

rent with the work of his Division. As a result of his personnel untiring efforts, the Division has not been in a backlog position on referred assignments.

The above summary of Dr. McCleery's accomplishments through 1966 was largely instrumental in his being granted the FDA Award of Merit in 1967. Beginning early in 1967, his personal participation and direction of the Division of Medical Advertising led to even greater demonstration of his effectiveness in bringing advertising and promotions of prescription drugs into compliance with the requirements of the Act.

Evidence of his success in accomplishing the mission of his Division is represented specifically in the following examples. Following the introduction of the "remedial letter" concept which corrects faulty advertising of prescription drugs, the efforts of Dr. McCleery in the areas of preparation of critiques, in participating in meetings held between the Commissioner, FDA officials and representatives of drug firms and in the development of detailed drafts of "Dear Doctor" letters, have resulted in the issuance of 20 such letters by manufacturers to all practicing physicians in the United States.

Conservatively, a total of over 4 million remedial letters have been mailed to physicians as a result of action initiated by Dr. McCleery. Copies of the 20 letters are attached to show the nature and extent of the corrections involved.

While some of the "remedial letters" involve corrections of monographs in the Physicians' Desk Reference (a comprehensive reference book used by physicians), Dr. McCleery directed the activities of his group in analyzing monographs in the book and initiating various other actions leading to correction such as issuing letter and telephone calls to firms requesting correction, participating in conferences with firms on specific problems, etc.

During the period January 1, 1967 to date over 150 corrective actions have been initiated by Dr. McCleery. In addition to "Dear Doctor" remedial letters, there have been about 93 meetings with industry representatives, 35 requests made to firms for corrective actions, one seizure (Indoklon), four prosecutions, and support given in 33 cases. Approximately 245 monographs in the Physicians' Desk Reference, and 138 prescription drug advertisements were reviewed and assessed as forerunners to remedial consideration.

In the support of cases forwarded for prosecution consideration, Dr. McCleery personally participated in citation hearings as well as in one judicial proceeding. In the latter, Dr. McCleery's testimony was considered to be largely instrumental in the success of the Government in obtaining a nolo contendere plea from the defendant and a resultant fine.

In addition to matters involving regulatory attention, Dr. McCleery provided written advice in voluntarily submitted promotional materials or other inquiries in over 80 instances.

On May 23, 1967, proposed revisions in the advertising regulations were published in the *Federal Register*. Dr. McCleery's participation in providing the basis for policy and language of those proposed regulations was a contribution of paramount importance.

Dr. McCleery's contributions to the mission of the Agency and the Department have been broadly recognized in the public press. A selection of copies of accounts in the press are attached to show the public impact of the efforts of Dr. McCleery.

The Food and Drug Administration's responsibility in the area of prescription drug advertising is a recent one. Since the passage of these regulations in 1962, Dr. McCleery has been the individual most responsible for stimulating the efforts of the Bureau of Medicine in the implementation of these regulations.

Senator NELSON. I assume you have no objection to being interrupted by questions from time to time?

Dr. McCLEERY. No, sir.

Senator NELSON. Please, go ahead, Doctor.