



**FOR IMMEDIATE RELEASE**

Contact:  
Elizabeth Hickman, Marketing Manager  
Pharmaceutics International, Inc.  
10819 Gilroy Road  
Hunt Valley, MD 21031  
Phone: (443) 858-0768  
Email: ehickman@pharm-int.com

**PHARMACEUTICS INTERNATIONAL, INC. (PII) SUCCESSFULLY COMPLETES EMA AND FDA INSPECTION**

HUNT VALLEY, MARYLAND (August 18, 2011) - Pharmaceutics International, Inc. (Pii), a leading contract development and manufacturing organization, today announced it has successfully completed the first-ever US-based joint European Medicines Agency (EMA) and Food and Drug Administration (FDA) inspection.

"Our entire team is very proud of the successful outcome of the joint FDA/EMA inspection," said Tony Horton, vice president of quality assurance at Pii. "This achievement validates our commitment to continuous improvement and our ability to continue to meet the requirements of the FDA, EMA and other international regulatory agencies."

The rigorous four day inspection was conducted by representatives for the EMA from the Medicines and Healthcare products Regulatory Agency (MHRA) and Medical Products Agency of Sweden (MPA) and from the FDA. The inspection is part of the FDA and EMA joint initiative, which focuses on increasing international regulatory collaboration among the agencies in order to enhance global drug quality and safety.

As part of the inspection, Pii's clients received EMA marketing authorization for a soft gel product and reauthorization for a tablet product. Additionally, during the audit the FDA performed an inspection of the company's quality systems as a follow up to its December 2010 inspection for four Pre Approval Inspections. Both FDA inspections have been closed as of June 2011, indicating that Pii is in substantial compliance with US GMPs.

"We are extremely pleased to have achieved this major regulatory milestone," said Steve King, senior vice president of Pii. "This approval allows Pii to continue providing commercial manufacturing services to the global pharmaceutical industry. We look forward to working with our clients to bring several other products to market."

**About Pharmaceutics International, Inc.**

10819 GILROY ROAD • HUNT VALLEY, MARYLAND 21031  
TELEPHONE 210.584.0001 • FAX 410.584.0007  
[www.pharm-int.com](http://www.pharm-int.com)  
Pharmaceutics International, Incorporated



Pharmaceuticals International, Inc. (Pii) is a privately held Drug Delivery Solutions company providing dosage form development and GMP Manufacturing services to the global pharmaceutical industry. Pii's vision is to become the benchmark in pharmaceutical product development outsourcing. Headquartered in Hunt Valley Maryland USA with European facilities in the UK, Pii offers preformulation testing, formulation development and clinical trial material and commercial manufacture of parenteral, solid, semi-solid and liquid dosage forms. For further information about Pii visit [www.pharm-int.com](http://www.pharm-int.com).

####

10819 GILROY ROAD • HUNT VALLEY, MARYLAND 21031  
TELEPHONE 210.584.0001 • FAX 410.584.0007  
[www.pharm-int.com](http://www.pharm-int.com)  
Pharmaceuticals International, Incorporated