



Food and Drug Administration
Rockville MD 20857

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July 16, 2003

Ms. Georgia C. Ravitz
Arent Fox Kinter Plotkin & Kahn, PLLC
1050 Connecticut Avenue, NW
Washington, DC 20036-5339

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

Dear Ms. Ravitz,

On July 1, 2003, you submitted a Request for Extension of Comment Period for the Food and Drug Administration's Notice of Intent to Withdraw 84 Proposed Rules and Other Actions, Docket No 02N-0434, on behalf of unnamed clients. You state the request for the extension of the comment period is to "enable interested parties to more thoroughly address the complex issues raised by the Notice of Intent." The comment period for Docket No. 02N-0434 closes on July 21, 2003.

A request to extend a comment period can be submitted under 21 CFR 10.40(b)(3). The request must "discuss the reasons comments could not feasibly be submitted within the time permitted, or that important new information will shortly be available, or that sound public policy otherwise supports an extension of the time for comment" (21 CFR 10.40(b)(3)(i)).

The Agency has decided that the comment period will not be extended for Docket No. 02N-0434. The request fails to establish that the comments could not feasibly have been submitted within the comment period nor is there important "new" information. Also, your letter does not support that there is a sound public policy reason to extend the comment period.

For the reasons stated above, I regret that your request to extend the comment period for Docket No. 02N-0434 is denied.

Sincerely,

Jeffrey Shuren
Assistant Commissioner for Policy

cc: Docket No. 02N0434

02N - 0434

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Georgia C. Ravitz
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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**

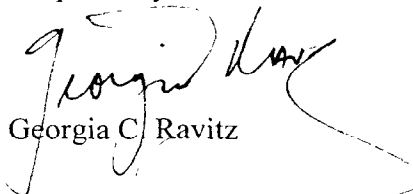
Dear Sir/Madam:

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,


Georgia C. Ravitz

02N-0434

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