

SATISH R. SHAH
66 LOCKWOOD PLACE
CLIFTON, NEW JERSEY 07012

May 8, 1998

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David T. Read, Acting Director
Regulatory Policy Staff
5600 Fishers Lane
HFD-7
Rockville, MD 20857

RE: Satish R. Shah
Docket No. 93N-0340

Dear Mr. Read:

The purpose of this letter is to support my petition to terminate my debarment. On July 18, 1994, I was informed by the Deputy Commissioner for Operations (FDA) that I cannot provide services in any capacity to a person that has an approved or pending drug product application.

On or about February 24, 1989 I was distressed because my employer, Par Pharmaceutical was performing unlawful procedures and activities in reference to ANDA submissions and production activities. Accordingly, I wrote a letter to Dr. Marvin Seife, (copy attached), Director of Generic Drugs, FDA, at that time. As a result of my letter to FDA, Mr. Thomas Holland from the Office of Inspector General, Washington, D.C. contacted me by telephone in the month of March 1989 and decided to meet me at Ramada Inn, Clifton, New Jersey in order to provide him further information about Par's unlawful activities. In that first meeting on 3/6/89 with Mr. Holland, I provided how Par Pharmaceutical has manipulated ANDA (Abbreviated New Drug Application) data, bioequivalency studies, and stability testing of the following generic drug products:

- (1) Triamterene 75 mg and Hydrochlorothiazide 50 mg tablets.
- (2) Orphengesic Forte tablets.
- (3) Leucovorin Calcium tablets.
- (4) Haloperidol 20 mg tablets and other several products.

Mr. Holland told me that the information was very helpful and he would report same to the appropriate person at the FDA for further investigation.

As indicated in Mr. Gary Tunkavige's letter of January 9, 1998, (copy attached) he initiated an inspection of Par Pharmaceutical based on the information provided by me on or about 6/22/89. The allegations of misconduct on the part of Par

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Pharmaceutical were forwarded to him by Mr. Edmund Fry, Director, Division of Manufacturing (FDA).

In the meantime, I was interviewed twice by the Assistant U.S. Attorney for the Southern District of New York (White Plains Office) and in each occasion I provided information regarding the activities of Par to the government. The information I provided to the government was essential to the prosecution of Par and obviously very incriminating as to my involvement. I freely admitted my activities in the furtherance of Par's plan to avoid and/or evade FDA regulatory procedures.

I was assured that the information I provided would not be used against me for the purpose of a criminal prosecution.

On 8/15/89, I consented to another interview with Mr. Gary Tunkavige and members of the inspection team in my attorney's office. During this interview, I discussed several other products which were associated with various irregularities. At the time my recollection does not allow me to remember the names specifically. My knowledge about these products was based upon my recollection and my involvement in the development of these products during my employment with Par.

The information collected by Mr. Gary Tunkavige and the members of the inspection team between May 1989 and October 1989 contributed to the evidence of misconduct on the part of individuals associated with Par Pharmaceutical, Inc. and I believe led to the ultimate indictments referred to in this submission.

As a result of the meetings with Mr. Holland, Mr. Tunkavige and White Plains Office of the U.S. Attorney it led to the meeting at the United States Attorney's Office in Baltimore, Maryland on October 16, 1989 with my counsel present on that day. By then the U.S. Attorney in Baltimore had all the information which I provided earlier. (My counsel has since died).

Perhaps, I was of the impression on that day that I will get immunity from the prosecution but now I know that I was not given immunity but I provided voluntarily all the information they needed but prior to the immunity discussions I had nothing more to offer and apparently therefore I did not receive immunity.

During the conversation at the U.S. Attorney's Office in Baltimore, Maryland, I was not told that I was a target of this investigation. I had agreed to cooperate and be a witness. Federal Authority and the FDA continued their investigation until

the beginning of 1992 and I was indicted in June 1992 along with Mr. R.K. Patel, Mr. Ashok Patel, Mr. Barry S. Geller and Mr. N.G. Rana. As a result of this investigation and my cooperation Mr. R.K. Patel, Senior Vice President and founder of Par, plead guilty on Jan. 11, 1993.

Mr. Ashok H. Patel, Senior Vice President and founder of Par plead guilty on Jan. 15, 1993.

Mr. Barry S. Geller, Vice President of Regulatory Affairs, plead guilty on Jan. 15, 1993.

Mr. N.G. Rana, Manager of the Quality Control Laboratory until 1991 plead guilty at a later date.

The other employees, including Dr. Atul Shah and Dr. Padam Bansal were also convicted of obstruction of justice and plead guilty at a later date.

I was under the impression that I will not be prosecuted because of the information I had given to Federal Authority and the FDA. Nevertheless, I was prosecuted and it was based on the information I provided.

I urged my trial counsel to make known to the court of these disclosures to the government before the trial. My trial counsel sought no protective relief from the court.

During my entire period of employment at Par Pharmaceuticals I reported to Mr. R.K. Patel, Mr. Ashok Patel, both senior vice presidents and founder of Par. Dr. Padam Bansal joined Par in 1986 as a Director of R&D and I was reporting to him also.

Occasionally, I was also directed to change or alter ANDA submissions by Mr. Barry Geller. During my interviews with Mr. Holland, Mr. Tunkavige and U.S. Attorney's Office (both White Plains, New York and Baltimore, Maryland) I explained to them that all the changes, alterations or falsifications of paperwork submitted to the FDA was directed by Mr. R.K. Patel, Mr. Ashok Patel, Mr. Barry Geller and Dr. Padam Bansal.

I was directed to falsify documents over which I had no control as an employee. I acknowledge nevertheless that this was wrong.

All of the above can be corroborated in letters written by Mr. Gary Tunkavige and Mr. Holland. (Copy attached).

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I regret this painful episode of my life that I have put my family through such misery and shame. I am unable to support my family due to this incident and would like to put this part of my life behind me.

I respectfully request if there is any question as to the facts set forth that a hearing be afforded to me. Originally at the time I could have had a hearing. I could not gather all my background material since I was incarcerated.

Very truly yours,

Satish R. Shah .

SATISH R. SHAH

SRS
Enclosures

Apprx. date
Feb.'89

Dear Dr. Seife:

Do you know that Par Pharmaceutical has manipulated many ANDA'S in the past 5 to 6 years.

Do you know that Par Pharmaceutical has manipulated many Biostudies in the past 5 to 6 years.

Do you know that Par Pharmaceutical has manipulated manufacturing sites during the past 5 to 6 years.

Do you know that Par Pharmaceutical has manipulated many paper work during the past 5 to 6 years to file fraudulent ANDA'S.

Do you know that Par Pharmaceutical has manipulated many Stability studies during the past 5 to 6 years.

Start your investigation before its too late.

Contact me at (201) 472-5660 if you need specific information.

February 20, 1998

To Whom It May Concern:

I am a Special Agent in the Office of Inspector General, U.S. Department of Health and Human Services. In about 1989, I had occasion to interview Mr. Satish Shah. Mr. Shah, a former employee of Par Pharmaceutical, came forward and provided information concerning wrongdoing by PAR officials in the form of the creation of false records and misrepresentations to the Food and Drug Administration. By coming forward, Mr. Shah made a significant contribution to the government's investigation of PAR. It should be noted that Mr. Shah took the initiative in contacting the authorities and continued to cooperate in the investigation.

Sincerely,



Thomas Holland

U.S. Department of Health and Human Services
Office of Inspector General
330 Independence Avenue SW, Rm. 5193
Washington, D.C. 20201

Gary Tunkavige
10 Exchange Place - Suite 804
Jersey City, N.J. 07302

January 9, 1998

Re: Docket No. 93N-0340

To Whom It May Concern:

Mr. Satish R. Shah has informed me that he has requested termination of debarment, and has requested that I prepare a letter regarding the assistance he had provided in an investigation of Par Pharmaceutical, Inc. Spring Valley, N.Y.

While I take no position as to Mr. Shah's merit for termination of debarment, I can make the following factual statements, which are a matter of record, relating to the investigation of Par Pharmaceutical and associated individuals:

In May, 1989, I was a Consumer Safety Officer (CSO) stationed at the Bridgeport, CT Resident Post. I am currently a Special Agent with the FDA Office of Criminal Investigations, stationed at the New York Field Office. In May, 1989, as a CSO, I was detailed to New York District to conduct an inspection of Par Pharmaceutical, Inc. I was the Lead Investigator for an inspection which was initiated on 5/24/89 and spanned the time period to 10/6/89. Reference is made to the Establishment File (EF) for Par Pharmaceutical, Inc. and the Establishment Inspection Report (EIR) dated 5/24/89 et al.

Satish Shah had forwarded a letter to Dr. Marvin Seife - Director, Division of Generic Drugs on or about 2/24/89 which contained various allegations of misconduct on the part of Par Pharmaceutical, Inc. The subject letter was forwarded to the Department of Health & Human Services (DHHS) Office of Inspector General (OIG). The record indicates that Mr. Shah was interviewed by an OIG Special Agent on 3/6/89 as a follow-up to this letter. A memorandum dated 6/14/89 pertaining to this interview, as well as Mr. Shah's letter, were provided to Edmund Fry - Director, Division of Manufacturing. On or about 6/22/89, the allegations of misconduct on the part of Par Pharmaceutical were forwarded to me for investigation as part of my ongoing inspection.

The allegations related by Mr. Shah in his letter to Dr. Seife and in his interview with the DHHS/OIG Agent pertained to the manipulation of Abbreviated New Drug Application (ANDA) data, bioequivalency studies, manufacturing sites and stability studies in regard to three

prescription drug products manufactured by Par Pharmaceutical, Inc.

Initial investigation of Mr. Shah's allegations entailed interviews of current and former employees. The information obtained in these interviews, combined with information developed independently by the inspectional team, corroborated most of Mr. Shah's allegations pertaining to the three products.

As investigational efforts at Par Pharmaceutical progressed, additional evidence of misconduct involving numerous products which had not been the subject of Mr. Shah's allegations was developed.

On 8/15/89, Mr. Shah consented to an interview by members of the inspectional team at the office of his attorney. At this time, Mr. Shah confirmed and supplemented the information for the three products which were the subject of his prior letter to Dr. Seife and discussed in his prior interview with the DHHS/OIG Agent. During this interview, Mr. Shah discussed seven additional products which were associated with various irregularities. Several of these products had been known by the inspectional team to be associated with irregularities previous to the 8/15/89 interview with Mr. Shah. Mr. Shah's knowledge of irregularities, in many instances, was based on his involvement in the subject activity. The information obtained from Mr. Shah during the 8/15/89 interview supplemented previously known information, and provided leads for investigation of additional issues. Reference is made to the Memorandum of Interview with Satish Shah dated 8/15/89.

Information provided by Mr. Shah, combined with information developed from other sources, contributed to the evidence of misconduct on the part of individuals associated with Par Pharmaceutical, Inc.

In a letter dated 8/24/89, FDA Chief Counsel Thomas Scarlett referred a proposal for criminal prosecution of Par Pharmaceutical, Inc. and various individuals associated with that firm to the Department of Justice.

Very truly yours,



Gary Tunkavige