contained less than 3 grs. of sodium-5-ethyl-secondary butyl barbiturate (brand of butabarbital sodium); 502(d)—the article contained butabarbital sodium, a derivative of barbituric acid, which had been found to be, and by regulations designated as, habit forming; and the label failed to bear the quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; and 503(b)(4)—the article was a drug subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

PLEA: Guilty.

DISPOSITION: 6-27-58. The sentence against the partnership was suspended, and a fine of $1,000, plus costs, was imposed against the individual.

5486. Arben capsules. (F.D.C. No. 40531. S. Nos. 65-351/5 M.)

QUANTITY: 1 bag containing 3,200 capsules, and 83 42-capsule boxes at Youngstown, Ohio, in possession of Dr. R. J. Turner and Fred C. Bennett.

SHIPPED: Between 12-31-56 and 4-18-57, from Miami Beach, Fla., by Arthur Bennett.

RESULTS OF INVESTIGATION: The capsules in the boxes had been shipped in bulk, and after receipt by the consignee, were repackaged. Various lots of the capsules, when shipped, were labeled as containing amphetamine sulfate in amounts ranging from 1.2 mg. to 5 mg. per capsule.

Examination showed that the capsules contained from 164 percent to 204 percent of the declared amount of amphetamine sulfate per capsule.

LIBELED: 7-24-57, N. Dist. Ohio.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess.

502(b)(1) and (2)—while held for sale, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; 502(e)(2)—the label of the article, while held for sale, failed to bear the common or usual name of each active ingredient; and 503(b)(4)—the article was a drug subject to 503(b)(1), and, while held for sale, its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 10-23-57. Default—destruction.

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

5487. Theraphone device and methyl salicylate ointment. (Inj. No. 315.)

COMPLAINT FOR INJUNCTION FILED: 10-10-57, N. Dist. Ill., against Neo-Sound Corp. of America, Wheeling, Ill., and William Dunkler, t/a Wm. Dunkler Laboratories, Chicago, Ill.

ACCOMPANYING LABELING: Leaflets entitled "Theraphone the Neo-Sound Instrument that can help you"; typed sheet bearing the Neo-Sound Corp. of America letterhead and a heading containing the words "Here's what Theraphone owners say"; leaflets entitled "Instructions for the Use of the Theraphone," "New Professional Model Theraphone . . . Dear Doctor," and "Letters of Satisfaction from Hospitals, Clinics and Doctors who have Used the Neo-Sound Instrument for some time"; form letter headed "Dear Doctor"; general "Out-Lay" chart showing location of areas of the human body where treatments should be applied; leaflet headed "Dear Doctor"; sheet headed "Direc-

tions"; pamphlets entitled "Naturopathic Medical Journal * * * of the Florida Naturopathic Physicians' Association Inc. Fall Issue Vol. 2 No. 1" and "Naturopathic Medical Journal * * * of the Florida Naturopathic Physicians' Association Inc. Winter Issue Vol. 2 No. 2"; and a sheet entitled "Selling Points for the Sale of the Professional Model Theraphone."

RESULTS OF INVESTIGATION: The device consisted of 2 models. One model was designated as a professional model, which was encased in a cylindrical-shaped, polished aluminum unit measuring approximately 7½ inches long by 1¾ inches in diameter and which had three sound heads for varying degrees of penetration and a push-button micro switch. The second model was similar to the professional model, but it was smaller in size and was encased in a plastic unit. Both models were operated by house current and had a rubber electric cord attached, with a common male plug. Each model purported to be an electrically operated massage vibrator which would produce sound waves of various frequencies.

CHARGE: The complaint charged that the defendants were violating the Act by causing the introduction and delivery for introduction into interstate commerce of *methyl salicylate ointment* and the *Theraphone device* which were misbranded as follows:

Methyl salicylate ointment. 502(b)(1)—the label of the article failed to bear the name and place of business of the manufacturer, packer, or distributor; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use, in that the labeling failed to bear any directions for use.

Theraphone device. 502(a)—the labeling of the article when viewed as a whole, as well as through specific claims, and in the setting in which it was presented, contained false and misleading representations that the action of the article was markedly different from the action of ordinary massage vibrators and that the article was adequate and effective in the treatment of arteriosclerosis, arthritis, muscular rheumatism, gout, inflammation of the muscles, gallbladder inflammation, gastritis, constipation, neuritis, migraine headache, facial palsy, neuralgia, sciatica, bursitis, muscular atrophy, hemorrhage, menstrual cramps, tonsillitis, sore throat, sinus conditions, head colds, cystitis, urethritis, prostatitis, aching feet, congestion, impaired blood circulation, and all ailments of an inflammatory or circulatory nature.

The complaint charged further that if the defendants were forced by injunction to refrain from using the above labeling on interstate shipments of the device, the defendants would not discontinue interstate distribution of the device but would, unless enjoined, continue to ship the device in interstate commerce without labeling stating the conditions and purposes for which the device was intended, namely, for the treatment of the above-mentioned diseases and conditions. In such case, the device would be misbranded within the meaning of 502(f)(1), in that its labeling would fail to bear adequate directions for use, because of the omission from the labeling of statements of the conditions and purposes for which the device was intended.

The complaint alleged also that the defendants had been warned by the Food and Drug Administration through establishment inspections made on March 16 and 18, September 16, and October 13, 1955, and June 17 and 19, 1957; by letters dated June 7, 1955, and February 8 and June 26, 1956; by a conference held on June 16, 1955; and by hearings held on January 19 and February 9, 1956, pursuant to Section 305, that the device was misbranded by reason of its false and misleading labeling, and that despite such warnings,

the defendants continued to introduce and deliver for introduction into interstate commerce the misbranded device.

DISPOSITION: 12–27–57. The defendants having consented, the court entered a decree of permanent injunction enjoining them against the acts complained of.

5488. Schramm's massage brushes, Diamix devices, and Model B–50 generators and B–50 cabinets. (F.D.C. No. 41301. S. Nos. 72–295/7 M.)

QUANTITY: 54 Schramm's *massage brushes*, 3 *Diamix devices*, and 4 *Model B–50 generators* and 5 *B–50 cabinets* at Hinsdale, Ill., in possession of Midwest Imports.

SHIPPED: Between 10–10–55 and 9–17–57, from Germany.

ACCOMPANYING LABELING: (Schramm's massage brush) leaflets entitled "Schramm's Massage Brush Ideal M.I."; (Diamix device) reference sheets entitled "Illinois Masonic Hospital Association," leaflets entitled "Diamix The Universal Apparatus," and a number of sheets entitled "Indications for the Helio-Therapy with Diamix"; and (Model B–50 generator and B–50 cabinet) booklets entitled "Praktische Erfahrungen," leaflets entitled "Statement—Alexian Brothers Hospital," and reprints entitled "Infrared Radiation Baths Protect Your Health."

RESULTS OF INVESTIGATION: Examination showed that the *Schramm's massage brush* was a rubber brush with a varnished wooden handle (de luxe model) or with a plain wooden handle (economy model); that the *Diamix device* was a radiant lamp with a wire-wound infraheat element and 5 interchangeable bulbs of different colors for ultraviolet, neon, red, blue, and green radiation, and with a fixed infrared emitter; and that the device, consisting of the *Model B–50 generator* and *B–50 cabinet*, comprised a cabinet, heater, and stool. The cabinet was covered with imitation leather, was heat and waterproof, with a steel spring inlayer, and was lined with reflective material. It had a top closure and floor cover of imitation leather and a thermometer for reading temperature. The cabinet weighed about 8 lbs., was 42 inches high when set up, and had a 10-inch radius when rolled. The heating unit was a nonglowing generator of rustproof metal, operated by an off-on switch inside the cabinet. The stool had a seat of plastic upholstery, was 12 inches in diameter, and had black, plastic-tipped legs.

The accompanying labeling of the articles, consisting of the above-mentioned booklets, was obtained by the consignee from Germany, and the other items of accompanying labeling were printed locally for the consignee.

LIBELED: 12–26–57, N. Dist. Ill.

CHARGE: *Schramm's massage brush.* 502(a)—while held for sale, the accompanying labeling of the article contained false and misleading representations that the article would be effective in the treatment and prevention of degenerative diseases, such as heart affections, rheumatism, sciatica, and circulation troubles; that it would stimulate the inner organism; that it would expedite skin regeneration; that it would help procure youthful complexion; that it would prevent debilitation of the back; and that it would strengthen nerve fibers of the spine.

Diamix device. 502(a)—while held for sale, the accompanying labeling of the article contained false and misleading representations that the colors of the visible spectrum (neon, red, blue, and green), which were provided by the article, had therapeutic value, and that those colors, together with the ultra-