LABEL IN PART: "Model E Home Vibrator," "Wheat Germ Oil Hormones As found in Wheat," "Ver-A-Loe Ointment * * * Contains Aloe-plant substance * * * in a Petrolatum base," "Papaya Rica Made from fresh papayas * * * Contains the pulp and juice, inverted papaya syrup, honey, citric acid, lemon juice and natural flavor," and "Kuba Kup * * * Contents Papaya Juice Pineapple Juice Sugar and Lime Juice."

CHARGE: 502 (a)—the above-mentioned book accompanying the *Ver-A-Loe ointment*, *Papaya Rica*, and *Kuba Kup*, while such articles were held for sale, contained false and misleading representations that the *Ver-A-Loe ointment* was an adequate and effective treatment for stomach disorders, indigestion, gastritis, ulcers, piles and hemorrhoids, fistulas, tumors, cancer, kidney troubles, cataract, arthritis, external ulcers, stomach ulcers, colitis, diabetes, burns, bruises, sprains, boils, swelling of the joints, eczema, and athlete's foot, and that the *Papaya Rica* and *Kuba Kup* were adequate and effective treatments for stomach disorders, indigestion, gastritis, ulcers, kidney troubles, stomach ulcers, colitis, and eczema.

502 (f) (1)—the labeling of all of the articles failed to bear adequate directions for use for the purposes, conditions, and diseases for which they were intended, namely, (home vibrator) heart trouble, rheumatism, neuritis, constipation, arthritis, gallstones, gallbladder trouble, spleen and pancreas trouble, kidney trouble, headaches, and sinus trouble; (wheat germ oil) heart trouble and improving the functions of the male and female regenerative organs and glands; (Ver-A-Loe ointment) bursitis, hemorrhoids, heart conditions, and burns; (Papaya Rica) bursitis, headache, toothache, diabetes, and to build up the heart; and (Kuba Kup) bursitis and to build up the heart.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 10–8–57, and was concluded on the same day, with the return by the jury of a verdict of guilty.

On 10–11–57, the court sentenced the defendant to serve 1 year in jail and placed him on probation for 2 years, which was to begin at the end of the imprisonment.

5313. Micro-Dynameter device. (F. D. C. No. 36854. S. No. 87–417 L.)

QUANTITY: 1 device at Mount Vernon, Wash.

SHIPPED: 2–21–52, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "Model SA–1 Micro-Dynameter."

ACCOMPANYING LABELING: Bulletins and pamphlets entitled "Supplement to Micro-Dynameter Handbook Drugs," "Bulletin T–2 Operating Instructions Model "S" Micro-Dynameter," "New Science in Body Analysis The Micro-Dynameter," "Supplement Micro-Dynamics * * * Opinions . . . Statements . . . Clinical Notes * * * The main object," "Bulletin of the Micro-Dynameter * * * New Device Detects Hidden Disease," "Bulletin of Micro-Dynameter Research Association Devoted to Scientific Body Analysis No. 2–S," "Bulletin of Micro-Dynameter Research Association Devoted to Scientific Body Analysis No. 8, September 1946," "Bulletin of Micro-Dynameter Research Association For Improving Clinical Results No. 1 * * * June 1951," "Bulletin of Micro-Dynameter Research Association For Improving Clinical Results No. 7," "Bulletin of Ellis Research Laboratories, Inc. The Micro-Dynameter No. M–3 September 1946," "Bulletin of Ellis Research Laboratories, Inc. The Micro-Dynameter No. 11 September 1950," "Bulletin of Ellis Research Lab-

oratories, Inc. The Micro-Dynameter No. M–2 Re-issue Jan., 1951," "Journal of Micro-Dynameter Research No. J–3," "Journal of Micro-Dynameter Research No. J–4," "Journal of Micro-Dynameter Research No. J–5," "Journal of Micro-Dynameter Research No. J–6," "Journal of Micro-Dynameter Research No. J–7," "Book Review Number Micro-Dynameter News Vol. 1 Chicago July 1946 No. 1," "Supplement Micro-Dynamics * * * 1935 * * * Clinical Notes . . . Statements . . . Opinions * * * Results Count," and "Bulletin T–3 Operating Instructions Model "SA–1" Micro-Dynameter"

RESULTS OF INVESTIGATION: The device appeared to be essentially a galvanometer for measuring electrical currents and electrical potentials of small magnitude.

LIBELED: 6–29–54, W. Dist. Wash., libel amended 10–17–55.

CHARGE: 502 (a)—the labeling accompanying the device, when shipped, contained false and misleading representations that the device was effective for diagnosing acidosis, alkalosis, anemia, angina pectoris, arthritis, asthma, brain injury, brain tumor, cancer, cerebral palsy, cholecystitis, chronic bronchitis, colitis, convulsions, cystitis, diabetes, epilepsy, gallbladder, gallstones, gingivitis, hay fever, heart disease, hernia, hypertension, hypotension, impinged nerves, infantile paralysis, influenza, insanity, intestinal "flu," kidney disorders, leukemia, migraine headaches, neuritis, pyorrhea, rheumatism, sciatica, strep. infection, stomach ulcers, thyroid condition, tuberculosis, and uremia; that the device was effective for treating asthma, blindness, cancer, uterine hemorrhage, palpitation of the heart, anemia, diabetes, dyspnea, hypertension, impaired vision, paralysis, polyarthritis, sarcoma of the uterus, strep. infection, tuberculosis, and uric acidosis; that the *Micro-Dynameter device* would measure the results of treatment, show what is actually going on deep down in the tissues of the body, was an aid to more accurate disease analysis, was a precision instrument for new clinical measurements, would measure nerve and tissue changes, and would give readings over a diseased area proportional to the extent of the disease, and thus disease could be mathematically diagnosed; that the *Micro-Dynameter device* would locate within the human body the cause of disease, help point to the correct differential diagnosis, provide the ability to make an accurate prognosis, provide the practitioner with the ability to restore at least 90 percent of previously unhelped cases to health by following its indications, tell patients how sick they really were and whether they could get well, give instantaneously the state of health or disease within the body, and determine the patient's recuperative ability; and that the device was the most scientific analytical instrument, would locate the exact origin or focus of disorder via an electrical method which was ultramodern and 100 percent accurate, and was the greatest step forward toward getting sick people well since December 18, 1895; and 502 (f) (1)—the labeling of the device failed to bear adequate directions for use, and it was not entitled to any exemption from that requirement.

DISPOSITION: Ellis Research Laboratories, Inc., intervened in the case and filed an answer denying that the device was misbranded. Thereafter, upon motion of the parties, the United State District Court for the Western District of Washington entered an order on 3–15–55, removing the case for trial to the United States District Court for the Northern District of Indiana. Interrogatories were served upon the intervenor, and after objection to certain interrogatories had been sustained, answers to the remaining interrogatories were filed.

On 11–5–56, upon the consent of the parties that a condemnation decree might be entered without any adjudication as to any issue of fact or law, judgment of condemnation was entered and the court ordered that the device and accompanying labeling be turned over to the Department of Health, Education, and Welfare.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

5314. Elixir Sonidel, triple sulfa suspension, and elixir butabarbital sodium. (F. D. C. No. 39844. S. Nos. 30–398 M, 43–265 M, 43–305 M.)

INFORMATION FILED: 7–24–57, E. Dist. Mo., against Halitosine Co., t/a Allan & Co., St. Louis, Mo.

SHIPPED: Between 1–30–56 and 10–30–56, from Missouri to Tennessee.

LABEL IN PART: (Btl.) "One Pint Elixir Sonidel [or "Contents I Pint Triple Sulfa Suspension" or "One Gallon Elixir Butabarbital Sodium"] * * * Allan & Co., St. Louis, Mo."

CHARGE: *Elixir Sonidel.* 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess since the article contained more phenobarbital than declared on its label; and 502 (a)—the label statement "Each 5 cc contains: Phenobarbital * * * 16.20 mg." was false and misleading.

Triple sulfa suspension. 501 (b)—the article, when shipped, purported to be a drug, the name of which "sulfacetamide, sulfadiazine, and sulfamerazine suspension" is recognized in the National Formulary, an official compendium, and its strength differed from the official standard since it contained less than 90 percent of the labeled amounts of sulfacetamide, sulfadiazine, and sulfamerazine, the minimum permitted by the standard; and 502 (a)—the label statement "Each 5 cc Contains: Sulfadiazine .167 gms. Sulfamerazine .167 gms. Sulfacetamide .167 gms." was false and misleading.

Elixir butabarbital sodium. 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess since the article contained more butabarbital sodium than declared on its label; and 502 (a)—the label statement "Each 30 cc Contains * * * 0.2 gms. Sodium Butabarbital" was false and misleading.

PLEA: Guilty.

DISPOSITION: 9–20–57. $150 fine.

5315. First aid kits containing halazone tablets. (F. D. C. No. 39426. S. No. 51–900 M.)

QUANTITY: 818 *first aid kits*, each containing 1 bottle of *halazone tablets* at Denver, Colo.

SHIPPED: Between 1–26–56 and 5–10–56, from Tulsa, Okla.

LABEL IN PART: (Btl.) "100 Water Purification Tablets For Purifying Drinking Water In Canteens Halazone N. N. R. (P-sulfonedichloramidobenzoic acid) Each tablet contains 0.004 Gm. (1/16 grain) of Halazone with sodium carbonate, sodium chloride and boric acid."

RESULTS OF INVESTIGATION: Analysis showed that the tablets contained from 75 percent to 98 percent of the declared amount of halazone. The National

*See also Nos. 5301, 5320 (veterinary preparation).