Bengert is away for several weeks, but Silliman, of Norwich, said that the notice of hearing came after failure to reach agreement following a number of discussions with the FDA. According to him, news of the hearing was first published in Werble's "Pink Sheet," and he says Werble appears to have a good "pipeline" into the FDA. He added that the FDA does publish notices of hearings to be held. (I am asking the Legal Department to run this letter down.)

Going on with the Norwich case, the hearing technically is still in progress. All testimony on both sides was completed before the Examiner months ago. Briefs were filed in April, with no decision yet. Anticipating an adverse decision, Norwich plans an appeal to the courts. The product is still on the market and available to the physician. It has not been promoted in any way since the notice of hearing, and this was an agreement which Norwich made with the FDA. Naturally, sales have dropped drastically, but the product is still being prescribed by these physicians who have found it a very valuable drug. Norwich made its own publicity release to the public and to the stockholders after the notice of hearing had been received.

In the McNeil case, I know nothing more than what I have read in the "Pink Sheet," which stated McNeil sent out letters to MD's and drug wholesalers, setting in motion a "voluntary" recall program because of jaundice, hepatitis and liver damage reports. As far as we can tell, McNeil, after conferences with Food and Drug in which a hearing was probably threatened, took this action rather than go through a hearing.

In the White Laboratories' Entecqual case, the Government seized the drug on the basis that representations in promotional material for MD's differed materially from the labeling claims permitted by the effective New Drug Application—in other words, false and misleading labeling. Apparently this followed a failure to agree with the FDA on appropriate disclosure of side effects and also an appropriate dosage exclusion limitation for children—these negotiations going on while the NDA was in effect. Other actions such as multiple seizures or a suspension of the NDA were being considered by the FDA before White withdrew the drug from the market.

This background is furnished in view of the request that I provide, in advance, a company statement in the event of government action. I told Art Boschen this morning that in view of our lawyers' advise on advance release didn't seem necessary, but after tying the above factors together I am making the following suggestions:

In the event of rumor that the FDA is about to suspend the NDA

"We have not received notice of any such hearing, as provided in the law. We are not in a position to comment until we do—if we do."

In the event of receipt of notice of hearing

"The Wm. S. Merrell Company, Division of Richardson-Merrell Inc., has today received a notice of a hearing from the Federal Food and Drug Administration to determine whether its effective New Drug Application on MER/29 should be suspended. In our opinion such suspension would be unwarranted and unnecessary, and we believe that evidence presented at the hearing will sustain this position," stated H. R. Marschalk, president of Richardson-Merrell (or Frank Getman, president of The Wm. S. Merrell Company Division).

Let me know your final preference on who makes the announcement.

Admittedly, the letter announcement is extremely brief, but I am proposing it in this form for two reason—the first is that the less said, the better, as long as it adequately covers our position—and secondly, it is hard to give added reasons until we get the notice of hearing, which is similar to a complaint and outlines the reasons why the NDA should be suspended. If it should be a claim we withheld evidence, that would call for one type of statement, whereas if it were based on certain kinds of toxicity, it would call for another.

It seems to me this is as far as we can and should go at the present time, but I will welcome any comments or suggestions.

P.S.—Needless to say, our preparation for the Thursday meeting is going on at full speed.

OCTOBER 26, 1961.

DEAR DOCTOR: The purpose of this letter is to advise you of those cases where MER/29 therapy should be discontinued.

The types of cases where the drug is to be withdrawn more not apparent from the several thousand clinical cases studied during the two-year period prior to