

inserts for the physician and, over the next several years, all prescription drug labeling will come into compliance with these regulations. Various drug categories will be taken on a priority basis under this program, and we consider anorectic drugs as properly among the priority drugs.

We also anticipate issuing in 1977 proposed regulations relating to patient package inserts for prescription drugs. This proposal will undoubtedly stimulate extensive public comment and may well require another year or more for development of a final order. It is our intent to develop patient package inserts for specific drugs only in the context of this general statement on policy and procedure. In specific cases in which the public health requires a patient package insert on a prescription drug, for important safety reasons, we will take such action on an ad hoc basis as we have for oral contraceptives and estrogens. For most drugs, however, we believe it is wiser to develop general policy ahead of specific patient labeling. We, therefore, anticipate at the present time that specific patient labeling for anorectic drugs will not be developed in the near term.

Finally, I would comment that whatever future action we in FDA might take in regard to this class of drugs, some degree of abuse may well continue. Clandestine manufacture and smuggling across international borders will remain a problem. Even if amphetamines are removed from the market, other stimulant drugs will remain available and abuse of these agents may grow. The abuse of stimulant drugs will thus remain a matter of continuing concern, and its control will require