type we have already mentioned, namely, a corrective letter or a corrective advertising program, or whatever other informal means of correcting might be available.

Senator NELSON. Has the Food and Drug Administration made any determination or decision as to what action it will take?

Mr. HUTT. No, sir.

Sentor NELSON. If there were, among other things, a requirement for another "Dear Doctor" letter—since this one was really written as a response to a study—does the FDA assert the right to approve the letter or disapprove it before it is sent?

Mr. HUTT. Yes, we do.

Dr. EDWARDS. Definitely.

Mr. HUTT. We would require that.

Senator NELSON. Then, I take it you would require them to state in full what the study said, rather than excerpts from it?

Mr. HUTT. Most certainly.

Senator NELSON. But the decision as to what action you will take hasn't been made as of yet?

Mr. HUTT. Except a corrective letter will be required.

Senator NELSON. At the minimum.

Mr. HUTT. At the minimum.

(The letter follows:)

ELI LILLY & Co.,
Indianapolis, Ind., May 19, 1972.

DEAR DOCTOR: The Food and Drug Administration has requested that we send you information about Darvon ® (propoxyphene hydrochloride, Lilly) relevant to certain statements in our letter to you of April 17, 1972, which the FDA regards as misleading.

Our letter referred to a recent article in the *New England Journal of Medicine* in which the authors concluded that single doses of aspirin (650 mg.) were superior in analgesic effectiveness to other drugs tested, including single doses of Darvon (65 mg.). The study included only single-entity products.

The FDA regards our April 17 letter as lacking in fair balance and states that our letter suggested that Darvon is more effective than aspirin and at least equivalent to codeine while producing fewer side-effects. The FDA regards none of these suggestions as valid.

Additionally, the Government states that our letter gave undue emphasis to the effectiveness of Darvon in combination with other analgesic drugs and failed to give adequate emphasis to the limitation of effectiveness of Darvon itself. Therefore, the FDA requests we inform you as follows:

1. There is no substantial evidence to demonstrate that 65 mg. of Darvon is more effective than 650 mg. of aspirin (two 5-grain tablets), and the preponderance of evidence indicates that it may be somewhat less effective.

2. The preponderance of evidence indicates that Darvon is somewhat less potent than codeine. The best available evidence is that Darvon is approximately two-thirds as potent as codeine. Furthermore, there is no substantial evidence that, when administered at equianalgesic doses, Darvon produces a lower incidence of side-effects than codeine.

Sincerely yours,

ELI LILLY & Co.

Senator NELSON. The hearings will resume tomorrow at 10 o'clock, and we will hear from Mr. Elmer B. Staats, the Comptroller General.

(Whereupon, at 11:52, the subcommittee adjourned, to reconvene at 10 a.m., on Wednesday, May 10, 1972.)