A Workshop: Botanicals as "New" Drugs

Co-Sponsored by the

Center for Drug Evaluation and Research,
Food and Drug Administration

Saturday, August 5, 2006
(11 AM – 4PM)

Crystal Gateway Marriott - Arlington, Virginia
(just across the Potomac River from Washington, D.C.)

In conjunction with

The 47th Annual Meeting of the American Society of Pharmacognosy
Aug 6 - 9, 2006

COURSE DESCRIPTION: This Workshop is an introduction to the drug development process for **naturally complex or heterogeneous products**, such as botanicals. Experts in the field will address the current status of USA drug development for botanical drugs. Learn how to select a product for development as a "drug." Learn what FDA is looking for in the Chemistry, Manufacturing, and Controls (CMC) and Pharmacology-Toxicology sections of an Investigational New Drug (IND) application for a Botanical Drug.

Conference Organizer: **Tawnya McKee**
mckee@ncifcrf.gov

- *How does FDA define "botanical?"*
- *When should a "botanical" be developed as a "drug"?*
- *What are the differences between botanical "foods" and botanical "drugs"?*
- *What kinds of marketing claims can be made for botanical drugs?*
- *When should an Investigational New Drug (IND) application be filed with FDA?*
- *How does the FDA process and review Botanical INDs and New Drug Applications (NDAs)?*
- *What are the pertinent FDA regulations, policies and individuals you should know about for botanical drug development?*

WHO SHOULD ATTEND: Ingredient Manufacturers, Suppliers, Directors of Research and Development, Researchers, Academicians, Potential Drug Sponsors, Medicinal & Natural Products Chemists, Pharmacologists, Toxicologists, Botanists, GMP Specialists, Clinical Investigators and Clinical Trials Experts, Policy-makers.

WORKSHOP REGISTRATION:

$295 – Workshop Only [Sat. Aug. 5]
$25 - ASP Attendees

For more information, see **The American Society for Pharmacognosy** at:
www.phcog.org/AnnualMtg/Washington.html