NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in the accompanying leaflets were false and misleading since they represented and suggested that the article was an adequate and effective treatment for sprains and bruises, swollen, stiff joints of wrists and ankles, neuralgia, rheumatic pains, lumbago, neuralgia of face, sore throat, colds and coughs, croup, wounds, frosted feet, poison ivy, sunburn, skin irritations, burns, scalds, cramps, and indigestion of humans, and for gapes, roup, colds, diarrhea, coccidiosis, cholera, worms, and allied ailments of poultry; that it would be effective to promote healthy, vigorous growth of poultry; and that it would be an adequate and effective treatment for scours in calves and colts and for distemper in horses and cattle, whereas the article was not an adequate and effective treatment for such conditions.

Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient.

The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: November 24, 1950. Default decree of condemnation and destruction.

DRUGS FOR VETERINARY USE*

3300. Misbranding of Solution 5–17, Tur-Abken, Hex-Emia, Avian iodine, solution sulfathiazole sodium, solution sulfamethazine sodium, Solution Sulfathia-Zine, Anti-Pick, and sulfathiazole ointment. U. S. v. 52 Bottles, etc. (F. D. C. No. 29378. Sample Nos. 75211–K, 75212–K, 75215–K to 75219–K, incl., 75221–K, 75222–K.)

LIBEL FILED: July 6, 1950, District of Colorado.

ALLEGED SHIPMENT: On or about March 21, 1950, by the Southwest Laboratories, from San Diego, Calif.

PRODUCT: 62 bottles of *Solution 5–17*, 62 bottles of *Tur-Abken*, 4 bottles of *Hex-Emia*, 4 bottles of *Avian iodine*, 11 bottles of *solution sulfathiazole sodium*, 10 bottles of *solution sulfamethazine sodium*, 10 bottles of *Solution Sulfathia-Zine*, 2 jars of *Anti-Pick*, and 4 jars of *sulfathiazole ointment* at Denver, Colo., together with a number of pamphlets entitled "Seal of Quality Remedies" and "Seal Brand Remedies Control Coccidiosis Enteritis Bronchitis And Colds."

Analysis disclosed that the *Solution 5–17* consisted essentially of lactic, tartaric, citric, and acetic acids, and phenolphthalein (0.3 percent), dissolved in water; that the *Anti-Pick* consisted essentially of an ointment containing guaiacol and colocynth extract in a base of petrolatum and paraffin, colored red; and that the *sulfathiazole ointment* consisted essentially of sulfathiazole, 2 percent, in an ointment base, perfumed with menthol. The remaining products were not analyzed, but apparently their composition conformed with that disclosed on the labels, which represented that the *Tur-Abken* contained eucalyptus oil, guaiacol, white pine oil, bland oil, and chlorophyll; that the *Hex-Emia* consisted of a liquid concentrate of pure lactic acid, iron chloride, and copper sulfate; that the *Avian iodine* was a mixture of iodine and iodide; that the *solution sulfathiazole sodium* contained 30 grains of sulfathiazole sodium sesquihydrate in each ounce; that the *solution sulfamethazine sodium* contained 17½ grains of sodium sulfamethazine per fluid ounce; that the *Solution Sulfathia-Zine* contained 17 grains of sodium sulfathiazole and 10 grains of sodium sulfamethazine per fluid ounce. The bottles and jars containing the product ranged in size from 2 ounces to 1 gallon.

*See also No. 3299.

LABEL, IN PART: "Solution 5–17," "Tur-Abken," "Seal Brand Hex-Emia (Solution)," "Seal Brand Avian Iodine (Liquid)," "Seal Brand Solution Sulfathiazole Sodium [or "Sulfamethazine Sodium" or "Sulfathia-Zine"]," and "Seal Brand Anti-Pick [or "Sulfathiazole Ointment"]."

NATURE OF CHARGE: *Solution 5–17.* Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since such statements represented and suggested that the article was effective for the prevention and treatment of coccidiosis, enteritis, other intestinal diseases in chickens, rabbits, and turkeys, and intestinal diseases and parasites of poultry and diarrhea of rabbits; and that the article would change the intestinal condition from an acid to an alkaline balance and so maintain a normal appetite, whereas the article was not effective for such purposes; and, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the name of the active ingredient, phenolphthalein, contained therein.

Tur-Abken. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since such statements represented and suggested that the article was effective for the prevention and treatment of colds and swell heads in turkeys, rabbits, and chickens, bronchitis in chickens, sprains, and lameness, whereas the article was not effective for such purposes.

Hex-Emia. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since they represented and suggested that the article was effective for the prevention and treatment of hexamitiasis, mycosis, enteritis, and anemia in poultry, and that it would lessen the percentage of mortality, whereas the article was not effective for such purposes.

Avian iodine. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since they represented and suggested that the article was effective for the prevention and treatment of enlarged livers, anemia, faulty blood conditions, weakened kidneys, blackhead, leukosis, and ailments of the liver and kidneys in poultry; that it would build disease resistance; and that such conditions are caused by an iodine deficiency in water and feed. The article was not effective for such purposes, and the conditions named are not caused by an iodine deficiency in water and feed.

Solution sulfathiazole sodium. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since they represented and suggested that the article was an effective treatment for coryza (colds) in poultry and colds in rabbits. The article was not an effective treatment for coryza (colds) in poultry or colds in rabbits when used as directed in its labeling, namely: "Add Two (2) Tablespoons (one ounce) of Seal Brand Solution Sulfathiazole in each gallon of drinking water for Five (5) Days. Sixth day replace with two (2) tablespoons of Soda or Epsom Salts. (One Day Only.) Ninth day repeat Solution Sulfathiazole dosage. Tenth day repeat Soda or Salts. (One Day Only.)"

Solution sulfamethazine sodium. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since they represented and suggested that the article was an effective treatment for coccidiosis, pullorum disease, and fowl cholera in poultry. The article was not effective in the treatment of coccidiosis, pullorum disease, and fowl cholera in poultry when used as directed in its labeling, namely: "Add Four (4) Tablespoons (2 ounces) Seal Brand Solution—Sulfamethazine in each gallon

of drinking water for Two Full Days. Give plain drinking water for the next four days. Then on the seventh day of the dosage period Repeat Seal Brand Solution—Sulfamethazine for One Day Only."

Solution Sulfathia-Zine. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since they represented and suggested that the article was an effective treatment for colds and coryza, pullorum disease, coccidiosis, and fowl cholera in poultry and rabbits. The article was not effective in the treatment of such disease conditions when used as directed in its labeling, namely: "Add Three (3) Tablespoons (1½ ounces) of Seal Brand Solution Sulfathia-Zine to each gallon of drinking water for Three (3) Days. Sixth day replace with Two (2) tablespoons of Soda or Epsom Salts. (One Day Only.) Ninth day repeat Solution Sulfathia-Zine dosage. Tenth day repeat Soda or Salts. (One Day Only.)"

Anti-Pick. Misbranding, Section 502 (a), the label of the article bore statements which represented and suggested that the article had healing properties when applied to fowls which had been picked by other fowls, whereas such statements were false and misleading since the article was not effective for such purpose; and, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient contained therein since its label bore no ingredient statement.

Sulfathiazole ointment. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since they represented and suggested that the article was healing; that it was an effective treatment for bruises and caked udders; and that it would aid in healing all cuts, burns, and swellings. The article was not healing; it was not an effective treatment for bruises and the several disease conditions of the mammary gland known as caked udders; and it would not aid in the healing of all cuts, burns, and swellings.

DISPOSITION: August 25, 1950. The shipper of the articles having executed an acceptance of service and authorization for taking of final decree, judgment of condemnation was entered and the court ordered that the products, including the pamphlets, be destroyed.

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]

3301–3320

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 the Federal Security Agency, and include, where indicated, the results of investigations of the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *April 4, 1951.*

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*For presence of a habit-forming narcotic without warning statement, see Nos. 3301-3308: omission of, or unsatisfactory, ingredients statements, Nos. 3302, 3303, 3305; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3301-3308, 3313; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3302-3305, 3307, 3308, 3313, 3316; cosmetics actionable under the drug provisions of the Act, No. 3316 (DermaCulture Formula No. 103, cleansing lotion herbal astringent, granular cleanser, DermaCulture Formula No. 102, and DermaCulture Formula No. 104)

933396—51——1

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3301. Misbranding of Seconal Sodium capsules. U. S. v. Jones Drug Co. and Walter W. Hafley. Pleas of guilty. Fine of $20 against each defendant. (F. D. C. No. 29478. Sample Nos. 31933–K, 31935–K, 58077–K, 58152–K.)

INFORMATION FILED: November 1, 1950, District of Arizona, against the Jones Drug Co., a partnership, Tucson, Ariz., and Walter W. Hafley, a partner in the partnership.

INTERSTATE SHIPMENT: Between the approximate dates of April 14 and June 15, 1949, from the State of Indiana into the State of Arizona.

ALLEGED VIOLATION: On or about July 20 and August 12, 23, and 25, 1949, while the drug was held for sale after shipment in interstate commerce, the defendant caused a number of the *Seconal Sodium capsules* to be repacked and sold without a prescription, which acts resulted in the capsules being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged capsules failed to bear a label containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the capsules contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the directions for use "One capsule at bedtime," borne on the labeling of the repackaged capsules, were not adequate directions for use.

DISPOSITION: November 15, 1950. Pleas of guilty having been entered, the court imposed a fine of $20 against each defendant.

3302. Misbranding of Seconal Sodium capsules and Benzedrine Sulfate tablets. U. S. v. Joseph P. Piszczek (Piszczek's Pharmacy). Plea of guilty. Fine $300. (F. D. C. No. 29445. Sample Nos. 15846–K to 15849–K, incl.)

INFORMATION FILED: September 6, 1950, Eastern District of Wisconsin, against Joseph P. Piszczek, trading as Piszczek's Pharmacy, Milwaukee, Wis.

INTERSTATE SHIPMENT: From the States of Indiana and Pennsylvania into the State of Wisconsin, of quantities of *Seconal Sodium capsules* and *Benzedrine Sulfate tablets.*

ALLEGED VIOLATION: On or about October 7, 10, 13, and 17, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused a number of the *Seconal Sodium capsules* and the *Benzedrine Sulfate tablets* to be repacked and sold without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing a statement of the quantity of the contents; Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use; and Section 502 (b) (1), a portion of the repackaged *Seconal Sodium capsules* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations