The meeting discussion was focused on planning for the negotiation process and exploring Industry’s PDUFA VII manufacturing interests related to communications. FDA and Industry reviewed action items from the previous meeting and discussed the schedule for the negotiation process. FDA and Industry agreed on the topic areas and order of discussing those topics over the course of the negotiation process.

Industry presented their interests in PDUFA VII related to communications, particularly around information request (IRs) that are issued during the review process and mid-cycle meeting communications. Industry provided insight on the issues with these types of communications and provided examples of how improved communications would allow for more efficient processes for their firms. FDA shared information on current practices and guidelines for IRs and mid-cycle communications. FDA and Industry agreed to continue the discussion on communications at a future meeting.
FDA and Industry also agreed to discuss Industry’s interests in COVID-19 lessons learned and practices as they relate to ongoing Agency workstreams and applicability to PDUFA VII at a future meeting.

There were no other substantive proposals, significant controversies, or differences of opinion discussed at this meeting.