Just recently, the Food and Drug Administration has changed that policy; and they will accept now an abbreviated New Drug Application. But under an abbreviated New Drug Application, under paragraph 8, a company has to certify that they will conform and shall comply with chapter 133—with part 133 of the good manufacturing practice.

Senator NELSON. Which part is which?

Mr. BARROWS. That is under paragraph 8 of the abbreviated New Drug Application Form No. 356–H.

Senator NELSON. I do not have it before me. What is that requirement?

Mr. BARROWS. The requirement is that the company manufacturing or submitting the abbreviated New Drug Application must submit a certification statment to the effect that they will comply and conform to the good manufacturing practice section of part 133.

Senator NELSON. Is that objectionable?

Mr. BARROWS. Not at all.

Senator NELSON. Then as of now, that item 1, the FDA does not require a New Drug Application for firms manufacturing and distributing meprobamate. It is just abbreviated.

Mr. BARROWS. An abbreviated New Drug Application.

Senator NELSON. Now, is the abbreviated NDA a particularly burdensome discipline to go through?

Mr. BARROWS. No, Mr. Chairman, our Association was the first to suggest to the Food and Drug Administration the vehicle of abbreviated New Drug Application; that was under Commissioner Goddard. At that particular time there was a question with regard to the nitrates, the effectiveness of nitroglycerin.

Senator NELSON. All right. Please proceed.

Mr. BARROWS. Another example of DPSC specifications which is in variance with existing compendial monographs, and which curtails competition is as follows:

FSN 6505–290–0022 for Reserpine tablets, U.S.P. 0.25 mg, which apparently was composed by Ciba for their Serpasil tablets.

The DPSC's specifications state under specific rotation:

"Shall be between —115° and —121° when determined as follows:" The USP has no such requirement.

The British Pharmacopeia under specific rotation states: —113° to —123°.

Several years ago at one of our annual association meetings I criticized Mr. Max Feinberg, Directorate of Medical Material Defense Personnel Support Center, for the unscientific specification his Agency required for dextroamphetamine sulfate with and without amobarbital sustained release Capsules (FSN 6505–526–0393, 6505–526–0394, 6505–754–2486, 6505–754–2507) which stated that each capsule had to contain a specific number of pellets which had no significance to the safety, efficacy, potency or release rate of the medicament.

There is no doubt that this specification was written by Smith,