commercial import programs, only unfinished pharmaceuticals may be purchased, except that contraceptives in finished dosage form are authorized.

Transactions involving commercial imports must comply with the provisions of AID Regulation 1 as supplemented by special requirements that the Agency applies to pharmaceutical products. AID Regulation 1 prescribes the basic rules that govern AID-financed transactions. It covers conditions of eligibility of commodities and services, the responsibilities of importers and suppliers, the payment and reimbursement requisites, and the price rules for commodities and commodity-related services. These provisions apply uniformly to all commodities financed by AID under a commercial import program.

There are, however, special requirements that apply only to pharmaceutical products. These relate to commodity eligibility, commodity quality, and commodity certification. As already indicated, pharmaceuticals in finished dosage form are not eligible for financing under our commercial import programs. In addition, drug substances and drug products must meet all requirements 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 United States.

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. These prior approval requirements were instituted for biologics several years ago, for antibiotics on June 6, 1969, and for oral contraceptives on May 4, 1967, when they first became eligible for AID financing. Ingredients for contraceptives were made subject to prior approval on January 1, 1970.

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.[1]

[1] See information beginning at p. 7368.