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## **Aegis Therapeutics Files Second Drug Master File with FDA**

**SAN DIEGO, CA October 12, 2005 / BusinessWire /--** Aegis Therapeutics, LLC today announced that it has filed its second Drug Master File (DMF) for Intravail™ with the U.S. Food and Drug Administration (FDA) as part of its goal of broadly enabling non-invasive transmucosal delivery of peptide, protein, and non-peptide macromolecular drugs across a wide spectrum of disease categories and administration routes.

Aegis' Intravail™ absorption enhancement agents are mild and non-irritating to mucosal membranes, providing exceptionally high and unmatched bioavailability performance, comparable in efficiency to subcutaneous injection via the intranasal, oral, and other mucosal membrane administration routes. These agents help deliver potent peptide, protein, and other small and large molecule drugs that currently can be delivered only by injection. To date, Aegis has licensed Intravail™ for beta-interferon, low molecular weight heparin, and for up to three undisclosed pediatric drugs. Several feasibility studies for additional drugs are underway.

A DMF provides key confidential, detailed regulatory and scientific information about the facilities, processes, and entities used in the proprietary manufacturing, processing, packaging and storage of Aegis' patented Intravail™ absorption enhancement agents intended for use in humans. The information contained in the DMF will be used to support future Investigational New Drug Applications (INDs) or a New Drug Applications (NDAs), an Abbreviated New Drug Application (ANDA), another DMF, an Export Application, or amendments to any of these. The content of a DMF is reviewed in connection with the review of an application to the FDA such as an IND or NDA and provides a strategic advantage by allowing the FDA to access Aegis' confidential regulatory and scientific material without disclosing that information privately or publicly to other parties. Pharmaceutical company licensees of Intravail™ receive reference authorization to our DMFs in support of their submissions to the FDA.

### **About Aegis Therapeutics**

Aegis Therapeutics LLC is a specialty pharmaceutical company commercializing its patented Intravail™ drug delivery technology that enables the non-invasive delivery of a broad range of protein, peptide and non-peptide macromolecular therapeutics that can currently only be administered by injection. Aegis' Intravail™ absorption enhancement agents are mild and non-irritating to mucosal membranes. They provide exceptionally high and unmatched bioavailability performance, comparable in efficiency to subcutaneous injection, via the intranasal and other mucosal membrane administration routes. Intravail™ also provides for rapid drug absorption and onset of action, controlled transient permeation of the nasal mucosal barrier, avoidance of gastric hydrolysis and "first pass effect" elimination by the liver, greater patient convenience and compliance, elimination of needle-stick injuries and associated transmission of blood borne pathogens, compatibility with current nasal delivery devices, and ease of formulation, scale-up, and production. For more information about Aegis, please visit the Aegis website at:

<http://www.aegisthera.com>.

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