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July 1, 2003

VIA HAND DELIVERY

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

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

Dear Sir/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 to FDA's April 22, 2003 Notice of Intent to Withdraw 84 Proposed Rules and Other Actions. A number of the Proposed Rules covered by the Notice are of significant importance to our clients. For this reason, we seek an extension of the comment period for sixty (60) days from July 22, 2003 to provide our clients with adequate time to prepare and submit substantive comments that address issues raised by the Notice.

The requested extension of the initial comment deadline will enable interested parties to more thoroughly address the complex issues raised by the Notice of Intent. Further, the additional time needed to prepare proper responses will in turn support development of a more complete administrative record and enable FDA to reach more fully substantiated conclusions. The requested extension would apply uniformly and prejudice no individual participant in the proceeding.

For the reasons above, the requested extension would serve the public interest and therefore should be granted.

Respectfully submitted,

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02N-0434

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