

**JERUSSI CONSULTING, INC.**

---

3311 Midland Road  
Fairfax, Virginia 22031 USA

4213 '03 JUL -1- P1 :48  
Tel: 703-273-3903 • Fax: 703-293-9161

June 26, 2003

Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

**01D-0368**

Dear Madame/Sir:

This docket, Guidance for Industry Submitting Marketing Applications According to the ICH-CTD Format-General Considerations, was reopened on April 15, 2003 via a Federal Register Notice (Vol. 68, #72, page 18248) with a closing date of June 16, 2003. Although it is past the closing date, I am hopeful that the one comment I have to made, which is listed below, will be accepted for consideration since I believe it to be of critical importance.

Comment about:

Section II. BACKGROUND, page 3, last sentence which reads "An application organized as described in this guidance will fulfill the regulatory format requirements for 21 CFR 314.50, 314.94 and 601.2."

The document under comment consideration is a guidance, not a regulation, and I do not understand how it can fulfill a requirement of a regulation if it is different than what is stated in the regulation? And it is indeed different.

Sincerely,



Robert A. Jerussi, Ph.D.

**01D - 0368**

**C9**