

**FEDERAL SECURITY AGENCY****FOOD AND DRUG ADMINISTRATION****NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG,  
AND COSMETIC ACT**

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

**1551-1600****DRUGS AND DEVICES**

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

MAURICE COLLINS, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., *May 21, 1946.*

**CONTENTS\***

	Page		Page
Drugs actionable because of potential danger when used according to directions.....	21	Drugs and devices actionable because of false and misleading claims.....	40
Drugs actionable because of failure to bear adequate directions or warning statements...	27	Drugs for human use.....	40
Drugs actionable because of contamination with filth.....	35	Drugs for veterinary use.....	53
Drugs and devices actionable because of deviation from official or own standards.....	36	Habit-forming drug actionable because of failure to bear warning statement.....	56
		Index.....	57

**DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED  
ACCORDING TO DIRECTIONS**

**1551. Action to restrain interstate shipment of Bullock's System Self-Treatment for Sinus and Catarrhal Infection. U. S. v. Bullock's Laboratories, Inc., Henry Spangler, Dr. Thomas J. Howerton, Theodore T. Golden, and G. M. Koutz. Permanent injunction granted. (Inj. No. 85.)**

**COMPLAINT FILED:** March 5, 1945, Eastern District of Virginia, against Bullock's Laboratories, Inc., Alexandria, Va., and Henry Spangler, principal agent of the corporation, Dr. Thomas J. Howerton, president, Theodore T. Golden, secretary-treasurer, and G. M. Koutz, vice president of the corporation.

**NATURE OF CHARGE:** Since February 24, 1944, the defendants had been preparing, packing, and distributing in interstate commerce a misbranded product known as *Bullock's System Self-Treatment for Sinus and Catarrhal Infection*, which consisted of drugs labeled "Bullock's Emollient," "Bullock's Nasal Salve," "Ear Oil," "Bullock's A. H. C." (formerly known as "Bullock's Antiseptic Healing and Cleansing Tonic"), and "KCK An Alkaline Combination" (formerly known as "King Cold Knockout"), and a device consisting of a douche or irrigation can, rubber tubing, and nasal tip, together with a nasal atomizer, a thermometer, and a measuring cup. The drugs had essentially the same

\*For failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, see Nos. 1555, 1556, 1558, 1577, 1600; failure to bear an accurate statement of the quantity of the contents, Nos. 1553, 1555, 1556, 1558, 1577, 1592, 1599, 1600; failure to bear in the English language the information required by Section 502 (f) (1), No. 1553; omission of, or unsatisfactory, ingredients statements, Nos. 1553, 1555-1557, 1559-1561, 1564-1566, 1585, 1599, 1600; product requiring certificate or release, for which none had been issued, No. 1554; no new-drug application effective, No. 1557; substitution of a drug and its sale under the name of another drug, Nos. 1571, 1586, 1587; deceptive packaging, Nos. 1581, 1586, 1587, 1594; imitation of another drug, Nos. 1586, 1587; giving of a false guaranty, No. 1571; cosmetics, actionable under the drug provisions of the Act, Nos. 1592-1594.

composition as those of similar articles involved in the case reported in notices of judgment on drugs and devices, No. 908.

The *System* was alleged to be misbranded in the following manner: Section 502 (a), certain statements in the labeling, including those in accompanying booklets entitled "Directions for Use of Bullock's System" and "Fight Infection with Bullock's System," and in an accompanying folder entitled "Infectious Catarrh Symptoms," were false and misleading since they represented and suggested that the *System* would constitute an effective treatment for acute or chronic sinus trouble, hay fever, nasal catarrh, nasal ailments, infectious catarrh, abscesses and infected teeth, throat and tonsil infections, bronchitis, mastoid trouble, asthma, colitis, ulcers and catarrh of the stomach, tumors, rheumatism, arthritis, blindness, and deafness. The *System* did not constitute an effective treatment for the conditions named. Further misbranding, Section 502 (j), the *System* would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling since it was intended for use in the irrigation of the nasal passages, whereas such irrigation is always accompanied by danger to the health of users by loosening the infected material from the nasal walls and spreading the infection to the opposite nasal passage, to the nasal sinuses, or to the ears.

It was also alleged in the complaint that, previous to the incorporation of Bullock's Laboratories, Inc., the business of preparing and distributing the *System* had been carried on by Henry Spangler as an individual trading under the name of National Laboratories, Inc.; that, while so operating, criminal proceedings had been instituted against Henry Spangler (as reported in notices of judgment on drugs and devices, No. 908), resulting in a sentence of 180 days in jail, which sentence was suspended on condition that he was not then selling and would not again engage in the sale of the *System*; and that, thereafter, Henry Spangler was instrumental in securing, for the purpose of preparing and distributing the *System*, the formation of the corporation known as Bullock's Laboratories, Inc.

**PRAYER OF COMPLAINT:** That a preliminary injunction issue, restraining the defendants from commission of the acts complained of; and that, after due proceedings, the preliminary injunction be made permanent.

**DISPOSITION:** On March 13, 1945, the corporation and Theodore T. Golden and Henry Spangler having entered their appearances, and the other defendants having failed to appear, a preliminary injunction was entered, restraining all defendants from shipping any misbranded drugs and devices, and particularly the so-called "Bullock's System," in interstate commerce for the period ending on April 16, 1945. On the latter date, the defendants having failed to answer or otherwise plead to the complaint, a decree was entered directing that the preliminary injunction be made permanent.

**1552. Adulteration and misbranding of Interferin. U. S. v. Don C. Keefer (Keefer Laboratories). Plea of nolo contendere. Sentence of 1 year in jail. (F. D. C. No. 7241. Sample Nos. 14766-E, 86683-E.)**

**INFORMATION FILED:** October 25, 1944, Northern District of Illinois, against Don C. Keefer, trading as the Keefer Laboratories, Chicago, Ill.

**ALLEGED SHIPMENT:** On or about November 3, 1941, and March 19, 1942, from the State of Illinois into the States of Pennsylvania and Wisconsin.

**NATURE OF CHARGE:** Adulteration (shipment of November 3, 1941), Section 501 (c), the purity of the article fell below that which it purported and was represented to possess. It purported and was represented to be sterile by reason of the fact that it was recommended in the labeling for injection into the cervix and pregnant uterus under conditions of the strictest asepsis, whereas it was not sterile but was contaminated with viable pathogenic micro-organisms.

Misbranding (same shipment), Section 502 (j), the article was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling; and, Section 502 (a), the labeling was false and misleading since it represented and suggested that the article, when used by or on the prescription of a physician, was a safe and appropriate medicament for use in effecting abortion, whereas, when used by or on the prescription of a physician, or otherwise, it was not a safe and appropriate medicament for use in effecting abortion, but was unsafe and dangerous, and capable of producing serious and even fatal consequences; and the label statements, "The placenta is usually expelled a few minutes after the fetus," "Severe hemorrhages are very rarely observed after the use of Interferin,"