



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 5 2003

Satish R. Shah
66 Lockwood Place
Clifton, NJ 07012

Re: Docket No. 93N-0349

Dear Mr. Shah:

I am in receipt of the three documents you faxed to Mr. Kevin Fain of FDA's Office of the Chief Counsel on April 22, 2003. The first is a letter dated April 19, 1993; the second is a motion filed January 25, 1993, with the U.S. District Court for the District of Maryland; and the third is a letter dated May 21, 1992. Due to their very personal nature, I will hold these in confidence and will not place them in the public docket. You are free to enter them into the docket if you wish (see address below).

The agency does not intend to take any action (namely, reconsideration of its decisions not to terminate your debarment) as a result of the submission of these documents, because they are irrelevant in determining whether you provided the necessary "substantial assistance" in the investigations or prosecutions of generic drug offenses. As the agency explained in its previous denials of your reinstatement requests, you have failed to make such a showing.

Sincerely yours,

David T. Read
Director, Division of Regulatory Policy I
Center for Drug Evaluation and Research

cc:

J. David Ash, Esq.
305 W. Chesapeake Ave., Ste. 113
Towson, MD 21204

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