not have an NDA or an ANDA—Abbreviated New Drug Application—for certain products.

Can we conclude that since an NDA or an ANDA will no longer be necessary for many drugs, both the VA and the DOD will have a wider choice of firms to buy from?

Dr. SCHMIDT. We think this would be a reasonable conclusion.

We have for some time felt it necessary to develop a monograph system for prescription drugs in the old drug category, just as we have developed monographs for over-the-counter drugs. Major regulations relating to old drug monographs for perscription drugs are in preparation and will be published as proposals later this year.

The CHAIRMAN. Dr. Schmidt, there is a rollcall on the Senate floor right now, and I will have to get over there. But I do not want to delay you; you only have a little bit left and I have one question I would like to have Mr. Gordon ask you. So I do not want you to have to wait until I return here for the last 2 minutes of your testimony.

Thank you very much for coming.

Dr. SCHMIDT. Thank you, sir.

In anticipation of these regulations about old drug monographs, the FDA will announce in the Federal Register that certain well-established prescription drugs shown to be safe and effective by the drug efficacy study and which do not have bioequivalence or special manufacturing problems will, in the future, be considered as old drugs. This is the point that Mr. Hutt just spoke to.

For these products, an approved New Drug Application is not essential to assure the quality of the product. They may be market without preclearance by FDA, providing they do meet certain conditions. Some have suggested that this policy would result in less effective FDA surveillance over these products, but I assure you that this is a mistaken assumption.

To the contrary, our regulations will impose strict conditions for the marketing of these old drugs. All such products appearing on the market must be listed with the FDA under the Drug Listing Act, and this listing will trigger appropriate plant inspections.

Further, all such products must comply with compendial standards and be produced in conformity with current good manufacturing practices, enforcement mechanisms to assure compliance are in operation.

I would emphasize also that this policy will *not* apply to any drug with a bioequivalence requirement or special manufacturing problem. Manufacturers of such drugs will be required to obtain premarketing clearance through the submission of an abbreviated NDA. The very purpose of the policy is to refocus FDA's use of the abbreviated NDA toward those drugs for which premarketing clearance is necessary for valid scientific reasons. As I have emphasized previously, strict enforcement of this requirement is an essential feature of the new policy. All of these quality assurance activities apply to all drugs whether bought by the individual patient or by the Federal Government.

The Government-wide quality assurance program for medical products is a high priority matter within FDA. We attach great importance to the responsibility for developing and implementing an