

been well received by physicians and pharmacists, and before the year ends we will be reprinting it for the third time.

APhA is still hopeful that the need for information on prescription legend drugs can be met promptly through the voluntary, cooperative efforts of the professions concerned and the pharmaceutical industry. We can assure the manufacturers and FDA that any soundly conceived effort will have our assistance.

In conclusion, we recognize that the health and life of people today increasingly depend upon drugs. For 115 years, the American Pharmaceutical Association has supported constructive steps—and initiated several—to improve the Nation's drug supply and, Mr. Gordon, as a matter of fact, just late this month our Academy of Pharmaceutical Sciences is sponsoring a program here in Washington, and the entire symposium is devoted to the subject of development of safer and more effective drugs. I would be glad to supply the committee copies of the program and abstracts for its files.

Mr. GORDON. Thank you very much. We do appreciate that.

Dr. APPLE. As I have indicated, we have supported constructive steps and initiated several, to improve the Nation's drug supply and the professional services involved in making drugs available to patients. This will continue to be one of our major objectives. Thank you.

(The attachments to Dr. Apple's statement follow:)

AMERICAN PHARMACEUTICAL ASSOCIATION,
Washington, D.C., September 20, 1960.

Re notice of proposal to amend labeling requirements (21 CFR 1, 130) dated July 18, 1960; appearing in Federal Register July 22, 1960 (25 F.R. 6985).

HEARING CLERK,
Department of Health, Education, and Welfare,
Washington, D.C.

DEAR SIR: The following statement is submitted in response to the opportunity afforded by the Commissioner of Food & Drugs for interested persons to express their views on the proposed labeling regulations.

Realizing that others will comment upon those phases of the proposed regulations of immediate interest to them, our remarks will be confined to matters directly affecting the American Pharmaceutical Association, the profession of pharmacy, and the efforts of pharmacists to discharge their professional responsibilities as drug and therapeutic device consultants to prescribers and as community custodians of drugs and such devices.

We are in complete agreement with the intent of the proposed amendments which are advanced in the interest of providing more complete information relevant to the professional use of any article bearing a prescription legend or otherwise limited to order of particular practitioners. Our Association has repeatedly advocated increased disclosure of product information in order that pharmacists may serve more proficiently in their capacity as consultants to prescribers of all prescription legend articles. To meet the demand for reliable information, individual pharmacists have, among other things, attempted to maintain product reference libraries and to develop extensive product reference brochure files within pharmacies. At their own expense, in order to be of service to prescribers, some pharmacists have even attempted to publish and distribute product information gleaned from a variety of reference sources.

For the guidance of every practitioner licensed by law to administer prescription legend articles, complete product information concerning use, dosage, cautions, and contraindications should be readily available. For these reasons, we believe in the principle, embodied in the proposed regulations; that is, of disseminating additional product information. However, we seriously question the practicality of certain aspects of the mechanism proposed for achieving our mutual purpose—the availability of complete product information for prescribers.