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Philip H. Armstrong, Esq.
Heeney, **Armstrong &** Heeney
Attorneys at Law
Adams Law Center
29 Wood Lane
Rockville, MD 20850

Re: David Brancato; Docket No. 92N-04 16

Dear Mr. Armstrong:

This is in response to your letter of September 17, 2001, addressed to Richard Schwartzbard. Mr. Schwartzbard **left** the Agency in September 1999. I apologize for the fact that you have been frustrated in your efforts in reaching us on this matter.

This case involves the debarment of David Brancato. As you know, Mr. Brancato is a former employee of the Food and Drug Administration. While working here, he was a review chemist in the Division of Generic Drugs. As the result of an unprecedented investigation of the generic drug industry, Mr. Brancato was found to have accepted illegal gratuities. He received approximately \$16,000, in cash, paid on several occasions between 1986 and 1988. He pled guilty and was convicted and sentenced in 1990 on the basis of three such occasions, for amounts totaling \$4,300.

As a result of this conviction, FDA initiated debarment proceedings against Mr. Brancato in a letter dated December 9, 1992. Mr. Brancato contested this debarment proceeding. In a *Federal Register* notice dated **January 6, 1994** (59 FR 75 I) FDA addressed the many arguments Mr. Brancato made in opposition to the proposed debarment, denied Mr. Brancato's request for a hearing, and permanently debarred him **from** providing services in any capacity to a person with an approved or pending drug product application. On May 22, 1998, on Mr. Brancato's behalf, you submitted a petition for termination of debarment.

As the **office** chiefly responsible for *the* administration within the Agency of the debarment provisions of the Federal Food, Drug, and Cosmetic Act, it is part of our job to prioritize any proposed or requested actions, taking into account such things **as** all the other responsibilities of our office (of which debarment is a very **small** part) and the Agency, the resources needed to process the action (the formal review of a petition for termination of debarment involves a fairly substantial commitment of resources), as well as the likelihood of a **particular** action resulting in a change of status. With respect to the latter, if upon initial evaluation a change of status is deemed likely, a proposed or requested action would be given a higher priority over an action for which a change of status is deemed less likely or, as in some cases, extremely remote. The

92N-0416

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Docket No. 92N-0416

formal review of Mr. **Brancato's** petition for termination has not been accorded a high priority. Nevertheless, I will attempt to expedite its processing.

Sincerely yours,

A handwritten signature in black ink, appearing to read "D. T. Read". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

David T. Read
Director, Division of Regulatory Policy I (HFD-7)
Office of Regulatory Policy
Center for Drug Evaluation and Research

cc: HFA-305 (Docket No. 92N-04 16)