request, Mr. Chairman, to submit a copy of the reply probably within the next week, when it will be going out, for the record.[1]

Senator NELSON. What is the current legal status of tolbutamide?

Mr. HUTT. It is an approved new drug. The question is whether the labeling needs clarification in light of the UGDP studies. This is the controversy in issue at the moment.

Senator NELSON. Has the labeling been changed, or is it just an issue?

Mr. HUTT. We announced a proposed labeling policy and the petition asked us to delay that until we gave consideration to the information that the committee supplied. Our reply will announce the new labeling that will be required in the future.

Mr. GORDON. I read quite a few medical publications, and I notice that announcements of the establishment of these committees, as well as articles attacking the FDA, seem to originate in the Medical Tribune. What kind of a publication is the Medical Tribune?

Dr. EDWARDS. Well, again, I don't know whether it is by coincidence or what, or how these committees get the announcement in the Medical Tribune at the time of the founding. I think that I won't exactly categorize the Medical Tribune any more than a publication which I know is given to all practicing physicians free of charge.

Mr. GORDON. How does this publication subsist?

Dr. EDWARDS. I imagine on the advertising, on the drug advertising.

Mr. GORDON. Do you know whether it is completely dependent on drug advertising?

Dr. EDWARDS. No, I wouldn't have any idea as to that.

Senator NELSON. Please continue.

Dr. EDWARDS. Mr. Chairman, excuse me.

Senator NELSON. Go ahead.

Dr. EDWARDS. Mr. Chairman, I would like, with your permission, to submit for the record beginning at the bottom of my prepared statement at page 5 over to the second paragraph on page 11. This is merely an added thought—or thoughts—on this whole problem of communications and I think it would be sufficient to have it placed in the record.

Senator NELSON. The whole statement will be printed in the record.

Dr. EDWARDS. I would like though, with your permission, to go ahead with page 11, which we conclude, with the present status of drug efficacy study which you have requested.

Senator NELSON. Yes.

Dr. EDWARDS. By July 1 of this year, we will have completed and published in the *Federal Register* our evaluation of all 3,000 drugs which were in the drug efficacy study. During 1971, 142 drugs named in the *Federal Register* announcements as "lacking substantial evidence of effectiveness," and 367 "related" drugs were effectively removed from trade channels 64 by recall.

To date 452 ineffective drugs specifically covered by the publication of 102 final orders in the *Federal Register* are off the market. This has resulted in the removal from the market of 1,473 additional related drugs. Of the 452 ineffective drugs specifically mentioned in the *Fed-*

[1] See Appendix I, p. 8793.