

Regulatory Consultants to the Food, Drug, and Cosmetic Industries

23276 South Pointe Dr., Ste. 204, Laguna Hills, CA 92653 (949) 470-7970 Fax (949) 470-7972 5 0 9 7 *01 JAN 17 72:18

January 11, 2001

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

RE: Electronic Filing of Drug Registration and Listing - Pilot Project

To Whom It May Concern:

My firm, R. FLORA & ASSOCIATES, is a regulatory consulting firm in Southern California. We have a number of drug manufacturers, both domestic and foreign, as clients. In the course of representing them, we are frequently called upon to register drug establishments and list drugs for our clients. We are also frequent users of FDA's website and are well-versed in current computer and Internet technology. Consequently, we would be very interested in volunteering as participants in your pilot program (Docket No. 00N-1669; FR Notice 1/9/01, Vol. 66, No. 6) regarding the electronic filing of information currently required by FDA.

Please notify us if you have an interest in accepting us as participants in this study and, if so, how we would will proceed. I look forward to hearing from you and would ask you to direct any further communications regarding this issue to my attention.

Sincerely

Vice President



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