first 6 months of 1967 vis-a-vis the first 6 months of 1968. And, of course, you have and are presenting the statistics of what happened the last 3 months of 1968 versus the last 3 months of 1967 when there was a dramatic increase in the use of the capsule form as contrasted with the injectable which went down.

The point, it seems to me, still is that it is widely misprescribed for nonindicated uses, and every conceivable effort has been made to assure that it will not be used for nonindicated uses. In the wording of the package insert, FDA, including Dr. Goddard and yourself, takes the position of the use of the drug should be limited to hospitals. The committee has had a number of distinguished experts who took that position. Yet FDA has not been prepared to confine it to hospital use. If it were administered only in hospitals, there is no question but that there would be much more significant control, and a more significant factor in educating the doctor about the precautions of this drug.

But since the FDA isn't prepared to do that, and since it continues to be prescribed widely for nonindicated cases, it seems to me that FDA ought to be doing every thing else within its power to stop it. And it seems to me this use of the reminder ad with the fine print attached still promotes the drug for nonindicated cases. You really ought to consider whether this type of ad—even with the fine print—can be justified.

(The information previously referred to follows:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington, D.C., April 25, 1968.

DR. AUSTIN SMITH,
Parke Davis & Co.,
Detroit, Mich.

DEAR DR. SMITH: Under the existing regulations pertaining to advertisements for prescription drugs, producer sponsored advertisements have been permitted an exemption from the requirement of providing a statement of information in brief summary relating to side effects, contraindications and effectiveness if an advertisement contains no information as to indications or dosage recommendations. In the case of Chloromycetin, we are aware of your use of so-called reminder advertisements for that product which contain no "Brief Summary."

Taking into account the recent disclosures regarding the broad use of chloramphenicol and the urgent need to bring warning information regarding the drug to the attention of physicians by every means feasible, I am asking that your firm immediately discontinue using so-called reminder advertisements and reminder labeling in the promotion of chloramphenicol, whether or not any such promotion is entitled to exemption under the reminder advertising or reminder labeling provisions of the existing regulations.

While we believe that we could require prior approval of chloramphenicol advertisements under the terms of section 1.105(j) of the regulations, I would prefer not to consider proceeding under that concept at this time.

Will you please let me have your comments as soon as possible concerning your willingness to meet the above request.

Sincerely yours,

JAMES L. GODDARD, M.D.,
Commissioner of Food and Drugs.