"Appellants complain that the attitude of the court was prejudicial. The court evidenced some lack of patience, as we read the record, against both sides. No objections were interposed. We think the impatience exhibited was not of a degree sufficient to constitute reversible error.

"They also complain of the cross-examination on immaterial matters. This amounts to nothing.

"In their brief under the subheading 'The court erred in refusing to permit appellants to prove various facts to show their good faith,' we have examined the claim and the argument and find no error.

"Appellants complain that the testimony of a Mr. Everett and of a Mr. Baumgartner was unduly limited upon objections that the questions call for the witnesses' conclusions. We agree but think the error inconsequential in the circumstances. It appears that counsel for defendants voluntarily abandoned the subject.

"Appellants sought to show they were wrongfully prevented from showing that the public was not misled by their advertisements. There is nothing to the point.

"Appellants claim that the third count is bad as being duplicitous. Upon authority of Weeks v. United States, 445 US 618, and United States v. Swift, 188 Fed. 92, we hold that the third count of the information is not duplicitous. In the latter cited case it is said, 'Duplicity in an indictment means the charging of more than one offense, not the charging of a single offense committed in more than one way. Duplicity may be applied only to the result charged, and not to the method of its attainment.'

"The government insists that there is substantial, even conclusive, evidence to support the conclusion that each package of drugs referred to in count III did not bear an accurate statement of the quantity of the contents in terms of weight or measure and that the verdict must stand as to this count upon that evidence alone. But the issue of guilt or innocence upon each separate count was submitted to the jury upon all of the material evidence relevant to each count. We have seen that reversible error was committed in the admission of evidence relative and material to count III and a verdict of guilty was returned. In these circumstances we cannot speculate as to whether the guilt was premised upon one or the other or upon all of the allegations contained in this count. Evidence was offered by appellants to show that any failure upon their parts to properly designate the amount of contents on labels used as charged in count III was accidental or by mistake of another. Upon objection that the evidence was immaterial, the court denied its reception.

"The instructions to the jury are in accord with the government's contention that no intent is necessary to a conviction upon the applicable statute and that no explanation of accident or mistake in any way affects the guilt or innocence of the accused. This subject is inadequately treated in the briefs, and since the judgments must be reversed upon the errors occurring during the examination of Dr. Von Hoover, we do not pass upon it.

"Reversed."

On October 7, 1943, the case was remanded for retrial and on December 10, 1943, the defendants entered pleas of nolo contendere. On December 23, 1943, the court imposed the same sentence upon the defendants that it had originally imposed.

1041. Misbranding of Vitaminerals VM No. 1, VM No. 150, VM 100, VM 120, and VM No. 204 Pneumatic Dilator. U. S. v. John Francis Gorman (Vitaminerals Co.). Plea of nolo contendere. Fine, $1,000 on 2 counts, and probation for 1 year on 3 counts. (F. D. C. No. 8791. Sample Nos. 81451–E, 81453–E to 81455–E, incl.)

On April 30, 1943, the United States attorney for the Southern District of California filed an information against John Francis Gorman, trading as the Vitaminerals Co., Los Angeles, Calif., alleging shipment on or about May 5, 1942, from the State of California into the State of Colorado of a quantity of the above-named products which were misbranded.

Examination of Vitaminerals VM No. 1 disclosed that this article was in the form of orange-colored tablets containing a large proportion of rhubarb root tissues together with Irish moss tissues (Chondrus), okra tissues, cranberry fruit tissues, parsley leaf tissues, and acid-insoluble material. It was alleged to be misbranded in that the statements in its labeling which created in the mind of the reader the impression that the article was a supplement in the dietary treatment of constipation; that the ingredient rhubarb root was a food; and that the article derived its physiological activity principally from concentrates and extracts from common vegetables used for food purposes, and from vitamins, were misleading since the article was not a supplement in the dietary treatment

of constipation, but was a laxative drug; the ingredient rhubarb root is not a food but is a drug; and the article did not derive its physiological activity principally from concentrates and extracts from common vegetables used for food purposes, and from vitamins, but derived its physiological activity principally from the plant drug rhubarb. It was alleged to be misbranded further (1) in that the statements in its labeling which represented and suggested that the article would be efficacious as a dietary treatment of constipation; that it possessed anti-infective value; that it would be an efficacious tonic treatment for the smooth muscle; that it would facilitate the changing of the colonic flora so as to reduce the colonic bacilli count and the resulting inflammation of the colonic mucosa; that it would promote peristaltic activity, and act practically in the treatment of constipation; that it would produce normal elimination; that it would be efficacious in the primary treatment of hemorrhoids; and that it would be efficacious in the secondary treatment of arthritis due to excess calcium, and arthritis due to systemic origin, colds, neuralgia, neurosis, obesity, and tonsilitis were false and misleading since the article would not be efficacious for the purposes recommended or accomplish the results claimed; (2) in that the name "Vitamineral" was misleading since the name suggested and created the impression in the mind of the reader that the article derived its physiological activity solely from vitamins and minerals and contained no other physiologically active ingredient, whereas the article contained rhubarb root, from which it derived its principal physiological activity; and (3) in that the statements in its labeling, "Ash (Mineral matters*) 22.20%," and "Mineral Matter includes: Calcium 2.18% Phorphorus 0.84% Potassium 1.15% Sodium 0.67% Magnesium 0.34% Chlorine 0.03% Sulphur 0.51% Manganese 0.0023% Iron 0.115% Copper 0.0013% Iodine 0.002%," were misleading since those statements suggested and created the impression in the mind of the reader that the article contained the minerals listed therein in amounts which, when taken in accordance with directions on the label, "Two to four tablets, one or two before breakfast and upon retiring," would furnish the minerals in quantities sufficient to contribute in an important respect to the daily requirements of the body for those minerals, whereas the article, when taken according to the directions, would not furnish such quantities of the minerals because the article contained inconsequential amounts of potassium, sodium, chlorine, magnesium, sulfur, manganese, and copper; and 4 tablets, the maximum amount recommended in the directions, would furnish less than one-thirtieth the minimum daily requirement of the body for phosphorus, less than one-tenth the minimum daily requirement for calcium, less than one-fifth the minimum daily requirement for iodine, and less than one-third the minimum daily requirement for iron.

Analysis of Vitaminerals VM No. 150 showed that it consisted of a brownish-yellow, perfumed ointment containing benzocaine. It was alleged to be misbranded (1) in that the statements in its labeling, "fortified with 8% Benzocaine Benzoate and Benzocaine," were false and misleading since the article contained no benzocaine benzoate and not more than 5.19 percent of benzocaine; (2) in that the statements in the labeling which represented and suggested that the article would be efficacious in the treatment of skin conditions, wounds, burns, hemorrhoids, ear infections, and tetany were false and misleading since the article would not be so efficacious; and (3) in that the name "Vitaminerals" was misleading since that name suggested and created the impression in the mind of the reader that the article derived its physiological activity solely from vitamins and minerals, whereas it derived its physiological activity from the physiologically active drug benzocaine.

Examination of the Pneumatic Dilator disclosed that this device was composed of 2 red rubber bulbs connected to each other through a one-way valve, and then through a foot of black rubber tubing to a steel tube partly covered with soft white rubber. This steel tube was equipped with a protective hard rubber or plastic cap at one end and a hard rubber or plastic, flanged shield near the other end in such a manner that the intervening portion of steel tubing was completely covered with the soft white rubber. This rubber covering could be inflated to a diameter of at least 2 inches by squeezing the first rubber bulb several times. The second rubber bulb produced a further inflation when compressed and was equipped with a release valve allowing for complete deflation when desired. The device was packed in a box containing 1 dozen white rubber finger cots and 1 jar of VM No. 150. The device was alleged to be misbranded because of the false and misleading statements in its labeling which represented and suggested that the device would be an efficacious and appropriate treatment for external and internal hemorrhoids, thrombotic type of simple varicosities with or without ulceration, prolapsed varicosities, benign

anal strictures, post-operative or post-injection strictures, spastic anal sphincters associated with inflammatory conditions of the intestinal tract, and with fissures, cryptitis, anal ulcers, anal excoriations, anal dermatosis, neurological conditions, genito-urinary conditions (prostatitis, uterine retroflexion, cervicitis, endometritis), pruritis and associated conditions, spastic constipation, also vaginismus, vaginodynia, prostatic disorders, spastic sphincters, proctitis, and other pathologies of the anorectal region; that the device was rapidly supplanting manual dilation, divulsion, and the use of solid or semi-solid dilators and digital prostatic massage; that the device would eliminate many unsatisfactory operations which are painful and injurious to inflamed tissues; that it would be efficacious to increase local metabolism and neuromuscular function; that it would bring about rapid healing, and would help progressively to re-establish normal physiological action in the rectum, anus, and contiguous structures; and that it would be an efficacious and appropriate treatment or prevention of nervous headaches, spastic colitis, low back pain or lumbago, biliousness, indigestion, dysmenorrhea, sciatica, lumbo-sacral soreness, nervousness, and neurasthenia.

Analysis of Vitaminerals VM 100 Vaginal Suppositories disclosed that the article consisted of plain gelatin capsules containing a mineral substance composed largely of sulfate, aluminum, acid-insoluble matter, and ferric iron, along with a small amount of ferrous iron and a possible trace of phosphate. It was alleged to be misbranded in that the statement in its labeling, "containing ferric sulfate, ferrous sulfate, and ferric phosphate," was false and misleading since it represented and suggested that the article contained significant amounts of ferric sulfate, ferrous sulfate, and ferric phosphate, and that it contained no aluminum sulfate, whereas the article contained no ferric sulfate or ferrous sulfate, and an insignificant proportion of ferric phosphate, and did contain a material amount of aluminum sulfate. It was alleged to be misbranded further because of false and misleading statements in its labeling which represented and suggested that the article would be efficacious to produce toning and granulation of new tissues; that it would cause pathological tissue to slough with every indication of a natural reaction, leaving no scar tissue; that it was an efficacious and appropriate treatment for endocervicitis, endometritis, vaginitis, polypus–vaginal and uterine, cysts, leucorrhea, dysmenorrhea, and amenorrhea; that it would be efficacious in the treatment of abnormal tissue growths; that it would be an efficacious and appropriate treatment in cases of hemorrhage; and that it was an efficacious and appropriate primary treatment for uterine cramps, dementia, and deficient menstruation.

Analysis of Vitaminerals VM 120 disclosed that it consisted of an acidic, aqueous solution containing sulfate, aluminum, glycerin, ferric iron, and a trace of ferrous iron. It was alleged to be misbranded in that the statements in its labeling, "An Astringent and detergent liquid concentrate containing Ferric Sulphate derived from natural sources," and "Ferric Sulphate, Ferrous Sulphate and Ferric Phosphate," were false and misleading, since those statements represented and suggested and created the impression in the mind of the reader that the article contained ferric phosphate and derived its astringent properties solely from ferric sulfate, ferrous sulfate and ferric phosphate, whereas the article contained little, if any, ferric phosphate, and did not derive its astringent properties solely from ferric sulfate, ferrous sulfate and ferric phosphate, but did contain a large amount of aluminum sulfate, from which its astringent properties were largely derived. It was alleged to be misbranded further because of false and misleading statements in its labeling which represented and suggested that the article would be efficacious to build tone and resistance to infection; that it would produce results in various colon disorders, and would combat colitis and other complicated diseases; that it would be efficacious in the treatment of stomatitis, tonsilitis, and kindred infections of the throat, pyorrhea and trench mouth; that it would be efficacious as a nasal douche in the treatment of nasal congestion, head colds, sinus, and like infections; that it would be efficacious as an eye wash to produce a soothing and healing action on the delicate membrane of the eye; that it would be efficacious in the prophylaxis of pterygium and in the treatment of local infections of the ear canal, cuts, sores, open wounds, ulcers, burns, and similar conditions, indicated by the abbreviation "etc."; that it would be efficacious in relieving inflammation, reducing pain, and restoring normal tissues in hemorrhoid cases, and would bring prompt relief and promote rapid healing in gastric ulcers; that the article would serve as a general body tonic; that it would be efficacious when administered orally in the primary treatment of albuminuria, anemia, cramps, diarrhea, enteritis, excessive men-

struation, gastritis, uterine hemorrhage, influenza, intestinal disorders, kidney disorders, kidney inflammation, disorders of the liver, such as catarrhal gall ducts, cirrhosis (alcoholic) and enlargement, malaria, nausea and vomiting, orchitis, lack of resistance, tentany, duodenal, gastric, stomach, and peptic ulcers, intestinal ulcers, and tape and helminth worms; that it would be efficacious when used topically in the primary treatment of acne, boils, exzema, empyema, and hives; that the article would be efficacious in the primary treatment by pack method of hemorrhages, including uterine hemorrhages; that it would be efficacious, when used as directed, in the primary treatment of ameba, amenorrhea, calcium in lenses, catarrh, corneal ulceration, uterine cramps, cystitis, dysmenorrhea, ear infections, endocervicitis, endometritis, eye infections, fistula, hemeralopia, impetigo, keratomalacia, laryngitis, leg ulcers, leukorrhea, excessive, deficient and painful mentruation, miscarriage, opthalmia, vaginal and uterine polypus, rectal polypus, prostatitis, proctitis, psoriasis, respiratory infections, shingles, skin disorders, sty, loose teeth, uterine prolapse, vaginitis, varicose ulcers, varicose veins, and xerophthalmia; and that it would be efficacious, when used orally, in the secondary treatment of acidosis, alcoholic neuritis, ameba, angina pectoris, asthenia, asthma, boils, Bright's disease, calculi of the bladder and kidneys, faulty digestion, eczema, gall bladder inflammation, gallstones, gastro-intestinal disturbances, hay fever, hemophilia, biliary stasis of the liver, engorgement and jaundice of the liver, lymph infections, mal-petit-grand, malnutrition, nausea and vomiting of pregnancy, neurasthenia, old age, septicemia, and tuberculosis.

All of the articles were alleged to be misbranded further in that the statement in their labeling, "We hereby guarantee that all Vitamineral products listed herein are not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act of June 25, 1938," was false and misleading, since the articles were misbranded within the meaning of that Act.

The information alleged in count 1 that the product "Vitaminerals VM No. 1" was also misbranded under the provisions of the law applicable to foods, reported in notices of judgment on foods.

On September 27, 1943, the defendant having entered a plea on nolo contendere, the court imposed fines of $500 on count 1 of the information, which involved charges against the Vitaminerals VM No. 1 both as a food and a drug, and $500 on count 3, which involved the drug Vitaminerals VM No. 150, and placed the defendant on probation with respect to the remaining 3 counts which involved the other products.

1042. Misbranding of Cel-Bio Mineral Tablets, Nos. 1 to 12, incl. U. S. v. Fred N. Haas (Cel-Bio Mineral Food Co.). Plea of guilty. Fine, $90 and costs. (F. D. C. No. 8790. Sample Nos. 73341–E to 73351–E, incl., 73558–E to 73564–E, incl.)

On May 12, 1943, the United States attorney for the District of Nebraska filed an information against Fred N. Haas, trading as the Cel-Bio Mineral Food Co., Omaha, Nebr., alleging that he had shipped, on or about May 7 and 8, 1942, from the State of Nebraska into the State of Iowa, quantities of Cel-Bio Mineral Tablets Nos. 2, 3, 4, 5, 8, 9, and 11, which were misbranded; and that within the period from on or about October 1 to 22, 1941, the defendant had repacked and relabeled quantities of Cel-Bio Mineral Tablets Nos. 1, 2, and 3, and Nos. 5 to 12, inclusive, while they were being held for sale after shipment to him in interstate commerce from the State of Illinois into the State of Nebraska, which acts by the defendant resulted in the misbranding of the products.

Analysis of the No. 9 Tablets showed that they consisted essentially of lactose containing a minute amount of sodium chloride. They were alleged to be misbranded because of false and misleading statements in their labeling which represented and suggested that the tablets would enable one to wake up in the morning with pep; and that they were efficacious in the cure, mitigation, treatment, or prevention of sneezing, water discharge from the eyes, nose, or any part of the body, hay fever, rose fever, vomiting of water and mucus, water blisters on the skin, diarrhea, slimy, transparent stools, inflammation of the eyes, a salty taste in the mouth, periodical pains, drug poisonings, drug habits, painful swellings of the ankles or legs, dropsy, dandruff, dry skin, cold sores, and catarrh with watery discharge.

Analysis of the No. 8 Tablets showed that they consisted essentially of lactose containing a minute amount of magnesium phosphate. They were alleged to be misbranded because of false and misleading statements in their labeling which represented and suggested that the tablets would relax the nerves, relieve pain