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February 3, 2003

Recd 3/12/03

Kevin Fain, Esquire
Office of the Chief Counsel
"FDA"
5600 Fishers Lane
Drop Box G-C-F-1
Rockville, Maryland 20857

RE: *Satish R. Shah - Reinstatement*
Docket No. 93N0349

Dear Mr. Fain:

It was a pleasure speaking with you regarding Mr. Shah. I am sorry that it has taken me so long to respond to your concerns, however, I have had in depth conversations with Mr. Shah and he has provided me with the enclosure which represents his recent employment activity. As you can see from the enclosed, Mr. Shah certifies that he has not acted as a Pharmacist subsequent to November, 1998. Mr. Shah's license was revoked due to the 1992 indictment from this episode.

The history of this case is very unfortunate. I can tell you as the trial attorney, I had hoped that Mr. Shah would plead guilty to the indictment, thereby reducing his potential incarceration significantly. Despite my position, Mr. Shah believed that he should pursue this matter in Court and present his case to the jury. Quite frankly, I have recurring thoughts that Mr. Shah may not have totally understood the ramifications of either his acts at Par or the information I provided him relating to the elements of the alleged crime as well as the law and the facts as they related to this case. I am consistently troubled in this regard.

In any event, as Mr. Shah's file will reflect, Mr. Shah was the first employee from PAR Pharmaceutical to contact FDA and report their illegal conduct to the FDS and Federal authorities. This was confirmed by Mr. Gray Tunkavige, Consumer Safety Officer of the FDS at the time of the misconduct and Mr. Thomas Holland, Special Agent, Office of the Inspector General, United States Department of Health and Human Services. Moreover, I was advised that certain representatives of Par Pharmaceutical would take the stand and testify against Mr. Shah as part of the respective individual's plea agreement. Despite my urging, as well as that of the

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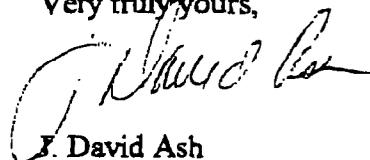
Assistant U.S. Attorney trying the case, Christopher Meade and, indeed, the Deputy United States Attorney, at the time, Mr. Gary Jordan, Mr. Shah believed strongly that he was not guilty and insisted on pursuing the matter in trial. This concern remains with me because of Mr. Shah's firm conviction that he did not break the law. I find him to be a very insightful and thoughtful individual.

As Mr. Shah's file will reflect, it was he who brought this matter to the attention of the FDA in the first place. His cooperation with the FDA in this regard is without dispute. As noted in Mr. Tunkavige's letter to the Administration, Mr. Shah was instrumental in moving the case forward. Mr. Shah's cooperation with the FDA resulted in numerous individuals being brought to justice. Clearly, without Mr. Shah, the illegality involved in this case would have continued indefinitely. After meeting with Mr. Shah, speaking with family members and, reviewing his history, I was left with the impression that Mr. Shah presented the information to the FDA because he believed it to be the correct and honorable thing to do. While Mr. Shah's view of the legality of his involvement may be incorrect, he was certainly pro-active with the Government and, has long since exhibited great remorse for what has been shown to him to be an illegal activity. He was sentenced to a considerable period of incarceration. He has had his license to practice as a Pharmacist in the State of New York and New Jersey revoked and, he and his family, have suffered enormous economic loss.

Of great note and importance to the Administration in terms of its reconsideration of Mr. Shah's position is the fact that the subject of his conviction occurred over ten years ago. With the exception of this event, Mr. Shah has been a productive and law abiding citizen. With the utmost of respect, I believe that the ends of justice would be served by the Administration reinstating Mr. Shah. If possible, perhaps the Administration would consider a probationary period during which representatives of the Administration could monitor Mr. Shah's activity.

I greatly appreciate your consideration in this matter. If you or other representatives of the Administration need any additional information, please feel free to contact me.

Very truly yours,



J. David Ash

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SATISH R. SHAH
66 Lockwood Place
Clifton, New Jersey 07012

Employment History

Dates:

Employer:

February 2001 - Present

Meadowland Plaza Hotel
Fairfield, NJ 07004
(973) 227-4333

March 2000 - February 2001

Herbo, Inc.
New York, New York 10001
Sales Consultant
Herbal Marketing Company

November 1998 - March 2000

Store Manager
RX 2000, Inc.
Jersey City, NJ 07305

December 1997 - November 1998

Unemployed
License Revoked in New Jersey

January 1997 - December 1997

Pharmacist
RX 2000, Inc.
Jersey City, NJ 07305

April 1995 - December 1996

Pharmacist
A&S Pharmacy
Jersey City, NJ 07305

November 1994 - March 1995

Half Way House
New York, New York

April 1993 - November 1994

“UNICOR”
Allenwood Federal Prison
Allenwood, PA

I HEREBY CERTIFY that I have not worked for any Pharmaceutical Company since debarment.

2/3/03
DATE

Satish R. Shah
SATISH R. SHAH

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