field. It will require a great deal of research in the laboratory and in the clinic. Through our own activities, those of the Public Health Service, hopefully those of the Veterans' Administration, with whom discussions are also being held, and Secretary Gardner's task force on prescription drugs, we are now embarked on such investigations.

TRUTHFUL INFORMATION

After the research, after the product comes off the production line, the sponsor must sell it. Most promotion of prescription drugs is directed to the prescriber, not the patient. Honest, fair promotion must be fully realized whether it is through circulars, detail men, magazine ads, TV or whatever medium is employed. The recent history of the regulation of prescription drug advertising is set forth in one of our newest FDA publications—"Compendium of Medical Advertising"—which I offer to the committee at this time.

Senator NELSON. Thank you.

Dr. GODDARD. I would also like to present for the committee's information a copy of our proposed advertising regulations, which reflect a number of items published in the "Compendium." We have extended to September 1 the period for comment on the proposed regulations; after that date, we will review all comments and objections, and then issue the best regulation possible. We solicit a constructive response from the pharmaceutical industry.

The promotion of a drug to physicians, Senator Nelson, is based upon the approved claims that may be made for the product. If a claim or an indication for use does not appear in the final printed labeling—the package insert—then it cannot appear in any of the promotion for the drug. The package insert, then, is a guide for prescription drug advertising and promotion. The insert represents the clinical data supporting the drug, it reflects the ability of the sponsor to produce it according to exacting specifications, and it is the authentic guide to the prescribing physician, short of a complete review of all the NDA files—an impossible task for the busy practicing physician to perform, even if the files were available to him.

Senator NELSON. We will print the proposed advertising regulations. What is the previous bulletin?

Dr. GODDARD. It is called "Compendium of Medical Advertising."

Senator NELSON. What does that mean? Is it a collection your agency has made of the different types of advertising?

Dr. GODDARD. The contents—I might read a portion of it to give you an idea of the coverage:

The "Pharmaceutical Manufacturers Association Principles"; excerpts from the Federal Food, Drug and Cosmetic Act; general regulations on drug advertising; questions on prescription drug advertising; answers on prescription drug advertising; memorandum of understanding between PMA, FDA, and industry——

Senator NELSON. Who published this?

Dr. GODDARD. We did.

Senator NELSON. I will make that available in the committee files, but it will not be printed in the record.

Dr. GODDARD. It is available through GPO.

Senator NELSON. But the listing of your advertising regulations, will be printed in the record.