

3. Albamycin-T (novobiocin sodium and tetracycline hydrochloride). It has not been shown that microorganisms are more susceptible to the combination than to either antibiotic singly. The comments in paragraph 2 regarding novobiocin also apply to this combination preparation.

4. Panalba products (tetracycline phosphate complex and novobiocin). This combination has not been shown to be more effective than when one of its components is used alone for the therapy of susceptible organisms. The preceding comments regarding novobiocin also apply to this fixed combination preparation.

These combination antibiotic drugs are still on the market. The distributors have been given the opportunity to provide evidence that the drugs are effective for the purposes for which they are intended. If adequate data are not forthcoming, the distributors of the drugs will be given an opportunity for a hearing. If a hearing is held and decided in favor of the Government, the final order may be appealed to the courts. Withdrawal of the drugs from the market would not preclude clinical investigation of them through the investigational new drug procedures. Based upon a demonstration of effectiveness by adequate and well-controlled studies a drug may be returned to the market.

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