

CUMBERLAND PHARMACEUTICALS RESOLVES FDA ISSUES REGARDING ACETADOTE SALES AID

NASHVILLE, Tenn. - September 2, 2010 – Cumberland Pharmaceuticals Inc. is pleased to report that it has worked closely with the Food and Drug Administration (FDA) to address the agency's recent concerns regarding a sales aid for Acetadote. The FDA has informed the company that the issues have been appropriately resolved and the matter is officially closed. Cumberland continues to market Acetadote for treatment of acetaminophen poisoning.

Cumberland was one of several companies contacted by the FDA in June regarding promotional efforts. Cumberland Pharmaceuticals is committed to compliance with all FDA regulations and worked with the agency to understand its concerns and to quickly resolve the issues. Cumberland remains dedicated to its mission of providing safe and effective products that improve patient care.

About Acetadote

Acetadote[®] (*acetylcysteine*) Injection is used in the emergency department to prevent or lessen potential liver damage resulting from an overdose of acetaminophen (paracetamol), a common ingredient in many over-the-counter painkillers. It is the only approved injectable product in the United States for the treatment of acetaminophen overdose. Acetadote is contraindicated in patients with hypersensitivity or previous anaphylactoid reactions to acetylcysteine or any components of the preparation. Serious anaphylactoid reactions, including death in a patient with asthma, have been reported in patients administered acetylcysteine intravenously. Acetadote should be used with caution in patients with asthma, or where there is a history of bronchospasm. The total volume administered should be adjusted for patients weighing less than 40 kg and for those requiring fluid restriction. To avoid fluid overload, the volume of diluent should be reduced as needed. If volume is not adjusted, fluid overload can occur, potentially resulting in hyponatremia, seizure, and death. For full prescribing information, visit <u>www.acetadote.net</u>.

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a Tennessee-based specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. The Company's primary target markets include hospital acute care and gastroenterology. Cumberland markets Acetadote[®] for the treatment of acetaminophen poisoning, Caldolor[®], the first injectable treatment for pain and fever approved in the United States, and Kristalose[®], a prescription laxative. Cumberland is dedicated to providing innovative products which improve quality of care for patients. For more information on Cumberland Pharmaceuticals, please visit the Company website at <u>www.cumberlandpharma.com</u>.

SOURCE: Cumberland Pharmaceuticals Inc.