N. J. D. D. N. J., F. D. C. 1001–1050 Issued March 1945

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]

1001–1050

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.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., *December 12, 1944.*

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

1001. Action to enjoin and restrain distribution of Sekov products. U. S. v. Sekov Corporation and Hazel Ruth Vokes (Sekov Studios). Permanent injunction granted. (Inj. No. 53.)

On April 17, 1943, the United States attorney for the Southern District of California filed a complaint for injunction against the Sekov Corporation and Hazel Ruth Vokes, trading under the name of the Sekov Studios, Hollywood, Calif. (The complaint also joined as party defendant Edwin Hoskin Vokes, but after hearing, the court ruled that it did not have jurisdiction over that person.)

The complaint alleged: (1) That the defendants were engaged in the manufacture of various capsules which contained desiccated thyroid, which were designated by the names "Sekov," "Sekov Reducer," "Sekov Reducer for Men," "Sekov Formula P," "Sekov Formula R," and "Sekov Formula T," and which were being introduced and delivered for introduction into interstate commerce in capsule form, for sale to the general public for self-medication in the treatment of obesity.

(2) That "Sekov" and "Sekov Reducer" each consisted of two types of capsules, designated as Capsule No. 1 and Capsule No. 2; that the No. 1 capsules contained glandular material including thyroid, the thyroid content varying from 1.87 grains to 2 grains per capsule, the recommended dosage suggested being 1 capsule before the noon meal; that the No. 2 capsules contained rhubarb, cascara sagrada, asafetida, and other ingredients, the recommended dosage being 1 capsule every other night (just before retiring); that the "Sekov Reducer for Men" consisted of 2 types of capsules, the No. 1 containing, in addition to other ingredients, thyroid and aloin, the thyroid content varying from 1.84 grains to 1.95 grains per capsule, the dosage recommended being "One capsule morning and one capsule evening (preferably half to one hour before meals)"; that the No. 2 capsule was identical with the "Sekov Reducer" No. 2 capsule, and the dosage recommended was "One capsule every night (just before retiring)"; that the "Sekov Formula P" contained, in addition to other ingredients, thyroid in an amount of approximately 1.73 grains per capsule; that the "Sekov Formula R" contained ingredients similar to the "Sekov Formula P," with a thyroid content of approximately 1 grain per capsule; that the "Sekov Formula T" contained ingredients similar to the "Sekov Formula P," with a thyroid content of 1.87 grains per capsule; and that the dosages recommended in the labeling of formulas "P," "R," and "T," were identical, "One capsule per day—taken ½ to 1 hour before morning meal."

*For omission of, or unsatisfactory, ingredients statements, see Nos. 1003, 1005, 1009, 1010, 1011, 1022, 1043, 1044; deceptive packaging, Nos. 1003, 1011; failure to bear accurate statement of quantity of contents, Nos. 1003, 1009, 1010, 1033, 1034, 1040, 1043, 1047, 1049; contamination with filth, No. 1011; cosmetics, subject to the drug provisions of the Act, Nos. 1021, 1040, 1043, 1047.

(3) That on February 17, 1940, on complaint of the Federal Trade Commission a preliminary injunction was issued by the United States District Court for the Southern District of California, enjoining the Sekov Corporation, Edwin Hoskin Vokes, and Hazel Ruth Vokes, as officers of the corporation and as individuals trading as "Sekov Reducing Studios," their agents, etc., from causing to be disseminated any advertisement by any means tending to induce the purchase in interstate commerce of the drug sold under the name of "Sekov Reducer", or "Sekov," or any other name, which advertisement represented directly or indirectly that such preparations were a safe, competent, and scientific treatment for obesity; and that on March 12, 1940, the Federal Trade Commission issued a complaint against the Sekov Corporation, Edwin Hoskin Vokes, and Hazel Ruth Vokes, as officers of the corporation and as individuals trading as "Sekov Reducing Studios," and on September 8, 1940, pursuant to a stipulation of facts, the Federal Trade Commission issued its order against the defendants to cease and desist from, directly or indirectly, doing, among other things, disseminating or causing to be disseminated any advertisement, (a) by means of the United States mail, or (b) by any means in commerce, as commerce is defined by the Federal Trade Commission Act, which advertisement represented directly or through individuals that said preparation was a safe, competent, and scientific treatment for obesity.

(4) That on July 21, 1941, a libel had been filed in the District Court of the United States for the Southern District at Houston, Texas, against capsules similar to those aforesaid, and on May 28, 1942, final judgment was entered ordering the libeled articles destroyed. On June 5, 1942, a little more than a month after the decision of the Texas court, the defendant shipped to Houston, Texas, a stock of drug products similar to those condemned by the Texas court, and a libel was filed by the United States against this shipment on July 29, 1942, to which an answer was filed by the Sekov Corporation. At the pre-trial hearing on October 24, 1942, counsel for the claimant, the Sekov Corporation, agreed to stipulate that the facts alleged in the libel were true, excepting the question of misbranding. On or about January 8, 1943, the defendants, trading as "Sekov Studios," shipped 6 cartons of Sekov to Reno, Nev., labeled "Manufactured for—Packed by—Sekov Corporation," and a libel was filed against this shipment on March 6, 1943, in the District Court of the United States for the District of Nevada.

(5) That the products were misbranded as follows: (a) that the "Sekov Reducer," "Sekov Formula T," and "Sekov Reducer for Men" were dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, or suggested in the labeling (this allegation was based on the fact that the capsules, when taken according to the directions, would supply a dangerous amount of thyroid); (b) in that the label on the carton of each of the preparations, including the design of a slender female figure, was false and misleading since it created the impression that the articles were safe and appropriate treatments for the reduction of weight, whereas they were not safe and appropriate treatments, but were dangerous drugs and could not be depended upon to reduce weight; and (c) that the "Sekov Formula P" and "Sekov Formula R" were misbranded in that the label on each carton, including the design of a slender female figure, was false and misleading since it created the impression that the articles were dependable and appropriate treatments for the reduction of weight, whereas they were not dependable and appropriate treatments, and could not be depended upon to reduce weight.

(6) That the defendants had attempted and were still attempting to circumvent the protection intended to be given for the health and welfare of the public, and that the Government had endeavored to have the defendants refrain from shipping the aforesaid products in interstate commerce, without success, over a period of years, and, by reason of the failure of the defendants to refrain from shipping the products, it became necessary for adequate protection to the general public that the defendants be forever enjoined from shipping such misbranded products in, or introducing or delivering them for introduction into, interstate commerce to be used as food or drugs.

On April 19, 1943, the court issued a temporary restraining order and an order to show cause why, pending final determination, a preliminary injunction should not be entered. On May 3, 1943, the court denied the motion for a preliminary injunction and the case was set for trial. On June 12, 1943, after hearing the testimony, the court gave its opinion in the following minute order:

LEON R. YANKWICH, *District Judge*:

"The above-entitled cause heretofore tried and submitted, is hereby decided as follows:

"Judgment is ordered entered for the plaintiff as prayed for in its complaint, restraining and enjoining the defendants, their servants, agents, officers, employees, attorneys and assigns, and each of them, from the introduction or delivery for introduction into interstate commerce of any of their said products herein before designated and described as 'Sekov', 'Sekov Reducer', 'Sekov Reducer for Men', 'Sekov Formula P', 'Sekov Formula R', and 'Sekov Formula T,' in violation of or contrary to Title 21, U. S. C. A., Sections 301 to 392.

"I am of the view that the evidence shows clearly that the preparation is misbranded because 'it is dangerous to health when used in the dosage or with the frequency or duration prescribed and recommended or suggested in the label thereof.' (21 U. S. C. A. Sec. 352 (j).) Even the physicians who testified for the defendants admitted that the use of thyroid extracts in the quantity prescribed by obese persons, whose obesity *was not due* to hypothyroidism, might prove injurious to health. The physicians who testified for the Government, each of whom is an expert in his field, were emphatic in their statement that such use not only might be detrimental, but in all likelihood would be so. If the defendants limited sales to persons who are suffering from obesity due to hypothyroidism,—either by requiring a physician's certificate to that effect, or by conducting an examination of the person before making a sale, it could well be contended that, with such precaution, any detrimental results would be only those incident upon any selfmedication, which the law does not prohibit. As the sale is not made through general outlets, but through agencies conducted by the defendants—studios located in various cities throughout the United States, such safeguards could easily be enforced. As it is, the record shows that any obese person who calls at one of these studios can obtain the product without any inquiry as to whether the conditions for which the product is intended as a remedy, co-existing obesity and hypothyroidism,—are present. In view of this, the statement on the carton that the preparation is 'a reducer for overweight due to a thyroid deficiency' and similar statements in the pamphlet are inadequate to forestall the evil inherent in the use of this preparation by persons whose hypothyroidism has not been established by a competent physician. It is to be noted, as stated by me during the argument, that nowhere is there a warning couched in imperative negatives such as are found in products which may have a deleterious effect. Nowhere is there a statement '*Do not use this* unless a physician has told you that your obesity is due to hypothyroidism'. The reference to the consultation of a physician is ineffective. It reads: 'We recommend that you consult physician to determine the cause of your overweight as the use of THYROID by a person not deficient in THYROID may result in serious or irreparable injury to the health of the user'.

"I am also satisfied that the contra-indications are inadequate. In the light of the expert testimony, I do not think that the average person seeking to reduce would be competent to detect the evils resulting from its use. Bearing in mind that the defendants in their advertising and literature, appeal especially to the vanity of women, I am of the view that the average woman, in her desire to achieve a beauty of form, would be more inclined to consider the manifestations of ill effect as the natural price to pay for the results to be achieved. So that if we consider the warnings in relation to the persons to whom they are addressed, as counsel bids us to, it is quite evident that they are ineffective for the purpose."

On June 25, 1943, the court handed down findings of fact substantially sustaining the allegations in the complaint, and conclusions of law sustaining the prayer of the complaint. On the same day a decree for permanent injunction was filed, ordering the defendants forever restrained and enjoined from introducing or delivering for introduction into interstate commerce any of their products designated and described as "Sekov," "Sekov Reducer," "Sekov Reducer for Men," "Sekov Formula P," "Sekov Formula R," and "Sekov Formula T."

1002. Misbranding of Sekov Reducer. U. S. v. 15 Cartons of Sekov Reducer. Tried to the court without a jury. Judgment for the Government. Decree of condemnation and destruction. (F. D. C. No. 5167. Sample No. 11274–E.)

Misbranding of Sekov and adulteration and misbranding of Sekov Formula "P." U. S. v. 47 Cartons and 6 Cartons of Sekov and 7 Cartons of Sekov Formula "P." Default decrees of condemnation and destruction. (F. D. C. Nos. 7992, 7993, 9500. Sample Nos. 11077–E, 11078–E, 11056–F.)

On July 21, 1941, July 29, 1942, and March 6, 1943, the United States attorneys for the Southern District of Texas and the District of Nevada filed libels against 62 cartons of a product labeled "Sekov," or "Sekov Reducer," and 7 cartons of Sekov Formula "P" at Houston, Tex., and 6 cartons of Sekov at Reno, Nev., al-