FDA Approves Cornerstone Therapeutics' ANDA for Generic Tussionex® Pennkinetic® Product. Neos Therapeutics developed the drug product formulation using its proprietary formulation technology and will be the exclusive manufacturer.

July 2, 2012--U.S. Food and Drug Administration (FDA) approved its Abbreviated New Drug Application (ANDA) for a generic Hydrocodone Polistirex and Chlorpheniramine Polistirex extended-release suspension product. The antitussive/antihistamine combination product is a generic equivalent for the product currently sold under the Tussionex® Pennkinetic® brand name.

CRTX 067 was developed through a collaboration including Cornerstone, Coating Place, Inc. and Neos Therapeutics, LP, a subsidiary of Neos Therapeutics, Inc. Cornerstone will market the product through its wholly-owned generics subsidiary, Aristos Pharmaceuticals, Inc. Coating Place manufactures and supplies the active pharmaceutical ingredients (APIs), including a patent-protected version of hydrocodone polistirex. Neos developed the CRTX 067 drug product formulation using its proprietary formulation technology, Dynamic Time Release Suspension® (DTRS®), and Neos will be the exclusive manufacturer of the approved drug product.