Meeting Summary and Next Steps

Today's Presentations

- Current paths forward for generic animal drug product approvals and their regulatory underpinnings
- A description of an in vitro bioequivalence approach for evaluating nonsystemically absorbed animal drug products and the reasons for this suggested approach.
- The scientific considerations that have integrated into the development of this in vitro approach.
- Points to be considered (rerquesting YOUR input) if a guidance (?) document is to be developed on this approach.

The FDA/CVM Website contains suggested references on issues pertinent to today's presentations and discussions.

http://www.fda.gov/AnimalVeterinary/NewsEvents/WorkshopsConferencesMeetings/ucm437827.htm

We welcome your thoughts and comments!

- Written comments should be submitted to **Docket No. FDA-2015-N-0684 by May 18, 2015.**

You can access this site through

www. Regulations.gov

Enter docket number **FDA-2015-N-0684**

The transcript of the proceedings from the public meeting will become part of the administrative record for rulemaking.

You will able to locate the transcripts at **www.fda.gov/animalveterinary/newsevents/workshopsconferencesmeetings**

Lastly, once the recording has been made 508 compliant, it will be accessible at FDA's CVM Web site at:

http://www.fda.gov/AnimalVeterinary/NewsEvents/WorkshopsConferencesMeetings/ucm435459.htm

Thank you for your attendance and for being part of this new step forward in animal health.