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March 24, 2000

**RE: Federal Register Docket No. 99D-5333**

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

To Whom It May Concern:

I am encouraged by the Agency's proactive approach to paperless submissions. My only hope is that the desire for a paperless archive will not supersede OGD's dedication to the established electronic submission program which promises to expedite reviews and enable cross-application queries. The September 1999 "Guidance for Industry: Preparing Data for Electronic Submission in ANDAs" expresses the database benefits best: "to improve Agency review staff's access to information about formulation, manufacturing, bioequivalence, and other data, thus improving the efficiency, quality, and consistency of product reviews." An ideal solution would add the benefits of a paperless archive to those of the current program. My plea to those developing the "Guidance on Submitting an Archival Copy of an ANDA in Electronic Format" is to retain the benefits of a structured submission format that will allow the continued use by reviewers of consistent data views and the continued population of a central database.

Sincerely,

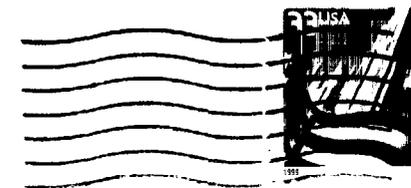
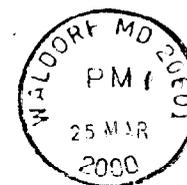
A handwritten signature in cursive script that reads "Michele Ritondo".

Michele Ritondo, Ph. D.

99D-5333

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