be listed with the FDA under the Drug Listing Act, and this listing will trigger appropriate plant inspections. All such products must comply with compendial standards and be produced in conformity with current good manufacturing practices, and enforcement mechanisms to assure this are in operation. For these products, an approved new drug application is not essential to assure the quality of the product.

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 marketing preclearance through the submission of an abbreviated new drug application. The very purpose of the policy is to refocus the FDA's use of the abbreviated new drug application 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.