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Re: Docket No. FDA-2009-D-0011; International Conference on Harmonisation; Draft Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Uniformity of Dosage Units General Chapter; Availability

The ANIMAL HEALTH INSTITUTE ("AHI") submits these comments to Docket No. FDA-2009-D-0011; International Conference on Harmonisation; Draft Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Uniformity of Dosage Units 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 one comment regarding Annex 6: Uniformity of Dosage Units General Chapter.

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<td>1</td>
<td>132-133</td>
<td>2.1.4</td>
<td>For Mass/Weight Variation, the PDG-harmonised definition for ‘W Bar’ should be used.</td>
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Where can we find the PDG-harmonised definition for ‘W Bar’? Is there another document we should be referencing? It is not really clear how this definition could be different from other definitions of ‘W Bar’, so we suggest including the definition that should be used in the document.

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