The Federal agency is requesting unnecessary additional tests as the U.S.P. XVIII under "Identification" requires, and I quote:

> The infrared absorption spectrum of a potassium bromide dispersion of it, about 1 mg. in 200 mg, previously dried at 60° for 3 hours, exhibits maxima only at the same wavelengths as that of a similar preparation of USP meprobamate reference standard.

The USP XVIII does not set a "chloride limit," nor does it require a "residue of ignition test"; both of which have no significance as modern techniques assure that all impurities are eliminated.

Embodied in "S5.8" of the same description under "Pre-Award or Pre-Acceptance Samples" are the duplication of inspection and sampling requirements, as follows, and I quote:

> The approval of these samples will not constitute approval of the sample as meeting the other requirements of this purchase description.

Included in the same "S5.8," and I quote:

> Unless otherwise specified in the contract or purchase order, the supplier is responsible for the performance of all inspection requirements as specified herein.
>
> The government reserves the right to perform any of the inspections set forth in the specification where such inspections are deemed necessary to assure supplies and services conform to prescribed requirements.

This is a typical example of unnecessary duplication of good manufacturing practice surveillance by another Government agency as the FDA requires the following:

A New Drug Application from all firms manufacturing and distributing meprobamate tablets, USP.

Samples of the active ingredients and of the final dosage form have to be submitted to the FDA.

A commitment by each manufacturer to the FDA that they will perform, or will have performed in their behalf, all compendial tests both on the active ingredients and the final dosage form.

The producer has to certify that they will manufacture the product in conformity to the good manufacturing practice section, part 133.

Stability reporting, and updating data pursuant to the NDA is a definite requirement. And routine inspections by the FDA monitors the compliance.

Senator NELSON. Let me ask a question at this point.

On item 1, you say the FDA requires a New Drug Application from all firms manufacturing and distributing meprobamate tablets, USP.

Mr. BARROWS. That is correct.

Senator NELSON. Do you mean an abbreviated NDA?

Mr. BARROWS Well, Senator, this goes back originally to the recommendations of the Kefauver committee at a time when they released under the patent controls of the Carter Wallace Co. They had to release at a certain rate according to the index, the price index at that particular time, to other companies to manufacture. And originally, the firms that went into meprobamate at that particular time had to file a full NDA.