



DEPARTMENT OF HEALTH & HUMAN SERVICES

FEB 28 2003

Food and Drug Administration
Rockville MD 20857

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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

Re: Satish R. Shah; Docket No. 93N-0349

Dear Mr. Ash:

This letter is in response to your letters to the Chief Counsel of the Food and Drug Administration (FDA) dated November 8, 2002, and September 23, 2002, as well as your letter to Kevin M. Fain, Associate Chief Counsel for Drugs, FDA, dated February 3, 2003. Your letters to the Chief Counsel included copies of a letter dated July 18, 2001, that was never received by FDA.¹ In these letters you request that the Agency reconsider the matter of Satish Shah's debarment.

As you are aware, on August 1, 1994, FDA permanently debarred Mr. Shah from providing services in any capacity to a person that has an approved or pending drug product application. See 59 FR 38983. FDA's administrative action of debarment followed Mr. Shah's criminal conviction in 1993 for conspiracy and making a false statement to a Federal agency while employed by Par Pharmaceuticals ("Par").

In 1997, Mr. Shah applied to FDA for special termination of his debarment. FDA denied this application by letter dated March 17, 1999, because Mr. Shah had failed to show substantial assistance in the investigation or prosecution of certain offenses. On May 24, 1999, Mr. Shah petitioned the United States Court of Appeals for the District of Columbia Circuit to vacate or set aside FDA's denial of his application for special termination. In an order filed November 19, 1999, the court denied Mr. Shah's petition for review. The court found that FDA's denial of Mr. Shah's application was reasoned and supported by the record, and therefore, was not arbitrary and capricious.

¹ The letter dated July 18, 2001, had no street address, and the addressee was listed as "Dr. Benjamin Sweatz," presumably intended for Dr. Bernard A. Schwetz, Acting Principal Deputy Commissioner at the time.

93N-0349

ANS 2

You now wish the agency to consider this matter yet again. The only new evidence you present is a letter dated November 8, 2001, from Christopher B. Mead.²

Mr. Mead's letter, however, does not support a finding of substantial assistance. In fact, Mr. Mead corroborates earlier statements by Lawrence McDade, Mr. Mead's former colleague at the Department of Justice (DOJ). *See* Letter from Lawrence McDade, Deputy Director, Office of Consumer Litigation, DOJ, to David Read, Regulatory Policy Staff, Center for Drug Evaluation and Research, FDA, dated May 28, 1998. As we explained in our March 17, 1999, denial of Mr. Shah's initial application, although Mr. Shah provided some truthful information about illegal Par activities, he also provided false information to DOJ and was involved in a scheme to extort funds in exchange for not providing information to DOJ. Mr. Mead reaffirms these failures by stating that Mr. Shah "ruined his value as witness for the government" by these extortion attempts and "did not volunteer information to FDA, or our office, about all of the ANDAs he helped to falsify." *See* Letter from Chris Mead to Greg Welsh, First Assistant U.S. Attorney, dated November 8, 2001.

You also raise the cases of former Par employees whose debarments were terminated by FDA. These cases, in fact, provide a helpful context for Mr. Shah's reinstatement request and further support FDA's position against the termination of his debarment. Unlike Mr. Shah, these two individuals presented clear and unqualified evidence of substantial assistance. In fact, both individuals relied on statements by Mr. Mead to show that they provided substantial assistance in the investigations and prosecutions of certain offenses. The statements by Mr. Mead regarding substantial assistance in both those cases were unqualified. These included, but were not limited to, statements to the court at the time of sentencing. Furthermore, as evidence of the substantial assistance of these two individuals, Mr. Mead points to their assistance in the prosecution of Mr. Shah, among others. Finally, we note that the convictions of these two individuals were not

² Mr. Mead is now a private attorney, but as he explains in his letter, he represented the government in the trial against Mr. Shah. In your letter dated September 23, 2002, you also refer to the debarment terminations of "several individuals" who, like Mr. Shah, were employed by Par. We note that the debarments of only two former Par employees have been terminated, and these debarment terminations are matters of public record. *See* 62 FR 11212 (March 11, 1997). We further note that these terminations preceded the submission of Mr. Shah's initial application for termination in April 1997, yet Mr. Shah failed to raise the issue of these debarment terminations in that application. In fact, our records indicate that Mr. Shah knew about these terminations prior to submitting his initial application for termination. The debarment of a former employee of Quad Pharmaceutical (a Par subsidiary) has also been terminated. *See* 63 FR 32013 (June 11, 1998).

Docket No. 93N-0349

for making false statements to the FDA (as was the conviction of Mr. Shah), but for false statements made to a grand jury about the extent of their knowledge of the underlying crimes committed by Mr. Shah and others.³

After evaluating your recent correspondence and submission, the Agency continues to find that Mr. Shah failed to provide substantial assistance in the investigations or prosecutions of generic drug offenses. Therefore, the Agency denies your request for special termination of Mr. Shah's debarment.

Sincerely yours,

A handwritten signature in black ink, consisting of a large, stylized loop followed by a long, horizontal, slightly wavy line extending to the right.

John M. Taylor, III
Associate Commissioner
for Regulatory Affairs

³ In your letter to Mr. Fain you describe the recent employment history of Mr. Shah. This history, however, is irrelevant in determining whether or not Mr. Shah provided "substantial assistance" to the government in the investigations or prosecution of the underlying criminal case. Furthermore, your suggestion that FDA consider a "probationary [reinstatement] period" for Mr. Shah is not authorized by the relevant statutory provisions for debarment.