

"2. Multiple seizures based on a 'New Drug' charge may be instituted without the making of any probable cause determination under Section 304 [21 U.S.C. 334].

"3. The newness of a drug, within the meaning of the Federal Food, Drug, and Cosmetic Act may arise by reason of, among others, a new or different recommended use for the drug, or a new or different duration of administration, even though the same drug may not be a new drug when used in another disease or other duration of administration.

"4. From the affidavits submitted it appears that a difference of medical opinion exists among the experts on whether topical neomycin sulfate is generally recognized as safe for the treatment of acne.

"5. Where there is a genuine difference of medical opinion among the experts on the question of whether a drug is generally recognized as safe for the treatment of a particular disease, it must be concluded that the drug is not *generally* recognized as safe for use in the treatment of that disease.

"6. It cannot be said therefore, that the defendant government officials have acted unreasonably or arbitrarily. The medical affidavits submitted by the defendants leaves no doubt as to the good faith of the officials.

"7. The institution of lawsuits alleging violation of the Federal Food, Drug, and Cosmetic Act is a matter of discretion vested in the defendant officials.

"8. Where discretion is vested in a government official and he acts in good faith in the light of the facts he ascertains and the judgment he forms, a Court cannot restrain him from acting, on the ground that he has exceeded his jurisdiction, even if his conclusion might have been induced by an error of fact or law.

"9. The defendant officials here were properly exercising the powers of the sovereign and the Court may not enjoin that action.

"10. The Court is without jurisdiction to enjoin the defendants.

"11. Plaintiff's motion for a Temporary Injunction will be denied.

"12. There exists no genuine issue as to any material fact and defendants are entitled to judgment as a matter of law on their motion to dismiss and for summary judgment.

"13. Defendant's motion to dismiss and for summary judgment will be granted.

"Let judgment be entered accordingly."

On the same day the court ordered that the plaintiff's motion for a preliminary injunction be denied, and further ordered that defendant's motion for summary judgment to dismiss the complaint be granted.

**5902. Pega Palo vine.** (F.D.C. No. 40293. S. No. 72-967 M.)

**QUANTITY:** 405 pliofilm pkgs. at Bountiful, Utah, in possession of B & E Distributing Co.

**SHIPPED:** 2-21-57, from Chicago, Ill., by A-1 Import Co.

**LABEL IN PART:** "Pega Palo."

**ACCOMPANYING LABELING:** Reprints entitled "Pega Palo The Vine That Makes You Virile" and leaflets entitled "Pega Palo Fact Sheet."

**RESULTS OF INVESTIGATION:** Some of the reprints and all of the leaflets were printed locally for the dealer.

**LIBELED:** 5-31-57, Dist. Utah.

**CHARGE:** 502(f)(1)—when shipped and while held for sale, the labeling of the article failed to bear adequate directions for its use as an aphrodisiac and as a sex rejuvenator which were the purposes for which the drug was intended; and 505(a)—the article was a new drug within the meaning of the law and an application filed pursuant to the law was not effective with respect to the drug.

**DISPOSITION:** 10-21-57. Default—destruction.