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July 8, 2013

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

**Re: Bayer HealthCare's Citizen Petition, Docket No. FDA-2006-P-0010  
(formerly 2006P-0249)**

Bayer HealthCare LLC, Animal Health Division ("Bayer") hereby informs the Food and Drug Administration ("FDA") that Bayer has moved in the US District Court of the District of Columbia for permission to submit Norbrook's confidential information that is relevant to FDA's determination of the above-referenced Citizen Petition.<sup>1</sup> In the event that the Court denies Bayer's motion, Bayer intends to further pursue relief from the Protective Order covering this information in the US District Court for the Eastern District of Wisconsin. Bayer respectfully requests that the Agency await the resolution of Bayer's efforts to provide it with a complete factual record before taking action relating to the Citizen Petition, which will be pursued as expeditiously as possible.

Respectfully submitted,

ALAN R. BENNETT

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<sup>1</sup> In particular, Bayer respectfully directs the Agency's attention to the Reply in Support of Bayer's Rule 60(a) Motion, filed on July 8, 2013, which sets out certain representative examples of the information Bayer seeks to provide.

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Food and Drug Administration  
May 6, 2013  
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cc: Elizabeth Dickinson, Annamarie Kempic, Peter Beckerman, Jim Delaney, Urvi Desai,  
Michael Stern, Thomas Cosgrove

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