VENABLE, BAETJER, HOWARD & CIVILETTI, LLP Including professional corporations

July 3, 2003

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VIA HAND DELIVERY

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

Docket No. 02N-0434; Request for Extension of Comment Re: Period

Dear Sir or Madam:

We are writing to respectfully request that the Commissioner of the Food and Drug Administration (FDA) extend the time for the public to submit comments for at least sixty days to FDA's Withdrawal of Certain Proposed Rules and Other Proposed Actions, published at 68 Federal Register 19766 (April 22, 2003).

Our clients will be affected by the withdrawal of many of the rules and request additional time to prepare better comments. For example, some of the rulemakings are quite old and interested parties can use the additional time to obtain and review old records. We note that FDA has not indicated that the public health or safety would be affected by granting such an extension. Additionally, no commenter would be prejudiced by granting the extension.

Accordingly, we submit that the public interest would be served by granting such an extension.

Respectfully submitted,

William C. Walla

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