prescribed by the Federal Food, Drug, and Cosmetic Act for interstate shipments.

Biologics for human use must have been manufactured at an establishment holding a product license issued under the Biological Control Provisions of the Public Health Service Act for such products; Veterinary Biologics must meet requirements of the Veterinary Biologics Division of the U.S. Department of Agriculture; Oral Contraceptives must comply with the Food and Drug Administration requirements relating to their marketing in the U.S.

Antibiotics, biologics, contraceptives and several other drugs must be approved in advance by AID on an individual transaction basis. This prior approval requirement was established for several reasons: First, to assure that AID financed purchases reflect Food and Drug Administration actions pursuant to studies by the Drug Efficacy Study Group of the National Research Council of the National Academy of Sciences; second, to assure that importers have adequate storage and distribution facilities to handle perishable products such as vaccines; and third, to assure that significant findings pertaining to proposed end products are transmitted to the importing government.

We now have an extensive list of medicinal chemicals that are eligible for AID financing if they are included in the list of commodities authorized under a given agreement and if they meet the special provision requirements established by AID. We have published and released to the trade, through our Small Business Memos, listings of both eligible and ineligible pharmaceuticals as well as other information regarding pharmaceutical requirements.

We also have a series of internal manual order issuances dealing with pharmaceutical policies and procedures. Copies of pertinent releases were supplied to the Subcommittee.

Most Commercial Import Program purchases are made by negotiation and not by formal bid procedures. This is standard commercial practice—in fact; procurement by formal bid procedures would be the exception rather than the rule. However, we still expect importers to canvass the market whenever possible and to place orders so as to obtain optimum economic advantage. Our system of notification prescribed in AID Regulation 1 was devised to keep U.S. small business informed of sales opportunities arising out of our Commercial Import Programs. Concurrently, however, it makes it possible for importers to solicit competition.

Under the Regulation 1 notification requirement, importers must, unless exempted for reasons stated in the regulation, advertise proposed purchases in the "AID Financed Export Opportunities" bulletin, published by our Office of Small Business. We require importers to identify proposed purchases of pharmaceuticals by generic terms rather than by trade name. This widens the range of potential competitive offers and alerts interested U.S. firms to possible trade opportunities, both for the immediate purchase and for future market explorations. Advertising by generic name enables importers to learn of competitive product availabilities. For AID in addition to its impact on price, generic designation permits routine determination of commodity eligibility or ineligibility when notice is first received regarding a proposed pharmaceutical purchase.

But whether or not an intended pharmaceutical purchase is advertised in the "AID Financed Export Opportunities" bulletin, we are alerted to all proposed shipments made under Regulation 1 rules, by the "Application for Approval of Commodity Eligibility" (Form AID–11) that every commodity supplier must submit to AID/Washington for approval. This prior approval procedure, which was developed in response to Section 604 (f) of the Foreign Assistance Act of 1961, enables us to reject in advance shipments of any pharmaceuticals on our ineligible list or of pharmaceuticals not authorized in the specific commercial import program concerned.

We also require suppliers to list in their invoices, opposite each item billed, the established generic name and the quantities of active ingredients in each item supplied. This offers an opportunity at the post-audit stage for a final check on commodity eligibility and for more effective determination of compliance with the Agency's price rules.

I have already indicated that notification of proposed procurement is not always required, and may be modified or waived under certain conditions.

For example, publication of *individual* purchase intentions is not required under the so-called "Colombia Plan", of notification. Instead, our Office of Small Business publishes general information regarding the commodities authorized under each program, together with the names and addresses of im-