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For immediate Release

Datafarm responds to Health Canada's announcement of Hybrid eCTD Submission Procedural Simplification

-Four of the top 10 pharmaceutical giants use Datafarm for production of Hybrid eCTD submissions to Health Canada-

Marlborough, MA November 9, 2009 —Datafarm Inc., a world leading provider of high performance electronic regulatory submission solutions for the life sciences industry, today announced that four of the top 10 global pharmaceutical companies as well as emerging and mid-level life sciences companies use Datafarm's software and services for production and delivery of Hybrid electronic Common Technical Document (eCTD) submissions to Health Canada. Datafarm's announcement comes on the heels of last week's 7th Canadian DIA Annual Meeting where Health Canada stated that, effective immediately, sponsor companies may submit Hybrid eCTD regulatory submissions for New Drug Submission (NDS) applications with no prior permission request.

Since 2004, a variety of sponsor organizations have used Datafarm's eCTD software and services, delivering in excess of 500 Hybrid eCTD submissions to Health Canada. Included in these were approximately 20 original NDS's and numerous clarifax sequences. Daniel Orfe, Vice President of Global Regulatory Submissions Services at Datafarm said, "This recent announcement by Health Canada will not only benefit directorates reviewers, but will also provide sponsors real time access to their regulatory filing information and a clear picture of their products' regulatory lifecycle. Datafarm's breadth of experience uniquely positions us to assist sponsor companies in their transition to Hybrid eCTD submissions," concluded Dan.

A Hybrid eCTD as defined by Health Canada denotes that a sponsor company may file an eCTD submission and provide hardcopy for only Modules 1 and 2. This reduces paper volumes required for submission, potentially by hundreds of volumes. Prior to last week's announcement from Health Canada, a sponsor company would need to notify the agency of their intention to

file a Hybrid eCTD. The agency could elect to deny the request. Effective immediately, Health Canada will accept Hybrid eCTD submissions with no prior permission request.

About Datafarm Inc.

Established in 1997, Datafarm is a world leader in high performance electronic regulatory submission solutions for the life sciences industry. Datafarm's open, modular technologies and professional services experts enable life sciences companies to meet the strict standards of regulatory authorities across the world, helping them achieve quality, accuracy, and compliance to efficiently deliver regulatory reports and submissions. Headquartered in Marlborough, MA, Datafarm has offices in the US, UK, France, and India. For more information, visit www.datafarminc.com.

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