting
2. Changes to the IID are not consistently captured
3. Inconsistent and unmarked changes in excipient name, CAS number and UNII code
4. Inconsistent and frequent changes in Potency amounts and/or rounding rules
5. Missing Dosage Form for commercially used excipient
6. Unclear Potency Unit designation

The ***second*** document contained additional examples of current industry (suppliers, users) concerns with respect to understanding and interpreting the information in the IID. Some of the specific categories include:

1. Redundant records not deleted when record with higher potency added
2. Nomenclature questions
3. Redundant dosage forms?
4. Maximum Potency questions
5. General IID clean-up questions
6. Improved database wish list
7. Drug manufacturer and the Agency reviewer use of IID information
8. Miscellaneous questions/comments

Majority of the time was spent further elaborating on the content and examples illustrated in these two documents. The following discussion points were noted:

- Clarification was provided by FDA with respect to the internal processes for how the OPQ and Office of Business Informatics (OBI) work together to publish the IID updates. The process as articulated by FDA is as follows:
    - OBI generates a QA report
    - The OPQ team reviews and cleans the data and prepares the update document
    - OPQ sends the prepared document back to OBI
    - OBI makes corrections where indicated and send the report to FDA's Office of Communications for publication on the FDA website.
- During the discussion it was learned that the majority of the discrepancies provided by the Industry EW could possibly be related to the IT problems. In light of this fact, Susan and Frank agreed to follow up with OBI staff to make them aware of the issues raised by the Industry EWG.

- The Industry EWG strongly expressed the need to have transparency with respect to the following areas: changes made, why a change was made, when a change was made. It was also suggested that the FDA could use the preface page of the IID webpage to provide clarity to acronyms, other abbreviations, and alike. Both IPEC-Americas and GPhA agreed to help communicate the existence of the "summary of changes" and to encourage their members to look to the changes for improvements in transparency.
- The Industry EWG agreed to share with the FDA its copy of an Excel workbook that contains IID download information for the past 6 IID updates.
- The Industry EWG recommended continued collaborations with the FDA to ensure concerns and issues with future updates to the IID were addressed in a timely manner. A routine schedule for these meetings will be forthcoming.
- The Industry EWG also recommended future collaboration in the form of focused working groups with FDA Subject Matter Experts to address other related topics of concern.

  Potential topics to discuss with appropriate offices:

  - Continued discussion on the "family approach."
    - Industry needs clarity with respect to when a family approach would be acceptable and when it would not so it can improve the quality of its applications. Without directive from FDA, industry is left to "guess".
  - Continued discussion on the RTR Guidance and how it defines novel excipients and the supporting documents required to support an application.
  - Continued discussion on updates made to the IID, where an excipient level is lowered or the excipient level "disappears" and an RTR may be consequently triggered.

Although OPQ indicated that it could not interfere with how other CDER offices made decisions, OPQ did agree to act as the liaison for the group and assist in identifying the primary points of contacts in respective offices.

The meeting concluded on a positive note. Industry acknowledged the continued efforts made by FDA to improve the IID. In addition, Industry requested that FDA look at developing an ***interim process*** to address the growing number of regulatory concerns created by the updates. These regulatory concerns are impacting potential access and availability of generic competition and affordable medicines for the American public.