

March 23, 2000

Dockets Management Branch
HFA 305
Rm #1061
5630 Fishers Lane
Rockville, MD 20855

8667 '00 MAR 29 A9:42

Reference: Docket No. 93N-0462

Dear Sir or Madam:

I am writing to you to seek further clarification of your letter dated April 5, 1999. Despite my efforts, I have not been able to secure suitable employment due to the conditions imposed by my debarment. I have recently investigated the possibility of seeking employment with a contract laboratory that does not have any New Drug Applications (NDAs) or Abbreviated New Drug Applications (ANDAs) of its own, but has pharmaceutical clients that do submit NDAs and ANDAs.

In your April 5, 1999 letter, you noted that under the terms of my debarment, I am prohibited *from providing services in any capacity to a person, including a company that has an approved or pending drug product application.* Accordingly, you suggested that it is possible for me to work for 1) a pharmaceutical company producing OTC products, 2) a company producing vitamins and herbal products, or 3) a company producing cosmetics products, as long as the company with which I seek employment does not have an approved or pending drug product application, such as NDA or an ANDA. Conversely, you stated that I "may not work for a company if it has an approved or pending drug product application regardless of what your job would be or even if the division you would work for does not submit such applications." To underscore this point you noted that it would have to be possible for me to work for a company that produces vitamin supplements, but that I would have to leave if that company was later purchased by a pharmaceutical company that has approved or pending drug product applications. Thus, the dispositive factor in your analysis appears to be whether the company with which I seek employment "has an approved or pending drug product application". If it does, then I cannot work for that company. If it does not, then I can work for that company, at least until that company submits a drug product application of its own or is purchased by a pharmaceutical company that does.

Applying your analysis to my current situation, it appears that I can work for a contract laboratory so long as that company does not have an approved or pending drug product application. In other words, the debarment prohibits me from working for a "company that has an approved or pending application," it does not extend to any company that does not have an approved or pending drug product application – in my case, a contract laboratory that has no such applications of its own.

Please let me know if this analysis is correct. If this analysis is incorrect, please provide me with an explanation of the agency's position, with relevant citations to the debarment language.

I would appreciate your prompt attention to this matter as it is of some urgency to me personally.

Thank you in advance for your consideration.

Sincerely yours,


Abu Quamruzzaman
178-10 Wexford Terr., Apt 5C
Jamaica, NY 11432
Tel #: (718) 526-0563
Fax #: (718) 526-3063

cc: Mr. David Read

93N-0462

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