

Formulary provides that halazone tablets contain not less than 90 percent of the labeled amount of halazone.

LIBELED: 8-23-56, Dist. Colo.

CHARGE: 501 (b)—while held for sale, the tablets purported to be and were represented as "Halazone Tablets," a drug the name of which is recognized in the National Formulary, an official compendium, and their strength differed from the official standard.

DISPOSITION: 2-8-57. Consent—claimed by Associated Traders, Inc., Denver, Colo. The bottles of *halazone tablets* were removed from the *first aid kits* and were destroyed.

5316. Clinical thermometers. (F. D. C. No. 39280. S. Nos. 51-556/7 M.)

QUANTITY: 1,469 *oral thermometers* and 358 *rectal thermometers* at Denver, Colo.

SHIPPED: Between 2-27-56 and 4-23-56, from Bronx, N. Y., by Dependable Thermometer Co.

LABEL IN PART: (Envelope) "Tested Clinical Thermometer Oral [or "Rectal"] Centigrade."

ACCOMPANYING LABELING: Leaflets designated "Certificate of Examination Fever Thermometer."

RESULTS OF INVESTIGATION: Examination revealed that 7 out of 24 oral thermometers and 3 out of 24 rectal thermometers failed to meet the labeled standard of accuracy and were not suitable for use as clinical thermometers because of faulty construction in that the gradation range was inadequate; there were too wide spaces between gradations; some had more than 5° C. per inch of scale; and some failed to retain pigment in markings when tested by recognized procedures.

LIBELED: 6-21-56, Dist. Colo.

CHARGE: 501 (c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess; and 502 (a)—the following statements in the labeling were false and misleading: "Tested" and "This Certifies that this registering clinical thermometer has been tested on the above date at 98°, 102°, and 106° F. or its equivalent in centigrade scale, and is correct within plus or minus .20° F. or .11° C. at any of these test points. The accuracy of this thermometer has been determined by testing and checking same with instruments tested by the National Bureau of Standards of the United States Dep't of Commerce, Washington, D. C."

DISPOSITION: 3-13-57. Default—24 thermometers of each type were turned over to the Food and Drug Administration and the remainder was destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

5317. Celluids. (F. D. C. No. 38958. S. Nos. 21-943/49 M, 21-951 M, 21-953 M.)

QUANTITY: 73 pkgs. at Seattle, Wash.

SHIPPED: Between 7-8-55 and 11-25-55, from Denver, Colo., by George Collingwood.

LABEL IN PART: (Pkgs.) "Celluids * * * Calcium Fluoride [or "Calcium Phosphate," "Calcium Sulphate," "Iron Phosphate," "Potassium Chlorid," "Sodium

*See also Nos. 5301, 5308, 5312-5314, 5316.

Chlorid," "Potassium Phosphate," "Potassium Sulphate," and "Sodium Sulphate"]."

ACCOMPANYING LABELING: Book entitled "Life Chemistry or the Healing Power of Nature Fifth Edition by George Collingwood, N.D., D.B.C., D.C."

LIBELED: On or about 2-20-56, W. Dist. Wash.

CHARGE: 502 (a)—the labeling accompanying the articles, when shipped, contained the following false and misleading representations:

1. That the *calcium fluoride* was an adequate and effective treatment for soft flabby muscles, broken down elastic fiber, enlarged heart, heart leakage, floating kidney, rupture, appendicitis, varicose veins, tumors, hardening of the arteries, hard knots on the mother's breast, hard tumors, high blood pressure, abscess, asthma, tired back, inability of the uterus to expel the fetus, corns, bunions, all hard and soft swellings, cough, diphtheria, gout, hard or soft glands, piles, pus, syphilis, diseased spine, vein enlargements, paralysis, and bladder and kidney stones;

2. That the *calcium phosphate* was an adequate and effective remedy for all chronic conditions of the human body, Bright's disease, consumption or TB, catarrh, anemia, asthma, brittleness of the bones, brain fag, scanty and salty milk, cancer, cataract, cholera infantum, weakness before and after childbirth, chronic diseases of all kinds, weariness, night sweats, epilepsy, gallstones, heart disease, paralysis, rheumatism, rickets, St. Vitus' dance, decayed teeth, toothache, typhoid, ulcers, whooping cough, yellow fever, and male and female disorders;

3. That the *calcium sulphate* was an adequate and effective remedy for cleansing the body, boils, carbuncles, abscesses, pimples, all pus conditions of the surface, inflamed bladder, pus in the urine, burns, colds, chickenpox, consumption, gonorrhoea, "gumboil," weakness of the liver and sickness of the stomach, sore throat, syphilis, ulcerated teeth, tonsillitis, ulcers that are not deep-seated, tubercular ulcers of the lungs, rheumatism, and cramps;

4. That the *iron phosphate* was an adequate and effective remedy for the blood stream, when there was a deficiency of iron phosphate, fever, congested conditions of any kind or place, such as an inflammation, coughs, colds, chills, pneumonia, abscess, high blood pressure, blood vessels that break easily, boils, inflammation of the brain, delirium during fevers, "wildness," meningitis, infantile paralysis, brain symptoms following fits of anger, Bright's disease, bronchitis, chickenpox, inflammation during or following labor, childbirth fever, cholera, delirium, diabetes, epilepsy, swollen, inflamed, painful glands, mild or severe inflammation, influenza, measles, inflamed nipples, piles, scarlet fever, sciatica, sleeplessness, smallpox, syphilis, yellow fever, paleness, anemia, and depression;

5. That the *potassium chloride* was an adequate and effective treatment for tonsillitis, scarlet fever, smallpox, measles, chickenpox, scalds, swollen conditions, chronic diseases in growing children, abscess, chilblains, Bright's disease, bronchitis, catarrh, croup, diabetes, epilepsy, diphtheria, any swollen gland, mumps, goiter, gonorrhoea, injuries, bruises, cuts, burns, pains in the liver, meningitis, pleurisy, pneumonia, scarlet fever, shingles, syphilis, whooping cough, yellow fever, and common sore throat;

6. That the *potassium phosphate* was an adequate and effective remedy for deficient brain power, nervousness, lack of energy, paralysis, palpitation of the heart, sleeplessness, insanity, abscess, anemia, asthma, blood poison of all

types where there is gangrene, Bright's disease, depression, irritability, brain fag, diphtheria, dizziness, epilepsy, fever, sluggish pulse, irregular palpitations, sinking spells, hemorrhage, hoarseness, hysteria, bronchitis, loss of voice, sciatica, spasms due to fright, spinal weakness caused by disease, syphilis, chancre, typhoid, wasting conditions, and whooping cough;

7. That the *potassium sulphate* was an adequate and effective preventive and remedy for clogging of the pores, hot, dry, and feverish condition, abscess, bronchitis, cancer, chickenpox, colds, colic, consumption, erysipelas, gonorrhoea, gleet, hoarseness, influenza, measles, pneumonia, scarlet fever, all skin diseases, smallpox, indigestion, syphilis, yellow fever, and to tone up the nerves;

8. That the *sodium chloride* was an adequate and effective remedy for dropsy, languidness, drowsiness, tearfulness, sadness, chilliness, hay fever, sunstroke, fresh colds, sneezing, anemia, green sickness, atrophy, bed-wetting, bites or insect stings, excessive urination, dry or watery constipation, brain and mental conditions, blues, wandering of the mind, stupor, sleepiness, melancholy, hopelessness, dejected spirits, gloomy thoughts, weariness, exhaustion, cancer, tumors, catarrh, chickenpox, colds, consumption, delirium, dropsy, fevers, gonorrhoea, hiccough, lockjaw, lumbago, bronchitis, mumps, stiff neck, piles, shingles, indigestion, sunstroke, sweats, vomiting, and whooping cough;

9. That the *sodium sulphate* was an adequate and effective remedy for cholera, chills, fever and ague, jaundice condition, yellow eyeballs, abscess, asthma, backache, bronchitis, catarrh, colic, consumption, diabetes, diarrhea, diphtheria, dizziness, erysipelas, "flu" or la grippe, ringworm, and typhoid fever and yellow fever.

DISPOSITION: 6-25-56. Default—destruction.

5318. Hoxsey treatment for internal cancer. Suit for injunction.

COMPLAINT FILED: On 7-9-57, Harry M. Hoxsey, Dallas, Tex., filed, in the District of Columbia, a complaint for preliminary injunction and permanent injunction against Marion B. Folsom, Secretary, Department of Health, Education, and Welfare, and George P. Larrick, Commissioner, Food and Drug Administration, to require the defendants to recall or modify the poster set forth below.

NATURE OF POSTER: The poster complained of is as follows:

PUBLIC
BEWARE!

WARNING AGAINST THE HOXSEY CANCER TREATMENT

Sufferers from cancer, their families, physicians, and all concerned with the care of cancer patients are hereby advised and warned that the Hoxsey treatment for internal cancer has been found worthless by two Federal courts. The Hoxsey treatment costs \$400, plus \$60 in additional fees—expenditures which will yield nothing of value in the care of cancer.

It consists essentially of simple drugs which are worthless for treating cancer.

The Food and Drug Administration conducted a thorough investigation of the Hoxsey treatment and the cases which were claimed to be cured. Not a single verified cure of internal cancer by this treatment has been found.

Those afflicted with cancer are warned not to be misled by the false promise that the Hoxsey cancer treatment will cure or alleviate their condition. Cancer can be cured only through surgery or radiation. Death from cancer is inevitable when cancer patients fail to obtain proper medical treatment because of the lure of a painless cure "without the use of surgery, x-ray, or radium" as claimed by Hoxsey.

Anyone planning to try this treatment should get the facts about it.

For further information write to:

U. S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Food and Drug Administration
Washington 25, D. C.

NATURE OF COMPLAINT: The complaint alleged that Defendant Larrick, during the fiscal year ending 6-30-57, arbitrarily, capriciously, without regard to plaintiff's rights, and without authority of law, caused the above poster to be issued and sent for display in thousands of public buildings throughout the United States; and that the Food and Drug Administration was without power to prepare, print, and distribute such a poster without an opportunity for plaintiff to be heard.

The complaint alleged also that the printing and distribution of the above poster violated plaintiff's constitutional right in that this was accomplished without according him a hearing, at which he could have established the falsity of the claims in the above poster; that the defendants exceeded their authority in planning, printing, and distributing the above poster without an investigation of the plaintiff and his treatment; that the defendants' action was in violation of the due process clause of the Constitution; that the defendants' acts were ultra vires, and beyond the scope of their authority authorized by law, as the law and the Constitution contemplate no condemnation of an accused without a trial, and no impairment of the rights of a citizen without a hearing; and the plaintiff had suffered irreparable injury.

DISPOSITION: Following the filing of the complaint, the plaintiff, on 8-1-57, filed a motion for a preliminary injunction and a motion for the appointment of a three-judge court to hear arguments on the constitutionality of Sections 705 (a) and (b).

On 8-8-57, a motion to dismiss and for summary judgment was filed on behalf of the defendants. The motion was based on the grounds that (1) the court was without jurisdiction, as the action was against the United States which had not consented to be sued or waived its immunity; (2) the complaint failed to state a claim in that it sought to enjoin the defendants from publishing statements in their official capacity as officers of the United States Government; (3) the warning was authorized by Section 705 (b); (4) the notice originally was published in the Federal Register on 4-7-56 and the poster was merely a condensation; (5) even if the poster were a libel, equity traditionally will not enjoin the publication of a libel, public officials are not liable to civil suit for presenting the facts about law enforcement litigation to the public in the course of their official duties, and a mandatory injunction should not issue to control discretionary actions of administrative officers pursuant to authority; and (6) the statements in the poster are true and accurate in all respects.

On 10-11-57, the motions came on for argument, after which the court handed down the following opinion:

HOLTZOFF, District Judge: "The Food and Drug Administration has issued a circular, copies of which are being posted in post offices throughout the country, warning the public that the so-called Hoxsey cancer treatment has been found worthless insofar as internal cancer is concerned. It also warns those afflicted with cancer not to be misled by the false promise that the Hoxsey cancer treatment will cure or alleviate their condition. This action is brought by Harry M. Hoxsey who claims to have treated patients afflicted with cancer, to enjoin the Secretary of the Department of Health, Education and Welfare, and the Commissioner of the Food and Drug Administration, against the dissemination of this circular.

"The defendants claim that they are acting pursuant to the authority of the United States Code Title 21, Section 375 (b) which reads as follows:

The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Agency.

"The plaintiff claims that this statute is unconstitutional and moves that a three-judge court be convened. He has also moved for a preliminary injunction. On the other hand the defendants move for summary judgment dismissing the complaint on the merits. The motions have been heard jointly.

"It is claimed in behalf of the plaintiff that the statute to which reference has just been made is unconstitutional as a denial of due process of law in that it does not provide for any notice or hearing, administrative or otherwise, before the Secretary disseminates information of the type described in the statute. It is elementary law, of course, that an order of an administrative agency adjudicating rights or directing someone to do or refrain from doing something must be based on a hearing after due notice. Here, however, the situation is entirely different. The defendants have made no order; they are adjudicating no rights; they are issuing no directions. What they are doing is disseminating information and warning the public against the use of certain medicines and of a certain treatment for internal cancer. There is no basis for requiring a hearing before information can be disseminated.

"But beyond that, even in the absence of this statute there would be nothing to prevent the defendants from disseminating information to the public. For example, only recently certain public officials have been urging the public to use a certain inoculation for poliomyelitis. The defendants are performing a public duty when they are urging the use of certain treatments. The only purpose of this statute is to place within the express scope of the duties of the Secretary something that was one of his implied functions.

"If, however, the contents of the circular were erroneous, then the question might arise whether they were libelous. It is a well-settled rule of equity that equity does not enjoin a libel or slander, and that the only remedy for libel or slander is an action for damages if the libelous character of a statement to which objection is made can be established. One of the leading cases on this point is the well-considered opinion of the Circuit Court of Appeals for the Second Circuit in *American Malting Company vs. Keitel*, 209 Fed. 351. Naturally in a libel suit the question would arise whether there is absolute or conditional privilege, and those questions are not before the court at this time.

"A three-judge court may not be convened merely because a constitutional question is raised in an action for an injunction and a preliminary injunction is applied for. The constitutional question must be a substantial one.

"The Court is of the opinion, for the reasons just stated, that there is no substantial constitutional question presented in this case, first, because the statute involved is obviously constitutional; and, second, because the question of constitutionality of that statute hardly arises since the defendants could disseminate information even without statutory authority.

"The Court will therefore deny the motion for the convening of a three-judge court and will grant the motion of defendants for summary judgment."

Appropriate orders were entered by the court.

5319. Neu-Clear Therapy Electronic Condensator (2 seizure actions). (F. D. C. Nos. 39643, 39644. S. Nos. 19-508/9 M.)

QUANTITY: 2 devices and various accessories at Portsmouth and New Boston, Ohio.

SHIPPED: 12-12-55 and 1-1-56, from Detroit, Mich., by Colo Products, Inc.

LABEL IN PART: (Device) "Neu-Clear Therapy Electronic 'Condensator' Generating 'Fluid' Electricity."

ACCOMPANYING LABELING: Booklet entitled "Holder's Electronic High-Frequency Condensator Operating Instructions."

RESULTS OF INVESTIGATION: The device consisted of an electronic, high-voltage oscillator and a group of glass electrode applicators. The electrodes were gas-filled and produced a glow discharge during application. The radio frequencies emanating were of such low power and low frequency as to have negligible absorption in the body.

LIBELED: 10-23-56, S. Dist. Ohio.

CHARGE: 502 (a)—the labeling accompanying the device, when shipped, contained false and misleading representations that the device was effective for locating trouble areas and toxic conditions and for determining the seriousness of the conditions; for treating all body ailments, including ailments of the eyes, ears, throat, tonsils, teeth, face, heart, lungs, liver, gallbladder, kidney, pancreas, spleen, stomach, bowels, anus, rectum, breasts, ovaries, uterus, vagina, cervix, brain, and frontal sinus; and for treating abscess, anemia, arthritis, rheumatism, paralysis, hay fever, hemorrhoids, varicose veins, leg ulcers, multiple sclerosis, mucous colitis, malnutrition, pain, influenza, indigestion, head noises, and allergic conditions due to a large variety of products.

DISPOSITION: 11-30-56. Default—destruction.

DRUG FOR VETERINARY USE

5320. King Castle Complete Minerals. (F. D. C. No. 40080. S. No. 56-719 M.)

QUANTITY: 77 50-lb. bags at Lancaster, Wis.

SHIPPED: 2-21-56, from Marion, Iowa, by Marion Feed Center.

LABEL IN PART: (Bag) "King Castle Complete Mineral * * * 1,000,000 U. S. P. Units of Vitamin D₂ Packed in Each 100 Lbs."

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 50 percent of the declared amount of vitamin D₂.

LIBELED: 4-12-57, W. Dist. Wis.

CHARGE: 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess; and 502 (a)—the label statement "1,000,000 U. S. P. Units of Vitamin D₂ Packed in Each 100 Lbs." was false and misleading.

DISPOSITION: 5-9-57. Default—consumption by animals.