



DEPARTMENT OF HEALTH & HUMAN SERVICES

MAR 18 2003

Food and Drug Administration  
Rockville MD 20857

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

3761 3 12 2003

Delfina Hernandez  
7858 Wexford Avenue  
Whittier, CA 90606

Re: Docket No. 00N-1528

Dear Ms. Hernandez:

Our purpose in writing is to let you know that the Food and Drug Administration does not intend to pursue your debarment under section 306(b)(2) of the Federal Food, Drug, and Cosmetic Act.

As you are now aware, the agency attempted to serve you with a letter dated May 6, 2002, proposing to debar you for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. We did not receive a response to the letter and therefore issued an order in the *Federal Register* of November 6, 2002, debarring you for 5 years (67 FR 67629). In a letter dated November 25, 2002, you informed us that you had not received the letter proposing to debar you. We then learned that the May 6 letter was sent to the wrong address and apparently signed for by a different person with the same name as yours. Because of the problems related to the service of the proposal, we published a notice in the *Federal Register* of January 16, 2003, rescinding the November 6 debarment order (68 FR 2339). Informally, however, we let you know that we still had to consider whether to pursue a debarment action.

After carefully considering the facts of your case, we have decided not to pursue debarment proceedings against you for your October 22, 1997 conviction.

Sincerely yours,

Janet Woodcock, M.D.  
Director  
Center for Drug Evaluation and Research

00N-1528

LET 3