e. By revising paragraph (b) (5) to read as follows:

(5) All labeling, except labels and cartons, bearing any information for use of the drug, or information relating to side effects, contraindications, safety, or effectiveness of the drug also bears the date when the labeling was placed into use and the same information concerning the ingredients of the drug as appears on the label and labeling on or within the package from which the drug is to be dispensed.

f. By revising paragraph (c) (3), (4), and (5) to be similar in effect to paragraph (b) (3), (4), and (5) as proposed above.

Any interested person may, within 60 days from the date of publication of this Notice in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington, D.C. 20201, written comments, preferably in quintuplicate, on this proposal. Comments may be accompanied by a memorandum or brief in support thereof.

Dated: May 17, 1967.

JAMES L. GODDARD,
Commissioner of Food and Drugs.

Senator NELSON. Does the law require a package insert?

Dr. GODDARD. The regulations and the law both require that a package insert be available. However, the Secretary of Health, Education, and Welfare may exempt the company or the industry from this requirement.

Senator NELSON. But the regulations now require it, and as I understood your testimony this morning, it costs the industry about $6 million a year?

Dr. GODDARD. I am told that this was their estimate when they were discussing with my predecessor the possibility and their desire to publish a compendium in lieu of the package insert. It would simplify their entire packaging problem; individual cartons would not be required.

Now, I think that is fine. More important, however, is the desire to get accurate, reliable information to all physicians, and this is not occurring today. I think it is extremely important. I am mystified as to why the industry will not pick up the ball and exert some leadership in this field and say, yes, we do want good information to get to the practicing physician; we do want them to know about the drugs that are available to them to be used, and we therefore on our own initiative, have caused this compendium to be published. I was hopeful that by now, we could say we are well down the road, but I still have not gotten any response from the industry on this issue.

Senator NELSON. As you know, the idea of a compendium has been widely supported by medical educators and practicing physicians. When the PMA appears before the committee, we will explore this in some detail to find out their viewpoint and to determine whether or not the industry is prepared to support it.

Dr. GODDARD. I think we really have a unique opportunity. The National Academy of Sciences' National Research Council review of the 2,000 drugs still in the marketplace that were marketed between 1938 and 1962 will provide a basis for updating the claims of efficacy of all of these drugs. This means, in effect, that we will have a sound basis for a good compendium as far as the therapeutic claims are concerned. It would seem to me with relatively little additional work, we could cause a truly important book on therapy to come into existence. It should be something that is done, hopefully, with private venture capital, and would not require us to come before Congress and say we