preclearance through the submission of an abbreviated NDA. The very purpose of the policy is to refocus the FDA's use of the abbreviated NDA toward those drugs for which marketing preclearance is necessary for valid scientific reasons. And, as I have emphasized previously, strict enforcement of this requirement is an essential feature of the new policy.

All of these quality assurances activities apply to all drugs whether bought by the individual patient or the Federal Government.

CONCLUSION

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 efficient and effective national and Government-wide Program within the Agency. A successful program necessitates that an appropriate portion of current resources which identified with quality assurance activities on drugs and biologics in the purchasing agencies be transferred to FDA in a timely fashion.

The Food and Drug Administration has received fine cooperation from DOD, VA, and PHS. We are confident that we can count on their continued cooperation as we move into the implementation stages of the plan. For these reasons, we anticipate no significant problems in completing the plan on the projected dates we have targeted.