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Manager, Regulatory Affairs

August 9, 2013

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

Re: Docket Nos. FDA-2013-N-0683, FDA-2013-N-0684, and FDA-2013-N-0685; Food and Drug Administration Safety and Innovation Act Title VII—Drug Supply Chain; Standards for Admission of Imported Drugs, Registration of Commercial Importers and Good Importer Practices; Notification of Public Meeting; Request for Comments

The ANIMAL HEALTH INSTITUTE (“AHI”) submits these comments to Docket Nos. FDA-2013-N-0683, FDA-2013-N-0684, and FDA-2013-N-0685; Food and Drug Administration Safety and Innovation Act Title VII—Drug Supply Chain; Standards for Admission of Imported Drugs, Registration of Commercial Importers and Good Importer Practices; Notification of Public Meeting; Request for Comments. 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.

AHI has two comments with regards to Title VII of FDASIA:

1) C. Section 714: Good Importer Practices

1. How might FDA structure the GIP regulations to avoid imposing redundant regulatory requirements on commercial importers that also are drug manufacturers and therefore would be subject to both the GIP and CGMP requirements?

There must be a mechanism to allow a drug manufacturer (currently registered with FDA) to register as a commercial importer based upon its current registration instead of a separate redundant requirement to register as a commercial importer.

2) General Comment:

Registration as a commercial importer should NOT circumvent the regulations regarding legal and illegal compounding. The regulations must prevent a company from registering as a commercial importer to perform illegal compounding.

Animal Health Institute Comments to Docket Nos. FDA-2013-N-0683, FDA-2013-N-0684, and
FDA-2013-N-0685

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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,



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