April 14, 2009

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2009-D-0012; International Conference on Harmonisation;
Draft Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts
for Use in the International Conference on Harmonisation Regions; Dissolution Test
General Chapter; Availability

The ANIMAL HEALTH INSTITUTE (“AHI”) submits these comments to Docket No. FDA-2009-D-0012; International Conference on Harmonisation; Draft Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Dissolution Test General Chapter; Availability. AHI is the national trade association representing manufacturers of animal health products -- the pharmaceuticals, biological products and feed additives used in modern food production, and the medicines that keep livestock and pets healthy. AHI member companies represent the majority of animal pharmaceuticals and animal insecticides, as well as serving a significant segment of the world market. As such, we have a tremendous interest in the international harmonization of technical and regulatory requirements.

AHI has two comments regarding Annex 7: Dissolution Test General Chapter.

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<td>2</td>
<td>150-152</td>
<td>2.1.9</td>
<td>When using the small cell tablet holder with the flow-through cell apparatus, only the dimensions described in the PDG harmonised text Figure 5 are considered interchangeable.</td>
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Where is the PDG harmonised text Figure 5 located? Is it located in the document referenced in Section 5.1 on Page 3? Please be specific about what the dimensions of the small cell tablet holder are instead of referencing a document that is located somewhere else.
An appropriately rigorous mechanical calibration method (such as ASTM International’s ASTM E2503-07, Standard Practice for Qualification of Basket and 1Paddle Dissolution Apparatus, or the procedures for Mechanical Qualification of Dissolution Apparatus 1 and 2, DPA-LOP.002, on the FDA Web site), when properly executed, will satisfy the current good manufacturing practice (CGMP) requirement for dissolution apparatus calibration under §211.160(b)(4) of Title 21 of the Code of Federal Regulations.

General Comment – AHI is pleased to see that mechanical calibration will be accepted.

Thank you in advance for your consideration of these comments. Should you have any questions, please do not hesitate to contact AHI at (202) 637-2440.

Sincerely,

Samata Veluvolu
Manager, Regulatory Affairs