

tronic Laboratory Analysis Rates: Numerically Arranged" and "Electronic Analysis," accompanying said device, contained statements which represented and suggested that said devices were capable of diagnosing and treating disease conditions of the brain, tonsils, prostate, spinal cord, trachea, lungs, kidneys, stomach, heart, liver, bones, eyes, and numerous other disease conditions, which statements were false and misleading since said devices were not capable of diagnosing and treating any disease conditions; and the devices were misbranded within the meaning of 502(f) (1), in that the labeling of said devices failed to bear adequate directions for use for the purposes for which they were intended, namely, for the diagnosis and treatment of disease in man and for the use of said *Radioclast Model 40* as a food tester and diet selector, in that said devices were worthless for use for such purposes, and adequate directions cannot be given for the use of said devices for such purposes.

The complaint charged also that when the *Electron-O-Ray Model 46* device, in a new, used, or repaired condition, was caused to be introduced and delivered for introduction into interstate commerce, the device was misbranded within the meaning of 502(a), in that its labeling, namely, pamphlets entitled "Manual Electron-O-Ray Model 500," accompanying said device, contained statements which represented and suggested that said device was capable of diagnosing and treating disease conditions of the uterine cervix, appendix, thyroid, testes, ovaries, mammary glands, lungs, kidneys, stomach, heart, liver, ears, eyes, teeth, brain, blood, and other disease conditions of the organs of the body, which statements were false and misleading since said device was not capable of diagnosing and treating such disease conditions and was worthless for any medical purpose; and the device was misbranded within the meaning of 502(f) (1), in that the labeling of said device failed to bear adequate directions for use for the purposes for which it was intended, namely, for the diagnosis and treatment of disease in man and for use as a food tester and diet selector, in that said device was worthless for use for such purposes, and adequate directions cannot be given for the use of said device for such purposes.

The complaint charged also that when the *Electron-O-Ray Model 51*, in a new, used, or repaired condition, was caused to be introduced and delivered for introduction into interstate commerce, the device was misbranded within the meaning of 502(f) (1), in that its labeling failed to bear adequate directions for use for the purposes for which it was intended, namely, for the diagnosis and treatment of disease in man, in that said device was worthless for use for such purposes, and adequate directions cannot be given for the use of said device for such purposes.

The complaint charged also that when the *Quto-Electronic Instrument Model 0-20-1 P*, in a new, used, or repaired condition, was caused to be introduced and delivered for introduction into interstate commerce, the device was misbranded within the meaning of 502(f) (1), in that its labeling failed to bear adequate directions for use for the purposes for which it was intended, namely, for the diagnosis and treatment of disease in man, in that said device was worthless for use for such purposes, and adequate directions cannot be given for the use of said device for such purposes.

The complaint alleged also that the defendants had been warned on several occasions that the devices were worthless, by various seizure actions between 1958 and 1961.

DISPOSITION: 4-18-62. The defendants consented to the entry of a decree but denied the allegations. The decree which was entered perpetually enjoined the defendants, their officers, agents, servants, employees, representatives, and

all and any persons in active concert or participation with them from directly or indirectly introducing or causing to be introduced and delivering or caused to be delivered for introduction into interstate commerce, and more particularly, from delivering or causing to be delivered to customers and other persons living outside the State of Ohio for transportation in interstate commerce, the devices, whether new, used, or repaired, designated as *Neurolinometer*, *Radioclast Model 40*, *Radioclast Model P*, *Radioclast Treating Unit*, *Electron-O-Ray Model 46*, *Electron-O-Ray Model 51*, and *Quto-Electronic Instrument Model 0-20-1 P*, including their components, parts, and accessories, the same devices by any other designation, and any similar devices.

7184. Neurolinometer device and Research Model device. (F.D.C. No. 47689, S. Nos. 50-154/5 T.)

QUANTITY: 2 devices at Woodland, Calif.

SHIPPED: Between 6-20-58 and 6-30-60, from Cumberland, Wis., by the Foundation For The Advancement of Chiropractic Research, Inc., and the **Toftness** Chiropractic Clinic.

LABEL IN PART: (On device) "Neurolinometer **Toftness** System, Cumberland, Wisconsin" and "Research Model * * * This instrument has no known therapeutic, diagnostic, or analytical value and shall not be used for any such purposes. Its use is strictly limited to personal research work by duly qualified practitioners in chiropractic."

ACCOMPANYING LABELING: Book entitled "In Sickness and In Health - a publication of The Foundation For The Advancement of Chiropractic Research, Inc., copyright 1958, First Edition"; reprint entitled "The Journal Reports on The Neurolinometer"; and booklet entitled "Researching The Chiropractic Adjustment by I. N. **Toftness**, D.C., Ph. C. copyright 1951."

RESULTS OF INVESTIGATION: Investigation indicated that the *Neurolinometer* was a device housed in a black, suitcase-type container, about 15 inches long, 9¾ inches wide, and 5½ inches deep. The face of the device contained 8 knobs variously labeled in part "ten," "one," "cervical," or "base." The device otherwise consisted of a monopolar electrode, a single-stage amplifier, and a power supply unit, the output of which was applied to a section of wire mesh attached beneath a sheet of bakelite.

The device was in the possession of David A. Tuscher, D.C., and was used by him as a diagnostic tool or adjunct in connection with other diagnostic procedures to determine the location of subluxations or points of nerve interference along the spine.

Investigation indicated that the *Research Model* was a device housed in a grey-colored box, one end of which was a storage well containing a white powder used to dry the surface of the bakelite detector plate in the upper right-hand corner of the box. The control panel contained two plugs for electrode outlets, a switch, fuse, and a variable dial graduated from 0 to 100. One electrode was a small metal disc attached to a wooden handle and the other electrode was a plastic-enclosed metal coil mounted on a metal gooseneck-type support. The device was intended to be used by placing the probe in contact with the supposedly affected part of the spine. Meanwhile, the operator rubbed his fingers across a metal plate attached to the device until a "pull" was felt on the fingers, while a numbered dial on the control panel was turned with the operator's other hand.

The device was in the possession of a doctor of chiropractic other than David A. Tuscher.

CHARGE: *Neurolinometer device*, 502(a)—while held for sale, the book entitled "In Sickness and in Health" accompanying the device, contained false and misleading representations that the article was adequate and effective as a diagnostic device in measuring nerve interference; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, for the diagnosis of disease in man, in that the article was worthless for use for such purpose, and adequate directions cannot be given for the use of the article for such purpose.

Research Model device, 502(a)—when shipped, the label statements "Research Model" and "This instrument has no known therapeutic, diagnostic, or analytical value and shall not be used for any such purposes. Its use is strictly limited to personal research work by duly qualified practitioners in chiropractic," were false and misleading, as applied to a product which was intended for use in the diagnosis of disease in the course of the professional practice of a practitioner in chiropractic; 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 for the purpose for which it was intended, namely, for the diagnosis of disease in man, in that the article was worthless for use for such purposes, and adequate directions cannot be given for the use of the article for such purpose.

DISPOSITION: 9-20-62. Default—delivered to the Food and Drug Administration.

7185. *Neurolinometer device*. (F.D.C. No. 47707. S. No. 17-796 T.)

QUANTITY: 1 device at Fulton, Ky., in possession of Virgil H. Barker, D.C.

SHIPPED: Between 1-1-54 and 12-30-55, from Cumberland, Wis., by *Toftness Chiropractic Clinic*.

LABEL IN PART: (Original label) "Neurolinometer *Toftness* System Cumberland, Wis."; (added sticker label) "This instrument has no known treating, diagnostic or analytical value."

ACCOMPANYING LABELING: Book entitled "In Sickness and in Health, a publication of the Foundation for the Advancement of Chiropractic Research, Inc. Offices at Cumberland, Wisconsin, Copyright 1957."

RESULTS OF INVESTIGATION: Examination indicated that the device was housed in a black, suitcase-type container about 15 inches long, 9 $\frac{3}{4}$ inches wide, and 5 $\frac{1}{2}$ inches deep. The face of the device contained 8 knobs variously labeled in part "ten," "one," "cervical," or "base." The device otherwise consisted of a monopolar electrode, a single-stage amplifier, and a power supply unit, the output of which was applied to a section of wire mesh attached beneath a sheet of bakelite.

The sticker label had been placed on the face of the device by the dealer, who had had the accompanying labeling displayed on a table with the device.

LICENSED: 7-25-62, W. Dist. Ky.

CHARGE: 502(a)—when shipped and while held for sale, the label statement "This instrument has no known treating, diagnostic or analytical value," was false and misleading, as applied to a product which was intended for use in the diagnosis of disease in the course of the professional practice of a practitioner in chiropractic; 502(a)—statements in the accompanying labeling represented and suggested that the article was of value in the diagnosis of disease in man, which statements were false and misleading, since the article was worthless for such purposes; and 502(f)(1)—the labeling failed to bear adequate directions for the use for the purposes for which it was intended, namely,

for the diagnosis of disease in man, in that the article was worthless for use for such purposes, and adequate directions could not be given for the use of the article for such purposes.

DISPOSITION: 9-11-62. Default—delivered to the Food and Drug Administration.

7186. *Neurolinometer device* (2 seizure actions). (F.D.C. Nos. 47711, 47712. S. Nos. 60-649 T; 18-135 T.)

QUANTITY: 2 devices, at Ironwood, Mich., and Conroe, Tex.

SHIPPED: Between 8-1-54 and 7-31-56, from Cumberland, Wis., by Emil Kuitunen, D.C., and Walter E. Moore.

LABEL IN PART: "Neurolinometer *Toftness* System Cumberland, Wisconsin."

LICENSED: 7-10-62, W. Dist. Mich.; 7-11-62, S. Dist. Tex.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use for the purpose for which it was intended, namely, for the diagnosis of disease in man, in that the article was worthless for use for such purpose, and adequate directions could not be given for the use of the article for such purpose.

DISPOSITION: 8-14-62; 10-5-62. Default—one device destroyed and one device delivered to the Food and Drug Administration.

7187. *Radioclast device and Electronic Analysis Instrument*. (F.D.C. No. 46558. S. Nos. 16-401/2 T.)

QUANTITY: 2 devices at Owensboro, Ky.

SHIPPED: 6-1-61 and 7-28-61, from Tiffin, Ohio, by L. L. Roby Manufacturing Corp.

LABEL IN PART: "Auto Electronic Radioclast Model 20 Series 800 Electronic Instrument Co. Tiffin, Ohio * * * Reconditioned" and "Electronic Analysis Instrument Model F * * * Manufactured by L. L. Roby Manufacturing Corp. Tiffin, Ohio."

RESULTS OF INVESTIGATION: The *Radioclast device* had been previously shipped by the dealer to the shipper for repairs. Examination indicated that the *Radioclast* was a wooden cabinet containing a combination of electronic circuits. The control panel contained pilot lights, line switch, heater switch, and a series of 3 dials intended for use in determining the identity of diseased organs. Three other dials purported to identify the disease conditions present, and additional dials purported to determine the identity of the disease conditions. The amount of current passing through the device was controlled by an intensity rheostat. A detector plate, as an attachment, purported to locate the point of maximum reaction and thus determine the location of the disease in the body.

The *Electronic Analysis Instrument* was a wooden console cabinet fitted with a control panel containing a direct current milliammeter, two pilot lights, switches, and 12 dials. The device did not generate an electric current but purported to measure electrical impulses allegedly emanating from disease tissue. The device had a detector plate as an attachment, used to diagnose the location and extent of disease.

LICENSED: 10-9-61, W. Dist. Ky.

CHARGE: 502(f)(1)—when shipped and while held for sale, the labeling failed to bear adequate directions for use.

DISPOSITION: On or about 12-14-61, Wayne E. Gore, D.C., Owensboro, Ky., claimed the articles and denied that they were misbranded. On 6-8-62, the

DISPOSITION: 1-21-63. Consent—claimed by Dr. J. A. Liner. A portion of the articles which could be brought into compliance with the law were released to the claimant and the remainder of the articles were destroyed.

7430. Amphetamine sulfate tablets. (F.D.C. No. 48082. S. No. 84-322 T.)

QUANTITY: 510,000 tablets at Hayti, Mo., in possession of Levi D. Denton.

SHIPPED: Prior to 8-22-62, from Knoxville, Tenn.

LIBELED: 8-31-62, E. Dist. Mo.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use, and the article was not exempt from such requirement since it was not intended to be dispensed on prescription as required by regulations.

DISPOSITION: 1-23-63. Default—5,000 tablets delivered to the Food and Drug Administration and the remainder destroyed.

7431. Various drugs. (F.D.C. No. 47691. S. No. 481 T.)

QUANTITY: Unknown number of tablets, capsules, and vials of *tranquillizers*, *barbiturates*, *antibiotics*, and other drugs at Rochelle, Ga., in possession of Ronald G. Shawver.

SHIPPED: On unknown dates, from outside the State of Georgia.

LIBELED: 6-11-62, M. Dist. Ga.

CHARGE: 502(f)(1)—the labeling of the articles failed to bear adequate directions for use, and they were not exempt from that requirement.

DISPOSITION: 1-21-63. Default—destruction.

7432. Turpentine. (F.D.C. No. 48224. S. No. 15-879 T.)

QUANTITY: 5 55-gal. drums, 77 cases, each containing 12 8-oz. btls., and 121 cases, each containing 12 3-oz. btls., at Terre Haute, Ind., in possession of Hulman & Co.

SHIPPED: 8-4-61 and 8-12-61, from Jacksonville, Fla.

LABEL IN PART: (Btl.) "Farmers Pride Brand Turpentine [or "Hulco Turpentine"] For Medicinal Purposes Made from Pure Gum Spirits Put Up By Hulman & Co. Terre Haute, Ind."

RESULTS OF INVESTIGATION: The article was shipped in bulk drums and repacked and labeled by the dealer, who also had additional repack labels on hand.

LIBELED: 10-17-62, S. Dist. Ind.

CHARGE: 502(f)—while held for sale, the labeling of the article (bulk and repack) failed to bear (1) adequate directions for use, and (2) a statement warning not to apply the article to irritated skin, or if excessive irritation develops, and to avoid getting it into the eyes or on mucous membranes, and that the product should be kept out of the reach of children.

DISPOSITION: 12-13-62. Consent—claimed by Hulman & Co. Previously unopened drums were returned to the supplier and the portion which had been bottled was returned to the bulk containers for use in maintenance. All bottles and labels were destroyed.

7433. Micro-Dynamometer devices (2 seizure actions). F.D.C. Nos. 47950, 47984. S. Nos. 17-199 T, 72-481 T.)

QUANTITY: 2 devices, at Lexington and Raceland, Ky.

SHIPPED: Between 3-1-54 and 3-31-58, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "For Scientific Body Analysis The Ellis Micro-Dynamometer Mfd. by Ellis Research Laboratories, Inc., Chicago U.S.A."

ACCOMPANYING LABELING: Various pieces of literature pertaining to the devices.

RESULTS OF INVESTIGATION: Examination indicated that the devices were essentially galvanometers for measuring electrical currents and electrical potentials of small magnitude. Each device was mounted in a metal cabinet, on the face of which was a scale or meter intended to measure the flow of current in milliamperes, together with a number of dials which could be set at numbered or lettered positions. The dial settings were intended to increase or decrease the resistance to the current flowing through the device. The current which flowed and was measured by the scale or meter was generated by closing the circuit between two dissimilar metal "probes." The circuit was closed by placing the "probes" at different points on the human body, by placing the "probes" together, or by immersing them in water.

LIBELED: 8-15-62; 8-16-62, label amended 12-3-62; E. Dist. Ky.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for diagnosing disease; and 502(f)(1)—the labeling of the articles failed to bear adequate directions for use and they were not entitled to any exemption from that requirement.

DISPOSITION: 1-10-63, 1-16-63. Default—delivered to the Food and Drug Administration.

7434. Micro-Dynamometer devices and Neurolinometer devices. (F.D.C. No. 48019. S. Nos. 11-472/3 T, 11-475/6 T.)

QUANTITY: 2 Micro-Dynamometer devices at McKeesport, Pa.; 2 Neurolinometer devices, at Wilmerding, Pa.

SHIPPED: On unknown dates, from Cumberland, Wis., and Chicago, Ill., by Ellis Research Laboratories, Inc., and Toftness System.

LABEL IN PART: (Micro-Dynamometer) "For Scientific Body Analysis The Ellis Micro-Dynamometer Mfd. by Ellis Research Laboratories, Inc. Chicago, U.S.A."; (Neurolinometer) "Neurolinometer Toftness System, Cumberland Wisconsin."

RESULTS OF INVESTIGATION: Investigation indicated that the Neurolinometer was a device housed in a black, suitcase-type container, about 15 inches long, 9¾ inches wide, and 5½ inches deep. The face of the device contained 8 knobs variously labeled in part "ten," "one," "cervical," or "base." The device otherwise consisted of a monopolar electrode, a single-stage amplifier, and a power supply unit, the output of which was applied to a section of wire mesh attached beneath a sheet of bakelite.

LIBELED: 9-10-62, W. Dist. Pa.

CHARGE: 502(f)(1)—when shipped, the labeling of the articles failed to bear adequate directions for use for the purpose for which they were intended, namely, for the diagnosis of disease in man, in that the articles were worthless for use for such purpose and adequate directions could not be given for the use of the articles for such purpose.

DISPOSITION: 10-1-62. Default—destruction.

7435. Magnetic bracelets. (F.D.C. No. 48229. S. No. 2-442 V.)

QUANTITY: 449 men's bracelets and 449 women's bracelets, at Miami, Fla., in possession of Max N. Lichy & Sons, t/a International Silk & Novelties Corp.

- (d) all labeling that furnishes or purports to furnish information for use of the device, contains adequate information for the use of the device, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented; and
- (e) all labeling, except labels and cartons, bearing information for use of the device also bears the date of the issuance or the date of the latest revision of such labeling.

7566. Neurolinometer devices and Research Model devices (4 seizure actions). (F.D.C. No. 47690. S. Nos. 33-289 T; 33-290 T; 34-287 T; 62-799 T.)

QUANTITY: 2 *Neurolinometer devices*, at Forest Lake, Minn., and 3 *Research Model devices*, at Anoka, Duluth, and Fairmont, Minn.

SHIPPED: On various dates, from **Toftness Chiropractic Clinic**, and **Foundation For The Advancement of Chiropractic Research, Inc.**, Cumberland, Wis.

LABELS IN PART: "Neurolinometer **Toftness System** Cumberland, Wisconsin" and "Research Model * * * Limitation of Use: This instrument has no known therapeutic, diagnostic, or analytical value and shall not be used for any such purpose. Its use is strictly limited to personal research work by duly qualified practitioners in Chiropractic."

RESULTS OF INVESTIGATION: The *Neurolinometer* was a device housed in a black, suitcase-type container, about 15 inches long, 9¾ inches wide, and 5½ inches deep. The face of the device contained 8 knobs variously labeled in part "ten," "one," "cervical," or "base." The device otherwise consisted of a monopolar electrode, a single-stage amplifier, and a power supply unit, the output of which was applied to a section of wire mesh attached beneath a sheet of bakelite.

The *Research Model* was a device housed in a grey-colored box, one end of which was a storage well containing a white powder used to dry the surface of the bakelite detector plate in the upper right-hand corner of the box. The control panel contained two plugs for electrode outlets, a switch, fuse, and a variable dial graduated from 0 to 100. One electrode was a small metal disc attached to a wooden handle and the other electrode was a plastic-enclosed metal coil mounted on a metal gooseneck-type support.

LIBELED: 6-27-62 and 6-28-62, Dist. Minn.

CHARGE: 502(a)—when shipped and while held for sale, the *Research Model devices* bore statements which were false and misleading as applied to a product which was intended for use in the diagnosis of disease in the course of the professional practice of practitioners in chiropractic; 502(b)(1)—the labels of the *Research Model devices* failed to bear the name and place of business of the manufacturer, packer, or distributor; and 502(f)(1)—the labeling of all the devices failed to bear adequate directions for use for the purpose for which they were intended, namely, for the diagnosis of disease in man, in that the articles were worthless for use for such purpose and adequate directions could not be given for the use of the articles for such purpose.

DISPOSITION: 10-26-62. Default—delivered to the Food and Drug Administration.

7567. Micro-Dynamometer devices (7 seizure actions). (F.D.C. Nos. 47818, 47940, 48215, 48219, 48321, 48353, 48413. S. Nos. 37-280 T; 20-859 T; 77-911 T; 96-125 T; 38-401 V; 36-409 V; 53-536 V.)

QUANTITY: 7 devices, at Ponchatoula, La., Amarillo, Tex., Enfield, Conn., Borger, Tex., Kosciusko, Miss., De Ridder, La., and Portland, Oreg.

SHIPPED: Between 1-1-54 and 9-27-62, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "For Scientific Body Analysis The Ellis Micro-Dynamometer Mfd. by Ellis Research Laboratories, Inc., Chicago U.S.A."

ACCOMPANYING LABELING: Various pieces of literature pertaining to the device.

RESULTS OF INVESTIGATION: Examination indicated that the devices were essentially galvanometers for measuring electrical currents and electrical potentials of small magnitude. Each device was mounted in a metal cabinet, on the face of which was a scale or meter intended to measure the flow of current in milliamperes, together with a number of dials which could be set at numbered or lettered positions. The dial settings were intended to increase or decrease the resistance to the current flowing through the device. The current which flowed and was measured by the scale or meter was generated by closing the circuit between two dissimilar metal "probes." The circuit was closed by placing the "probes" at different points on the human body, by placing the "probes" together, or by immersing them in water.

LIBELED: 8-10-62, E. Dist. La.; 9-6-62, N. Dist. Tex.; on or about 10-18-62, Dist. Conn.; 11-21-62, N. Dist. Tex.; 11-7-62, N. Dist. Miss.; 11-21-62, W. Dist. La.; 12-18-62, Dist. Oreg.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for diagnosing disease; and 502(f)(1)—the labeling of the articles failed to bear adequate directions for use and they were not entitled to any exemption from that requirement.

DISPOSITION: 1-10-63; 12-17-62; 12-14-62; 2-12-63; 4-15-63; 3-11-63; 2-6-63. Default—6 devices destroyed; 1 device delivered to the Food and Drug Administration.

7568. Micro-Dynamometer devices (24 seizure actions). (F.D.C. Nos. 47726, 47825/6, 47902, 47904, 47916, 47930, 47957, 48011, 48018, 48294, 48304, 48309. S. Nos. 69-823/5 T; 50-333/6 T, 50-339 T; 15-793 T, 16-446 T, 58-293/4 T, 72-129/30 T, 72-689/90 T, 72-693/7 T; 22-317 T; 55-370 T, 77-165/8 T, 77-644/5 T; 76-463 T; 40-542 T, 41-461 T, 74-242 T; 64-348 T, 64-350 T; 47-289 T, 47-291 T, 67-868 T; 73-149/52 T; 37-873 T, 60-283/4 T; 36-328 T, 36-330/1 T, 37-299 T, 38-260 T, 59-807 T; 95-721 T, 95-527/30 T, 10-526/7 V.)

QUANTITY: 58 devices, at Warwood and Wheeling, W. Va.; San Jose and Santa Cruz, Calif.; Henderson, Fulton, Lone Oak, Greenville, Louisville, Elizabethtown, and Vine Grove, Ky.; Roy, Utah; Jacksonville, Orlando, Winter Park, Ocala, Nokomis, and Fort Myers, Fla.; Denver, Colo.; New York, Kingston, and Bronx, N.Y.; West Columbia and Barnwell, S.C.; Paragould, Little Rock, and Jonesboro, Ark.; Rochester, N.Y.; Booneville, Aberdeen, and Amory, Miss.; Hartselle, Jasper, Huntsville, Gadsden, Tuscaloosa, and Decatur, Ala.; and Buffalo, Kenmore, Hamburg, Cheektowaga, Horseheads, Jamestown, and Dunkirk, N.Y.

DISPOSITION: 4-4-63. Default—the *Micro-Tabulometer*, the *Neurolinometers*, and 17 *Micro-Dynameters* delivered to the Food and Drug Administration; the remaining devices destroyed.

7805. *Micro-Dynamometer device*. (F.D.C. No. 48326. S. No. 21-426 V.)

QUANTITY: 1 device at Rexburg, Idaho.

SHIPPED: Between 9-1-58 and 9-30-58, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "For Scientific Body Analysis The Ellis Micro-Dynamometer Mfd. by Ellis Research Laboratories, Inc. Chicago U.S.A."

LIBELED: 10-19-62, Dist. Idaho.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for diagnosing disease; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use, and was not entitled to any exemption from that requirement.

DISPOSITION: On or about 3-1-63, the Government served written interrogatories upon C. S. Green, D.C., in which questions concerning the possession, location, custody, and disposition of a *Micro-Dynamometer* were asked. On 3-15-63, C. S. Green moved for an extension of time in which to file answers or objections to the interrogatories.

On 3-18-63, C. S. Green delivered the device to the U.S. marshal. On 3-20-63, the Government moved for a default judgment. On or about 3-22-63, the court filed *nunc pro tunc* an answer in letter-form, dated Nov. 4, 1962, from C. S. Green, and granted the motion of C. S. Green for an extension of time in which to file an answer or objections to interrogatories. On 4-9-63, the Government served written interrogatories upon C. S. Green concerning the use, purposes, and labeling of the device; and, on 8-21-63, C. S. Green filed answers to such interrogatories. On or about 10-15-63, the Government filed supplemental interrogatories upon C. S. Green and, on 1-29-64, C. S. Green filed answers to the supplemental interrogatories.

On 2-18-64, pursuant to stipulation, Dr. C. S. Green withdrew his answer and a default decree of condemnation was entered ordering the device delivered to the Food and Drug Administration for investigational purposes.

7806. *Micro-Dynamometer devices (5 seizure actions)*. (F.D.C. Nos. 47827, 47922, 47996, 48314. S. Nos. 66-968 T, 89-008 T; 63-555 T; 31-191 T, 31-936 T, 31-188/90 T, 31-476 T, 31-539/40 T, 31-934 T, 31-937/8 T, 65-176/81 T; 72-256 T.)

QUANTITY: 2 devices at Flint and Detroit, Mich.; 1 device at Stoughton, Wis.; 2 devices at San Diego and Oceanside, Calif.; 15 devices at Los Angeles, Buena Park, Long Beach, Burbank, Glendale, Pomona, Joshua Tree, Huntington Park, Anaheim, Bell, and Santa Monica, Calif.; and 1 device at Bristol, Tenn.

SHIPPED: On various dates, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "For Scientific Body Analysis The Ellis Micro-Dynamometer Mfd. by Ellis Research Laboratories, Inc. Chicago U.S.A."

LIBELED: 8-16-62, E. Dist. Mich.; 7-31-62, W. Dist. Wis.; 8-29-62 and 8-24-62, S. Dist. Calif.; 3-19-63, E. Dist. Tenn.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for

diagnosing disease; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use, and was not entitled to any exemption from that requirement.

DISPOSITION: Between 10-10-62 and 6-28-63. Default—3 devices delivered to the Food and Drug Administration; 18 devices destroyed.

7807. *Research Model devices (4 seizure actions)*. (F.D.C. Nos. 47710, 47983, 48014, 48090. S. Nos. 34-286 T, 34-288 T, 51-825 T, 60-650/1 T.)

QUANTITY: 5 devices, at Duluth and Hibbing, Minn., Marquette, Mich., and Spokane, Wash.

SHIPPED: On various dates; from Cumberland, Wis., by *Toftness* Chiropractic Clinic, or Foundation for the Advancement of Chiropractic Research, Inc., by M. H. Cole, D.C., and by unknown shippers; and from Elkhart, Ind., by H. C. Lindahl.

LABEL IN PART: "Research Model" or "Neurolinometer *Toftness* System Cumberland Wisconsin" and/or "This instrument has no known analytical or therapeutic value" and/or "Limitation of Use: This instrument has no known therapeutic, diagnostic, or analytical value and shall not be used for any such purpose. Its use is strictly limited to personal research work by duly qualified practitioners in Chiropractic."

RESULTS OF INVESTIGATION: Examination indicated that the device was housed in a grey-colored box. One end of the box was a storage well containing a white powder used to dry the surface of the bakelite detector plate located in the upper right-hand corner of the box. The control panel contained two plugs for electrode outlets, a switch, fuse, and a variable dial graduated from 0 to 100. One electrode was a small metal disc probe attached to a wooden handle and the other electrode was a plastic-enclosed metal coil mounted on a metal gooseneck-type support. The device was used by placing the metal disc probe in contact with the supposedly affected part of the spine. Meanwhile, the operator rubbed his fingers across a metal plate attached to the device until a "pull" was felt on the fingers, while a numbered dial on the control panel was turned with the operator's other hand.

LIBELED: Between 7-11-62 and 9-10-62, Dist. Minn., W. Dist. Mich., and E. Dist. Wash.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use for the purpose for which it was intended, namely, for the diagnosis of disease in man, in that the article was worthless for use for such purpose, and adequate directions could not be given for the use of the article for such purpose.

DISPOSITION: Between 10-16-62 and 11-19-62. Default—destruction or delivery to the Food and Drug Administration.

7808. *Mathison Electropsychometer*. (F.D.C. No. 49107. S. No. 61-361 V.)

QUANTITY: 3 devices at Boerne, Tex.

SHIPPED: Prior to 5-23-63, from Los Angeles, Calif., by Arcon Manufacturing Co. (Mathison Manufacturing Co.).

LABEL IN PART: "Mathison Electropsychometer * * * Manufactured under license by Arcon Mfg. Co. * * * Los Angeles 7, California."

ACCOMPANYING LABELING: Leaflets bearing facsimiles of 2 different Food and Drug Administration Notices of Inspection (Form FD-482) and leaflets en-

adequate directions for use, and it was not entitled to any exemption from that requirement.

DISPOSITION: 11-16-62. Consent—delivered to the Food and Drug Administration for investigational and exhibit purposes, and to be maintained intact and available under court process to Ramsarut Maraj, D.C., the original purchaser of the device, if such device should be needed in litigation between Dr. Maraj and the firm from whom he had purchased the device.

7910. Research Model device. (F.D.C. No. 48017. S. No. 60-662 T.)

QUANTITY: 1 device at Grundy Center, Iowa.

SHIPPED: 8-14-62, from Elkhart, Ind., by H.C. Lindahl.

LABEL IN PART: "Research Model."

RESULTS OF INVESTIGATION: Investigation indicated that the *Research Model* was a device housed in a grey-colored box, one end of which was a storage well containing a white powder used to dry the surface of the bakelite detector plate in the upper right-hand corner of the box. The control panel contained two plugs for electrode outlets, a switch, fuse, and a variable dial graduated from 0 to 100. One electrode was a small metal disc attached to a wooden handle and the other electrode was a plastic-enclosed metal coil mounted on a metal gooseneck-type support.

LIBELED: 8-30-62, N. Dist. Iowa.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use for the purpose for which it was intended, namely, for the diagnosis of disease in man, in that the article was worthless for use for such purpose, and adequate directions could not be given for the use of the article for such purpose.

DISPOSITION: 10-10-62. Default—destruction.

7911. Research Model device. (F.D.C. No. 48068. S. No. 12-079 T.)

QUANTITY: 1 device at West Bend, Wis.

SHIPPED: Prior to 8-30-62, from Tiffin, Ohio.

RESULTS OF INVESTIGATION: Only the dial face of the device was seized since the remainder of the device had been destroyed by the dealer.

LIBELED: 9-4-62, E. Dist. Wis.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use for the purpose for which it was intended, namely, for the diagnosis of disease in man, in that the article was worthless for use for such purpose, and adequate directions could not be given for the use of this article for such purpose.

DISPOSITION: 10-2-62. Default—destruction.

7912. Research Model devices. (F.D.C. No. 47824. S. Nos. 34-283/5 T.)

QUANTITY: 4 devices at Cumberland, Wis.

SHIPPED: 6-30-62 and 7-2-62, from St. Paul and South St. Paul, Minn. These were return shipments.

LIBELED: 8-16-62, W. Dist. Wis.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use for the purpose for which it was intended, namely, for the diagnosis of disease in man, in that the article was worthless for use

for such purpose and adequate directions could not be given for the use of the article for such purpose.

DISPOSITION: 10-13-62. Default—delivered to the Food and Drug Administration.

7913. Research Model device. (F.D.C. No. 48000. S. No. 95-819 T.)

QUANTITY: 1 device at Buffalo, N.Y.

SHIPPED: Prior to 8-21-62, from Cumberland, Wis., by *Toftness* Chiropractic Clinic.

LABELS IN PART: "Research Model Serial No. 47B" and "Limitation of Use: This instrument has no known therapeutic, diagnostic, or analytical value and shall not be used for any such purpose. Its use is strictly limited to personal research work by duly qualified practitioners in chiropractic."

LIBELED: 8-27-62, W. Dist. N.Y.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use for the purpose for which it was intended, namely, for the diagnosis of disease in man, in that the article was worthless for use for such purpose and adequate directions could not be given for the use of the article for such purpose.

DISPOSITION: 10-31-62. Default—destruction.

7914. Research Model devices (3 seizure actions). (F.D.C. Nos. 47682, 47685, 47968. S. Nos. 10-919 T; 4-697 T; 10-857/8 T.)

QUANTITY: 5 devices, at Newport News, Va., and Orchard Park, Hamburg, and Buffalo, N.Y.

SHIPPED: On various dates, from Cumberland, Wis., by *Toftness* Post Graduate School of Chiropractic, Inc., Foundation for the Advancement of Chiropractic Research, Inc., and *Toftness* Chiropractic Clinic.

LABELS IN PART: "Research Model" and "This instrument has no known analytical or therapeutic value."

LIBELED: Between 6-22-62 and 8-17-62, W. Dist. N.Y., and E. Dist. Va.

CHARGE: 502(a)—when shipped, the labeling of the articles contained statements which were false and misleading as applied to a product which was intended for use in the diagnosis of disease in the course of the professional practice of practitioners in chiropractic; 502(b)(1)—the labeling of the articles failed to bear the name and place of business of the manufacturer, packer, or distributor; and 502(f)(1)—the labeling of the articles failed to bear adequate directions for use for the purposes for which they were intended, namely, for the diagnosis of disease in man, in that the articles were worthless for use for such purpose and adequate directions could not be given for the use of the articles for such purpose.

DISPOSITION: 10-31-62; 8-13-62; 10-31-62. Default—destruction.

7915. Research Model device. (F.D.C. No. 47961. S. No. 200 T.)

QUANTITY: 1 device at St. Petersburg, Fla.

SHIPPED: Between 2-1-62 and 3-31-62, from Cumberland, Wis., by *Toftness* Post Graduate School of Chiropractic, Inc.

LABEL IN PART: "Research Model * * * Limitation of use: This instrument has no known therapeutic, diagnostic or analytical value and shall not be

used for any such purposes. Its use is strictly limited to personal research work by duly qualified practitioners in chiropractic. Manufactured for and leased for research purposes only by **Toftness** Post Graduate School of Chiropractic, Inc., * * * Cumberland, Wisconsin."

ACCOMPANYING LABELING: Leaflet entitled "The **Toftness** System of Spinal Correction Copyright 1955 I.N. **Toftness**, D.C., Cumberland, Wis."

LIBELED: 8-16-62, S. Dist. Fla.

CHARGE: 502(a)—when shipped, the above-mentioned label statements were false and misleading as applied to a product which was intended for use in the diagnosis of disease in the course of the professional practice of a practitioner in chiropractic; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, for the diagnosis of disease in man, in that the article was worthless for use for such purpose and adequate directions could not be given for the use of the article for such purpose.

DISPOSITION: 1-3-63. Default—destruction.

7916. Neurolinometer devices and Research Model device. (F.D.C. No. 48015. S. Nos. 70-401/2 T.)

QUANTITY: 2 *Neurolinometers* and 1 *Research Model*, at Wahpeton, N. Dak.

SHIPPED: Between 1-1-58 and 8-29-62, (*Research Model*) from Cumberland, Wis., by the Foundation for the Advancement of Chiropractic Research, Inc., and (*Neurolinometer*) from Virginia, Minn.

LABELS IN PART: "Neurolinometer **Toftness** System Cumberland, Wisconsin and "Research Model 110 Volts A.C. This instrument has no known analytical or therapeutic value."

RESULTS OF INVESTIGATION: The *Neurolinometer* was a device housed in a black suitcase-type container, about 15 inches long, 9¾ inches wide, and 5½ inches deep. The face of the device contained 8 knobs variously labeled in part "ten," "one," "cervical," or "base." The device otherwise consisted of a monopolar electrode, a single-stage amplifier, and a power supply unit, the output of which was applied to a section of wire mesh attached beneath a sheet of bakelite.

LIBELED: 8-31-62, Dist. N. Dak.

CHARGE: 502(f)(1)—when shipped, the labeling of the articles failed to bear adequate directions for use for the purpose for which they were intended, namely, for the diagnosis of disease in man, in that the articles were worthless for use for such purpose, and adequate directions could not be given for the use of the articles for such purpose.

DISPOSITION: 10-29-62. Default—delivered to the Food and Drug Administration.

7917. Halox generator device. (F.D.C. No. 48138. S. No. 85-641 T.)

QUANTITY: 1 device at Menlo Park, Calif.

SHIPPED: Some time in 1958, from Summit, N.J., by Anthony Caporaso.

LABEL IN PART: (Panel) "Halox Therapeutic Generator" and (metal plate on back of device) "Halox Therapeutic Generator Co. * * * Scientific Chlorine Inhalators * * * Central, New Mexico."

ACCOMPANYING LABELING: Book entitled "The Miracles of Father Aull."

RESULTS OF INVESTIGATION: Inspection indicated the article to be designed as a portable cabinet containing components capable of producing chlorine gas from table salt by means of electrolysis.

LIBELED: 10-2-62, N. Dist. Calif.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use in overcoming various disease conditions for which the article was recommended, and it was not feasible to devise adequate directions for use, since the article as designed was worthless for any medical purpose.

DISPOSITION: 1-17-63. Default—delivered to the Food and Drug Administration.

7918. Various devices. (F.D.C. No. 49615. S. Nos. 18-006/70 V.)

QUANTITY: 1 *Pathoclast device*, 1 *Cardiolectameter device*, 1 *Electronic Magnetic Model G device*, and 2 *Pathosine devices*, at Midwest City, Okla., in possession of King Health Clinic (George E. King, naturopath).

SHIPPED: On unknown dates prior to 4-13-62, from Chicago, Ill., Denver, Colo., Tiffin, Ohio, and North Hollywood, Calif.

RESULTS OF INVESTIGATION: The *Pathoclast* was a desk console-type, electrically operated diagnostic and therapeutic device, with a control panel and circuitry on top of the desk, containing a variety of meters, knobs, dials, switches, lights, and specimen wells for the operation of the device, and the electronic components of such device were intended to measure the electrical vibrations from the body and reradiate similar radiations through the electrodes to the body.

The *Cardiolectameter* was a wood console-type, electrically operated diagnostic and therapeutic device, with a control panel containing a series of switches, a rheostat dial, meters and a speaker which emitted sounds representing circulatory pressure. The device contained numerous wires, a speaker, tubes and other electrical parts. The name plate on the front read "Cardiolectameter Reg. U.S. Patent Office Pat. Pending Denver Colo. Made in U.S.A."; the rear panel read "Cardiolectameter designed to operate on A.C. current only 60-cycle 110 volts Model H. No ———."

The *Electronic Magnetic Model G* was a suitcase-type unit which, on opening, displayed a control panel and detector plates. The control panel contained an array of switches, dials, push buttons, electrode terminals, and indicator lights. There were electronic components within the case for a power supply, oscillators, and amplifier for the detection and/or operation of hertzian waves.

The *Pathosine* was a wood and metal console-type, electrically operated therapeutic device. The control panel contained a series of dials, switches, lights, and plug outlets. Used as accessories with the device were electrodes and pads. The electrical components of such device were intended to measure and perform therapy to eyes and muscles for diseases determined by the device.

LIBELED: 11-22-63, W. Dist. Okla.

CHARGE: 502(f)(1)—while held for sale, the labeling of the *Cardiolectameter* and *Pathosine* failed to bear adequate directions for use and they were not exempt from such requirements, since they were not labeled in accordance with the labeling requirements of the exempting regulations; the labeling of the *Pathoclast* and *Electronic Magnetic Model G* failed to bear adequate directions