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September 20, 2013

The Honorable Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

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

Dear Commissioner Hamburg,

Bayer HealthCare LLC, Animal Health Division ("Bayer") respectfully requests that FDA initiate a regulatory hearing regarding the above-referenced Citizen Petition pursuant to 21 C.F.R. § 16.1(a).

On April 19, 2013, FDA voluntarily stayed approval of Norbrook's ANADA No. 200-495 in order to consider the issues raised in Bayer's Citizen Petition.[1] Subsequently, Bayer and Norbrook have collectively provided to the Agency over half-a-dozen submissions, appending and/or directing the Agency to hundreds of exhibits, amounting to thousands of pages of

[1] FDA's actions followed the issue of a temporary restraining order on April 12, 2013 staying FDA approval of Norbrook's ANADA. *Bayer HealthCare, LLC v. United States FDA, et al.*, Case No. 1:13-cv-00487-RMC (D.D.C.). On April 23, 2013, Bayer and FDA filed a joint stipulation to convert the TRO into a preliminary injunction to maintain the stay of approval pending FDA's decision on Bayer's Citizen Petition, which the District Court adopted on April 24, 2013.

documents, testimony, expert reports, videos, and other evidence pertaining to the issues in the Citizen Petition. In addition to the volumes of supporting evidence, these submissions also contained lengthy legal arguments reflecting a profound divergence between Bayer and Norbrook as to what the evidence shows, when and how the governing statute applies, and the ultimate question the Agency has to answer. The requested hearing would bring all the interested parties together in real time, facilitating feedback on the arguments already submitted and the opportunity to uncover and correct any confusion or uncertainty related thereto. A hearing would thereby allow the Agency to focus the respective arguments and narrow the scope of disputed issues, and work to ensure a well-reasoned and correct decision. Moreover, a hearing would greatly reduce the need for the parties to continue their *seriatim* written submissions, and permit the Agency to define the "complete" record pertaining to this Citizen Petition and set a workable timetable for its final resolution.

For those reasons, Bayer respectfully requests the Agency initiate a regulatory hearing.

Respectfully submitted,

ALAN R. BENNETT

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