DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

MAY 27 1976

Honorable Gaylord Nelson
Chairman, Subcommittee on Monopoly
Select Committee on Small Business
United States Senate
Washington, D.C. 20510

Dear Senator Nelson:

I wish to correct two errors in our testimony before your subcommittee on April 28, 1976.

In discussing scientific exhibits, I referred to the written programs for scientific exhibits at two recent meetings of the American Academy of Family Practice and the American College of Physicians and pointed out in each a listed exhibit on prazosin hydrochloride, an antihypertensive drug. I indicated that the program did not note that the physician-exhibitor was a full-time employee of the manufacturer which had developed the drug. In addition, I said that prazosin hydrochloride had not been approved for marketing at the time of either meeting, and that regulations did not permit pharmaceutical manufacturers to promote drugs prior to their approval for marketing. When asked about this by Mr. Gordon, I said that "this type of thing is a violation of the current regulations on drug labeling."

I have subsequently learned that the manufacturer of prazosin hydrochloride (Pfizer) prepared the exhibits in anticipation of the approval of the drug but, when this approval was delayed, did not in fact display them at either meeting although they remained listed in the printed programs. I did not know this at the time of my testimony, and I regret that we did not check this point before preparing our testimony. Thus, no violation of FDA regulations occurred, and I extend my apologies to you and to Pfizer, Inc. for suggesting otherwise.

Let me add, however, that this type of presentation remains a valid illustration of our concerns regarding the promotional aspects of scientific exhibits. As I testified, it is FDA's view, which we intend to incorporate into proposed regulations, that a scientific exhibit on a drug must be prepared independently of a drug manufacturer's control if it is to be exempt from drug labeling requirements. I believe the