ceived by the pharmacist and thrown away after he has a file of them, you see. The physician can call the pharmacy and get information on a drug. And some of them do this. But by and large they do not see them. So the system does not accomplish what it set out to accomplish at all.

Senator NELSON. And do I understand that it is your position that if an acceptable compendium were adopted and published, you would be willing to remove the requirement that an insert be used except for biologicals?

Dr. GODDARD. That is correct.

Senator NELSON. Is the insert required by law or is it the result of an administrative ruling?

Dr. GODDARD. Those are the conditions for the approval of a new drug. Yes, sir; statutory.

Senator NELSON. By statute or by a ruling of the FDA?

Dr. GODDARD. Statute.

Senator NELSON. So you would have to change the law respecting the insert——

Dr. GODDARD. Mr. Goodrich, do you want to comment on that?

Mr. GOODRICH. We have authority to exempt a prescription drug from the requirement of that detailed label where it is not necessary for the protection of the public health. We could do so if we had an alternative compendium available to the physician. Then it would not be necessary to carry that information in the packages.

Senator NELSON. Go ahead, Doctor. I have some more questions, but I think you cover some of them in the statement.

Dr. GODDARD. Let me just skip to the third page of the statement.

These label requirements are obviously most essential for proper usage and in order to monitor recalls. The concept of a compendium should in no way abrogate such label information.

Additionally, the regulations require that—

> Labeling on or within the package from which the drug is to be dispensed bears adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented; and
>
> If the article is subject to—the new drug, antibotic and insulin provisions—of the Act, the labeling bearing such information in the labeling authorized by the approved new-drug application or required as a condition for the certification or the exemption from certification requirements applicable to preparations of insulin or antibiotic drugs: Provided, however, That the information required by (the above paragraph) may be omitted from the dispensing package if, but only if, the article is a drug for which directions, hazards, warnings, and use information are commonly known to practitioners licensed by law to administer the drug.

The information required by this regulation is appropriate and useful. I wouldn't believe that anyone would say that the physician relies on promotional literature in medical journals and publications such as the PDR. As you know, we have instituted several regulatory actions against drugs because of their advertisements, and we are presently requesting four drug firms to issue "Dear Doctor" remedial letters in order to correct PDR monographs.