



American Society for Pharmacognosy
presents:
A Workshop: Botanicals as “New” Drugs
Co-Sponsored by the
*Center for Drug Evaluation and Research,
Food and Drug Administration*

In Memoriam

This Workshop is dedicated to the memory of



Floyd E. Leaders, Jr., PhD
Pharmacognosist & Regulatory Scientist
December 11, 1931 – February 26, 2006

Saturday, August 5, 2006
Crystal Gateway Marriott - Arlington, Virginia

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|---------------------|---|
| 11:00 AM – 11:30 AM | Welcome Remarks/ Why develop botanicals as drugs?
What’s in it for the Manufacturer?
Freddie Ann Hoffman, MD, HeteroGeneity, LLC |
| 11:30 AM – 12:00 PM | Botanicals as “New” Drugs.
Shaw Chen, MD, PhD, Food and Drug Administration |
| 12:00 PM – 12:30 PM | Selecting the “Product”: What to look for in the Plant.
Edward M. Croom, Jr., PhD, Croomia, LLC |
| 12:30 PM – 1:45 PM | Luncheon |
| 1:45 PM – 2:15 PM | Facility Requirements for Pharmaceutical Production.
Barbara Immel, Immel Resources, LLC |
| 2:15 PM – 2:45 PM | Developing Botanical Drugs: The Drug Review Process.
Jinhui Dou, PhD, Food and Drug Administration |
| 2:45 PM – 3:00 PM | Break |
| 3:00 PM – 3:30 PM | Chemistry, Manufacturing, and Controls Information
Recommended for a Botanical Drug
Rajiv Agarwal, PhD, Food and Drug Administration |
| 3:30 PM – 4:00 PM | Pharmacology & Toxicology Requirements for Botanical Drugs.
Kuei-Meng Wu, PhD, Food and Drug Administration |
| 4: 00 PM | Adjourn |



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