9. It would be expected that accredited institutions engaged in preparing persons to practice any of the professions in the health science group would also be supplied with copies of the "official brochure."

A unique feature of this proposal is the added benefit of having the "official brochure" information locally available to the practitioner through every pharmacy although supplies of the drug may not be at hand. Furthermore, the "official brochure" information could thereby be available to the practitioner even before the manufacturer begins the initial marketing and distribution of his product.

If, as we trust, our suggestion meets with favor, we will be pleased to cooperate with the Food and Drug Administration, the United States Pharmacopeia, the National Formulary and the pharmaceutical industry in order to make this essential distribution of information on each product subject to the regulations effective.

SECTION 1.106(b)(4)

This proposed regulation would require that *full* information accompany all labeling "that furnishes or purports to furnish information for use or which prescribes, recommends, or suggests a dosage" for use. Some modification is needed. It is our belief that journal advertisements and promotional literature sent directly to professional personnel should be clearly differentiated from "labeling." Because of inclusiveness usually associated with the term "labeling," we fear that without modification unreasonably long, involved, and extensive advertising copy could be required for otherwise simple advertisements.

Under the proposed regulation, serious questions arise about possible significant curtailment in the degree of advertising in professional and scientific journals. We believe such advertising curtailment will adversely affect the continued publication of professional journals, the principle purpose of which is the dissemination of scientific, technical, and research information irrespective of products advertised. The sale of advertising space in professional journals helps in large measure to defray the costs of these essential publications.

It is our opinion that the purposes intended by the proposed regulations would be achieved through an arrangement by which all advertisements would contain a precautionary statement referring the reader to the "official brochure" for additional necessary information and indicating its availability from (a) any pharmacy, (b) the non-governmental, non-profit agency approved for that purpose by the Food and Drug Administration, the United States Pharmacopeia Revision Committee, and the Committee on National Formulary, or (c) the manufacturer of the drug. By employing the mechanism we have just suggested, the purposes of the proposed regulations would be achieved without placing unreasonable burdens upon advertising copy and interfering with the publication of essential professional journals and the dissemination of scientific information.

SECTION 1.106 (c)(3) AND (d)(3)

Because our comments, opinions, and suggestions pertaining to these sections parallel those stated in relation to Section 1.106(b)(3), in the interest of conserving your time, we will not repeat them.

SECTION 1.106 (c)(4) AND (d)(4)

Because our comments, opinions, and suggestions pertaining to these sections parallel those stated in relation to Section 1.106(b)(4), in the interest of conserving your time, we will not repeat them.

The American Pharmaceutical Association, its facilities, and its entire personnel, are ready to assist the Food and Drug Administration in effecting the objectives we have outlined. We also respectfully request that our Association be given the opportunity to participate in any future hearings which may be held to resolve differences of opinion over the proposed regulations which have been expressed by interested persons.

Sincerely,

WILLIAM S. APPLE, *Secretary.*