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February 2, 2001

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VIA FACSIMILE

James C. Morrison
CDER Ombudsman (HFD-1)
5600 Fishers Lane
Rockville, MD 20857

Re: Oakhurst Company Petition – Docket No. 80N-0146

Dear Mr. Morrison:

Thank you for your response to our January 10, 2001 letter concerning our client's, Oakhurst Company, petition. We recognize that FDA has acted on and denied the petition and that our client could file a new petition. However, the purpose of our letter was to inform the agency that it had improperly denied the petition before our client had adequate time to respond to Dr. Ganley's letter, and that Oakhurst should not have to file a new petition. In essence, Oakhurst should not be required to start this whole 5 year process over again when it was led to believe that it would have an opportunity to respond to the issues raised by Dr. Ganley before its petition would be subject to final agency action.

We therefore believe that FDA should reopen docket number 80N-0146 and allow the data to be submitted to that docket. We intend to submit Oakhurst's response to the "original" docket as we stated in our letter of January 10, 2001. To the extent that your office could be helpful in resolving this dispute and, in the interest of equity and fairness, reopen the docket, we would welcome your assistance.

Very truly yours,

Gary L. Yingling

cc: Mr. Dennis E. Baker, Association Commission for Regulatory Affairs
Dr. Charles J. Ganley, Director, Division of OTC Drug Products
Docket No. 80N-0146
Oakhurst Corporation

80N-0146

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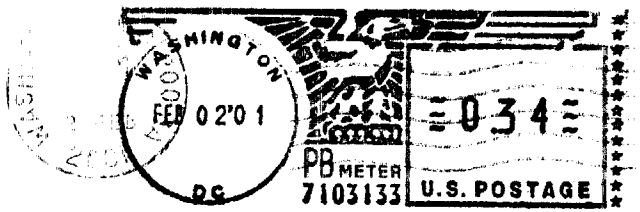

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