

THE STATE UNIVERSITY OF NEW JERSEY

# RUTGERS

The Nutraceuticals Institute  
Department of Food Science • Cook College  
Rutgers, The State University of New Jersey  
65 Dudley Road • New Brunswick • New Jersey 08901-8520  
Paul A. Lachance, Ph.D. Executive Director  
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14 June 2001

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fisher Lane (Room 1061)  
Rockville, MD 20852

Cc: Dr. Jeanne Rader  
Division of Science and Applied Technology  
(HFS 840) CFSAN  
Food and Drug Administration  
200 C Street, SW  
Washington, DC 20204

Re: Safety of Natural Products – FDA sole source intention for award of cooperative agreement to the University of Mississippi Center for Natural Products Research (UM-NCNPR) (Federal Register document # 01-11159)

Dear Ms/Sir:

FDA seeks the ability to identify and analyze specific components in ingredients, including botanical ingredients, and in dietary supplement products as an essential component of research and regulatory programs directed at ensuring that dietary supplements are safe and their labeling is truthful and not misleading. The FDA recognizes the need for authenticated reference material as an essential prerequisite to the accurate identification and the quantitative analysis and of ingredients of finished products under its' regulatory jurisdiction. Therefore, the FDA recognizes that it is essential that principles and criteria for ensuring the scientific validity of products, such as botanicals be developed by consensus and that research into the identification and safety of natural products be designed and implemented. The FDA "believes" that a sole source cooperative agreement with the UM-NCNPR will provide for the needed research (but not regulatory policy) needs of the agency.

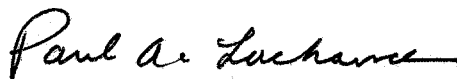
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The Nutraceutical Institute at Rutgers University includes natural products chemical and immuno-assay research. We are recognized as competent and capable of the research that such a cooperative agreement entails; therefore we would have preferred that such a research opportunity would emerge as a multi-source Request for Application. We also offer foundational research into the technology for the traceability of any and all botanical and manufactured chemical ingredients from source to consumer purchase.  
If we can be of assistance

Sincerely,



Paul A. Lachance, Ph.D., D.Sc., CNS  
Professor and Executive Director

Cc: Dr. Robert T. Rosen  
Associate Director, Analytical Services  
Center for Advanced Food Technology

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