

identical product available in any free world country, provided such non-U.S. price was established by the patent holder or his licensee.

(2) AID will not finance from an authorized source country a bulk pharmaceutical product at an FAS price which exceeds the lowest FAS price at which the same product, by whatever description, is available from the same source country.

(3) AID will not finance from an authorized source country a bulk pharmaceutical product at a price which exceeds the price at which another lower priced product can be obtained from any free-world source, if there is evidence that the lower-priced product, although of different generic description, is, for the purpose intended, pharmacologically a substantial equivalent to the higher priced product for which AID approval is solicited. Items which AID has determined to be subject to this rule will be indicated in the implementing document issued by AID which authorizes the use of AID funds for the procurement of pharmaceutical products.

(4) AID will not finance a bulk pharmaceutical product at a price which exceeds the lowest price charged by the supplier in any export sale of the item to any country, whether or not such sale has taken place under AID financing. A supplier under this rule may exclude in his calculation of his lowest price, the lowest priced 5% of his sales volume within the most nearly relevant sales period. The "lowest price" shall take into account all sales by the supplier of the product in export, without regard to any trade mark or other differentiation between items which are pharmacologically identical.

(5) With respect to any bulk pharmaceutical product for which AID does grant commodity approval under the foregoing special rules, a supplier shall continue to execute AID Form 282 which binds the supplier to the price tests set forth in Subpart G of AID Regulation 1. Upon post audit, a supplier of any bulk pharmaceutical product shall be held to the price tests set forth in that subpart of the regulation.

AID expressly reserves its right to determine any product unsuitable for AID financing within the meaning of § 604(f) whether or not the price for the product complies with the foregoing special rules.

AID will endeavor to provide a supplier, upon request, preliminary advice as to whether the price, at which the supplier proposes to sell a product in export, will be eligible for approval under the foregoing special rules prior to his entering into a contract to sell. AID will not supply this type of advice unless the supplier provides with his request to AID an indication that the solicitation may reasonably result in an agreement to sell.

AID intends to coordinate its eligibility standards for bulk pharmaceutical products with the Food and Drug Administration and shall attempt to amend on a continuing basis its policy and regulations to reflect new evaluations concerning the safety and efficacy of pharmaceutical products which it finances. AID will continue to supply its Missions and aid-recipient governments with such various information as may become available to AID concerning the safety and efficacy of end-use products manufactured from ingredients eligible for AID financing.

Effective Date: This Notice shall enter into effect upon publication in the "Federal Register."

MAURICE J. WILLIAMS,  
*Deputy Administrator.*

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Mr. DWINELL. After indicating that it is AID policy not to finance pharmaceutical products in finished dosage form to the private sector, the published notice provides new pricing standards for bulk pharmaceuticals that are substantially as follows:

Rule No. 1 provides that AID will not finance a bulk pharmaceutical product at a price which exceeds by more than 10 percent the price at which the product is generally available from free world countries. In applying this test, we exclude prices of pharmaceuticals sold in violation of U.S. patents.

Senator NELSON. Now, the purpose of this new practice is to avoid that situation in which foreign buyers were purchasing—we have