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**CUMBERLAND PHARMACEUTICALS ANNOUNCES  
FDA APPROVAL OF ACETADOTE®**

*New drug is first injectable treatment for acetaminophen poisoning*

**Nashville, Tenn. (February 4, 2004)** – Cumberland Pharmaceuticals announced it has received U.S. Food and Drug Administration (FDA) approval for Acetadote®, an injectable drug used to treat acetaminophen overdose.

Acetadote® (acetylcysteine) injection will be used in an emergency room setting to prevent or lessen potential liver damage resulting from an overdose of acetaminophen, the leading cause of drug toxicity in the United States. According to the FDA, more than 56,000 emergency room visits and 100 deaths occur each year due to unintentional overdoses of acetaminophen, a common ingredient in many over-the-counter painkillers.

“We are delighted to be able to bring this life saving new drug to the market,” said A.J. Kazimi, chief executive officer of Cumberland Pharmaceuticals. “We believe this FDA approval distinguishes Cumberland among companies in the specialty pharmaceutical industry. We have now demonstrated the capability to both acquire product rights and successfully complete the development of our own products, from conception to approval.”

Acetadote® is the first injectable treatment for acetaminophen overdose available in the United States. The FDA has granted it orphan drug designation, which allows seven years of marketing exclusivity from the date of approval. Orphan drugs are products used to treat conditions affecting fewer than 200,000 Americans each year.

Cumberland is assembling a hospital sales force to promote the product in hospital emergency rooms and poison control centers and expects to have it available for use in the second quarter of 2004.

**Cumberland Pharmaceuticals Inc.** is a Tennessee-based company formed to acquire rights to and actively market a portfolio of niche pharmaceuticals for specific physician segments such as gastroenterology, critical care, pulmonology and emergency medicine. For more information, visit the Cumberland Pharmaceuticals Inc. website at [www.CumberlandPharma.com](http://www.CumberlandPharma.com).

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