

1940, by the Dawes Products Co. from Denver, Colo.; and charging that it was misbranded.

Analysis showed that it consisted essentially of concentrated buttermilk and combined iodine.

The article was alleged to be misbranded in that the following statements in the labeling were false and misleading since they represented that it was efficacious for the purposes recommended; whereas it was not efficacious for such purposes: "Digestive Tract Control of Cocci \* \* \* An Aid in Control of Coccidiosis Blackhead in Poultry Ducks Turkeys Game Fowls." It was alleged to be misbranded further in that the label failed to bear an accurate statement of the quantity of contents; in that the label failed to bear the name and address of the manufacturer, packer, or distributor; and in that it failed to bear the common or usual names of the active ingredients of the article.

On September 6, 1940, the Dawes Products Co., claimant, having admitted the allegations of the libel and having consented to the entry of a decree, judgment of condemnation was entered and it was ordered that the product be released under bond for relabeling under the supervision of the Food and Drug Administration.

**366. Misbranding of Ko-Ex-7 Powder and Ko-Ex-7 Mastitis Detector. U. S. v. 11 Packages of Ko-Ex-7 Powder and 11 Packages of Ko-Ex-7 Mastitis Detector. Default decrees of condemnation and destruction. (F. D. C. Nos. 2250, 2251. Sample Nos. 3665-E, 3666-E.)**

The labeling of these veterinary products bore false and misleading representations regarding their efficacy in the conditions indicated hereinafter. The label of the Mastitis Detector failed to bear the common or usual name of the active ingredient, namely, bromthymol blue.

On June 25, 1940, the United States attorney for the Western District of Pennsylvania filed libels against 11 16-ounce packages of Ko-Ex-7 Powder and 11 packages of Ko-Ex-7 Mastitis Detector at Meadville, Pa., alleging that the articles had been shipped in interstate commerce on or about May 3, 1940, by the Sunset Feed & Grain Co., Inc., from Buffalo, N. Y.; and charging that they were misbranded.

Analysis showed that the Ko-Ex-7 Powder consisted essentially of potassium nitrate, ferrous sulfate, boric acid, together with small proportions of ammonia and plant material; and that the Ko-Ex-7 Mastitis Detector consisted of a square of blotting paper, a portion of which had been impregnated with an indicator such as bromthymol blue, the purpose of which was to determine whether a solution placed thereon was acid or alkaline in reaction.

The mastitis detector was alleged to be misbranded in that the following statements in the labeling were false and misleading: "To stop losses from Mastitis—Use the Ko-Ex-7 Mastitis Detector \* \* \* If detector shows milk derangement segregate cow at once, and begin treatment." It was alleged to be misbranded further in that the label failed to bear the common or usual name of the active ingredient.

The Ko-Ex-7 Powder was alleged to be misbranded in that representations in the labeling that it was efficacious in the treatment of mastitis, or garget, that it would help correct faulty metabolism, that it would bring about normal milk secretion, that it would be efficacious to control mastitis and stop mastitis losses, were false and misleading since it would not be efficacious for such purposes.

On July 30, 1940, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

#### CRIMINAL PROSECUTIONS

**367. Misbranding of Axine Plates. U. S. v. Walter Gordon Pervis. Tried to the court and a jury. Verdict of guilty. Defendant sentenced to 6 months in jail and \$1,000 fine. Jail sentence suspended and defendant placed on probation for 2 years. (F. D. C. No. 958. Sample No. 72023-D.)**

The labeling of this device bore false and misleading representations and designs regarding its efficacy in the conditions indicated below.

On June 1, 1940, the United States attorney for the Middle District of Georgia filed an information against Walter Gordon Pervis, of Tennille, Ga., alleging shipment on or about September 30, 1939, from the State of Georgia into the State of Missouri of a quantity of Axine Plates which were misbranded. Accompanying the article was a circular headed "Health Without Medicine" which bore a design showing two individuals, one an invalid on crutches opposite whom was a figure purporting to be the same individual but healthy and vigorous. Emanating from the heels of the healthy individual were radiations indicating

electrical energy. Underneath the design were the words "Vigor" and "Produced by Electricity in the Human Body."

Examination showed that the article consisted of two plates, of which one consisted essentially of copper and the other consisted essentially of zinc.

The article was alleged to be misbranded in that the above-described design and certain statements in the circular represented that it would produce health and vigor by means of electricity in the human body; would relieve the stiffness of old age and make one feel young again; would rid the blood of uric acid; would be efficacious in the mitigation, treatment, and prevention of high blood pressure, low blood pressure, headache, asthma, paralysis, kidney trouble, rheumatism and diabetes, eczema, cold hands and feet, poor circulation; and would be efficacious "to draw the acid from the larynx glands and thus stop excessive coughing of asthma," were false and misleading since the article would not be efficacious for such purposes. The article was alleged to be misbranded further in that certain statements in the circular were false and misleading since they represented that uric acid forms in the stomach; that it forms as the result of eating food that disagrees with the stomach; that the acid then filters through the blood and travels through the blood as a very fine crystal; that the device consisted of a composition of metals which "would act upon the human electricity, and would make human electricity fast"; that it would heat the blood about 2 degrees, and thus dissolve uric acid in the blood; that uric acid would pass through the blood into the device, i. e., metal plates worn in the heels of the shoes; whereas uric acid does not form in the stomach, it does not form as the result of eating food that disagrees with the stomach; it does not filter through the blood and travel through the blood as a very fine crystal; the device would not act upon human electricity, and would not make human electricity fast; it would not heat the blood about 2 degrees, and would not dissolve uric acid in the blood; and uric acid would not pass through the blood into the device. The article was alleged to be misbranded further in that certain statements in the circular represented that the cause of high blood pressure is the uric acid crystals stopping in the arteries, hardening the arteries and enlarging the heart; that the device would stimulate one's own electric current; that the electric current would pass through the brain and dissolve and draw away clot on the brain caused by high blood pressure; whereas the cause of high blood pressure is not uric acid crystals stopping in the arteries, hardening the arteries and enlarging the heart; the device would not stimulate one's own electric current; and the electric current would not pass through the brain and dissolve and draw away the clot on the brain caused by high blood pressure. It was alleged to be misbranded further in that certain statements in the labeling represented that uric acid stiffens the prostate gland; that because of uric acid the prostate gland stands open and will not "pan down"; that failure of the prostate glands to "pan down" causes diabetes; that the device would produce heat by the metals acting as a battery on the human electricity; that the heat produced by the device would cause the prostate gland to "pan down" and relieve the patient, which representations were entirely false and misleading, since uric acid does not stiffen the prostate gland and cause it to stand open and fail to "pan down"; the failure of the prostate gland to "pan down" does not cause diabetes; the device would not produce heat by the metals acting as a battery on the human electricity; and it would not cause the prostate gland to "pan down" and relieve the patient entirely.

On November 11, 1940, a plea of not guilty having been entered, the case came on for trial before the court and jury. The trial was concluded on November 13, 1940, on which date the court delivered the following instructions to the jury:

DEAVER, *Judge*: "Gentlemen of the Jury. Without attempting to state to you all the provisions of the Food and Drug Act, it is only necessary for me to state one provision of it, and that is very short and simple. Congress has made it a crime to ship in interstate commerce, that is to say from one State into another State, any device which is misbranded. Now, misbranded under the terms of the statute is this: A device is misbranded when the label and statements in connection with it are false or misleading. That is the whole provision of the law applicable to this case.

"Now, the information in this case, which you will have out with you, is somewhat long but it charges in substance that this defendant shipped in interstate commerce a certain device, which you already know about, certain heel

plates known as Axine Plates, from this State into another State, and that the shipment was misbranded, that the device was misbranded; that is to say, that the statements or representations on the label or these circulars, which you have seen here in evidence and which you will have out with you, are false or misleading. Now, that is the question that you are to determine, whether the label or statements in connection with this device are false or misleading.

"Now, you will find in this indictment set out, I take it—I haven't read it but I think that you will find that true, you may read it all if you care to—the statements which were either on the label or in these circulars and the allegations in the information that certain things in here are false or misleading, and you will follow that right straight on through. It sets out one provision after another and then alleges that those statements are false or misleading in certain respects.

"Now, to that charge the defendant has entered on the back of this information a plea of not guilty. That plea is in substance a denial of every essential allegation in the information, and the information together with the plea of not guilty makes up an issue of fact, a question of fact, for this jury to determine.

"Then, the trial begins and the burden is on the Government to produce evidence sufficient to convince the jury beyond a reasonable doubt that the defendant is guilty, as charged.

"In the beginning of the trial, the defendant is presumed to be innocent and that presumption continues unless it is overcome by the testimony in the case, testimony sufficient to overcome the presumption and to convince the jury beyond a reasonable doubt that the defendant is guilty.

"The testimony has been somewhat long, necessarily long. There is no criticism of anybody in that connection because it was necessary to bring you the evidence bearing on this question and you are to take all of that evidence on both sides and consider all of it, oral testimony and documentary testimony, and say from it all what you honestly believe about it, what your honest conviction is as to whether the statements made by the defendant in these circulars or printed matter sent out with the shipment are false or misleading. If those statements are false and misleading, then the shipment was misbranded and, therefore, the shipping constituted a crime.

"That is all there is to the case. I say there is a lot of testimony but the question to be decided is very simple and easy to state.

"Now, I might just repeat it this one time: You determine from all the evidence in the case whether the statements made by this defendant in connection with the shipment of these heel plates are false or misleading. Oh, of course, there are a great many facts set out here in the information that are necessary with reference to jurisdiction and shipment in interstate commerce and various things of that sort, but, as you have heard here in the trial of this case, there is really no dispute between the parties here as to any of those things, and that's the reason why I say you haven't got but one question. It is admitted, I believe, here that the shipments were made in interstate commerce, that they contained these circulars and these representations and all those various things, and for that reason I say you have, in substance, only the one question to decide: Were these statements false or misleading? If they were, then he is guilty. If they were not, or if the Government has failed to convince you beyond a reasonable doubt that they are, then you ought to turn the defendant loose.

"You will write your verdict on the back of this information. There is a blank verdict there that you can fill out and let your foreman sign it, date it, and, if you think under all this testimony that the statements and representations made are false or misleading, then you ought to find this verdict, 'We the jury find the defendant guilty.' If you think the Government has failed to carry the burden of showing that fact, then your verdict ought to be, 'We the jury find the defendant not guilty.'"

Mr. DAVIS. "Your Honor, will you charge the jury that if they find that any of the statements are false, they should find the defendant guilty? There are quite a number of statements on there. They wouldn't have to find all of them were false."

"Yes, any of the statements, gentlemen of the jury, which in this information are alleged to be false or misleading. It wouldn't be necessary to prove that every statement in the circular or every statement set out in the copy of the circulars or representations in this information is false or misleading, but it is necessary to find, in order for you to find the defendant guilty, that some statement copied in this information and alleged to be false or misleading is false or misleading."

The jury retired and after due deliberation returned a verdict of guilty, and the court sentenced the defendant to 6 months in jail and imposed a fine of \$1,000. On December 12, 1940, the court suspended the 6-months' jail sentence and placed the defendant on probation for 2 years.

**368. Misbranding of Dr. Burnham's San-Yak K-L-B Pills. U. S. v. Robert H. Lee (Lee Chemical Co.).** Plea of guilty. Sentence: 6 months' imprisonment which was suspended and defendant placed on probation for 2 years. Fine of \$100 also imposed. (F. D. C. No. 2106. Sample No. 5761-E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated below and falsely represented that it complied with the law.

On September 5, 1940, the United States attorney for the Eastern District of Michigan filed an information against Robert H. Lee, trading as Lee Chemical Co. at Birmingham, Mich., alleging shipment on or about March 15, 1940, from the State of Michigan into the State of Indiana of a quantity of the above-named product which was misbranded.

Analysis showed that the article contained extracts of plant drugs including cinchona, sandalwood, and a laxative drug, and compounds of magnesium, calcium, and iron.

The article was alleged to be misbranded in that representations in the labeling that it would be efficacious in establishing proper functioning of the kidneys and liver; that it would be beneficial in correcting rheumatism, sugar in the blood and high blood pressure; that it was an efficacious treatment and remedy for kidney, liver, and bladder disorders; that it would reduce sugar in the blood and urine, would relieve frequent urination, would alleviate aches and pains in the back and joints, and was efficacious in the treatment of constipation and piles; and that "each and all of the 15 ingredients used in the composition of the article were not misbranded within the meaning of the Pure Food and Drug Act," were false and misleading since the article would not be efficacious for the purposes claimed and was misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.

On November 29, 1940, a plea of guilty having been entered, the court imposed a fine of \$100 and sentenced the defendant to 6 months' imprisonment, which sentence was suspended for a period of 2 years and the defendant was placed on probation for the same period.

**369. Misbranding of Double Quick Liver Tablets, Compound Herb Tea, Blessed Herb Tea, Herb Wash, and St. Bernard Compound Herb Tea. U. S. v. Dr. Lynch A. Johnson.** Plea of guilty. Fine, \$1,500. Sentenced to 6 months' imprisonment in a jail or a Federal prison camp. (F. D. C. No. 2112. Sample Nos. 84175-D to 84183-D, incl., 84380-D, 84641-D, 84642-D, 84645-D to 84647-D, incl.)

These products were misbranded because of false and misleading representations in the labeling regarding their efficacy in the treatment of the ailments for which they were recommended; false and misleading representations regarding the efficacy of herbs in the treatment of a great number of ailments, including the most serious disorders; and in some instances because of false and misleading representations regarding their ingredients.

On October 8, 1940, the United States attorney for the Western District of Tennessee filed an information against Dr. Lynch A. Johnson, trading as Dr. Lynch A. Johnson, at Memphis, Tenn., alleging shipment within the period from on or about January 4 to on or about January 16, 1940, from the State of Tennessee into the States of Arkansas and Missouri of quantities of the above-named proprietary herb remedies that were misbranded.

Analyses of samples of each of the four shipments of Double Quick Liver Tablets showed the following facts: (1) tablets contained plant materials, including ginger and emodin-bearing drugs such as senna, aloe, and podophyllum; (2) tablets contained plant material, including aloe, podophyllum, emodin-bearing drugs such as senna and buckthorn, and calomel (slightly less than 1 grain per tablet); (3 and 4) tablets consisted essentially of plant material (including ginger, podophyllum, and a laxative plant drug such as senna), and unidentified cellular plant tissues.

The Double Quick Liver Tablets were alleged to be misbranded in that the statement "Active Ingredients: Buckthorn, Aloes, Mandrake, Senna," borne on the box, was false and misleading since it represented that buckthorn, aloes, mandrake, and senna were the sole active ingredients of the article, whereas the article in three of the shipments contained a material proportion of ginger