Industry Regulatory Science Work Group Meeting
April 10, 2018

1 - Introductions (All) 10:00-10:05am

2 – Inhalation (Industry) 10:05-10:35am

FDA and Industry discussed research on inhalation products.

- Industry found FDA's Jan 2018 workshop to be a very useful update
- Industry would want future research to focus on the following areas:
    - in vivo relevance of inhalation product characterization
    - the optimization or minimization of comparative clinical endpoint bioequivalence studies
- FDA indicated that research on in vivo relevance often requires cGMP manufacturing of products for administration to human subjects, and this might be a place where industry could bring this capability to the table for collaboration with FDA
- FDA encouraged industry to present these recommendations at the May 24, 2018, public workshop
- FDA suggested that individual firms can also provide recommendations based on their experience, either in person or by submitting to the docket, for the May public workshop

3 – Complex Products – Establishing Equivalence, Sameness, and Characterization of API in Lieu of Clinical studies (Industry) 10:45-11:15am

FDA and Industry discussed research on peptide products.

- Industry identified the need for guidance on impurities in peptide products
- FDA clarified that the recent draft guidance "ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin" was not intended to provide general advice on peptide impurities from the quality/specification perspective.
- FDA and industry discussed scientific challenges related to peptide impurities.
    - FDA believes that analytical methods are generally available to identify and quantify peptide impurities. If there are cases where analytical methods are the limiting factor, FDA would appreciate that industry use the May public workshop or docket to identify these cases
    - FDA discussed current research on immunogenicity that is intended to provide tools to identify the risk that a peptide impurity may raise immunogenicity issues.

FDA and Industry discussed research on complex injectable products.

- Industry identified in vitro approaches to bioequivalence as a goal for this area.
- Discussion identified simple suspensions as a category where in vitro approaches to BE might be first be used
- FDA agreed, and noted that this item is already on the FY2018 priority list

4 – Upcoming Public Workshop (All) 11:15-11:25am

FDA requested that the industry WG provide 3 panel members for the upcoming workshop, and that 20 minutes is allotted for an industry WG presentation. Individual companies may request to speak in the open public hearing.

The FR notice is available at:
https://www.federalregister.gov/documents/2018/03/29/2018-06260/meetings-fiscal-year-2018-generic-drug-regulatory-science-initiatives-public-workshop

The agenda will be posted at:
https://www.fda.gov/Drugs/NewsEvents/ucm583766.htm

5 – Potential Topics for the next meeting (All) 11:25 – 11:30am

- Tentatively planned for September, 2018
- At the next meeting FDA, will discuss what it learned from the May 24, 2018, public workshop and docket comments.