

30964. Misbranding of Formula No. HBP 98 For Controlling High Blood Pressure, Formula No. FH 60 Endocrine Compound Female, Formula No. FH 60 Endocrine Cycle Food Female, Acid Eliminating Powder, Formula No. DP 64 Duodenin—Pancreas Tablets, Formula No. RS 63 Useful in Secondary Anemia. U. S. v. Ray Alma Richardson, Helen Richardson (Mrs. R. A. Richardson), and Myra Deane Richardson, copartners, trading as the Myra Deane Co. Pleas of guilty. Fines, \$240. F. & D. No. 42729. Sample Nos. 48704-C, 48705-C, 48716-C, 48717-C, 36862-D, 36864-D.)

The labeling of these products bore false and fraudulent representations regarding their curative and therapeutic effectiveness and false and misleading claims regarding their composition.

On August 29, 1939, the United States attorney for the Western District of Missouri, acting upon a report by the Secretary of Agriculture, filed in the district court an information against Ray Alma Richardson, Helen Richardson (Mrs. R. A. Richardson), and Myra Deane Richardson, copartners, trading as the Myra Deane Co., Kansas City, Mo., alleging shipment by said defendants in violation of the Food and Drugs Act as amended, within the period from on or about March 10, 1937, to on or about November 8, 1938, from the State of Missouri into the States of Kansas and Oklahoma of quantities of the above-named drug preparations which were misbranded. The articles were labeled in part: "Dr. R. A. Richardson's Special Formula."

Analyses showed that the Formula No. HBP 98 For Controlling High Blood Pressure consisted of compressed tablets composed essentially of glandular material, including 0.09 gram of thyroid per tablet; that the Formulas No. FH 60 Endocrine Compound Female and Endocrine Cycle Food Female consisted of compressed tablets composed essentially of milk sugar and animal protein matter resembling glandular substance (feeding tests on animals showed that the product when administered in doses of one or two tablets per animal was inert); that the Acid Eliminating Powder consisted essentially of sodium bicarbonate, sodium carbonate, calcium carbonate, magnesium oxide, and peppermint; and that Formulas DP 64 and RS 63 contained a considerable amount of animal tissues, apparently glandular in nature, and crystalline milk sugar—RS 63 also containing finely ground bone.

The Formula No. HBP 98 was alleged to be misbranded in that the statement on the label, "No Drugs," was false and misleading in that it represented that no drugs were present in the article; whereas it contained thyroid and other glandular material. It was alleged to be misbranded further in that the statements "For controlling high blood pressure" and "contains pancreas and thyroid substances in balanced combination to aid in controlling high blood pressure," regarding its curative and therapeutic effects were false and fraudulent since it was inert.

The Formula No. FH 60 Endocrine Compound Female was alleged to be misbranded in that the statements, "Endocrine Compound Female Contains interrelated gland substances of the female endocrine cycle," were false and misleading since it was inert animal material resembling glandular substance and milk sugar. It was alleged to be misbranded further in that the statements on the label, "Endocrine Compound Female" and "Contains interrelated gland substances of the female endocrine cycle," regarding its curative and therapeutic effects, falsely and fraudulently represented that it was capable of remedial, corrective, and regulative action when administered in the treatment of the organs whose functions are related to and affect the female menstrual cycle.

The Formula No. FH 60 Endocrine Cycle Food Female was alleged to be misbranded in that the statements, "Contains interrelated gland substances and enzymes of the female endocrine cycle" and "Endocrine cycle food Female," borne on the label, were false and misleading in that they represented that the ingredients of the article were active gland substances and that it was capable of producing an enzymic action; whereas it consisted of inert animal matter resembling glandular substance and milk sugar, and was incapable of producing enzymic action. It was alleged to be misbranded further in that representations in the labeling regarding its curative and therapeutic effects falsely and fraudulently represented that it was capable of remedial, corrective, and regulative action when administered in the treatment of organs whose functions are related to and affect the feminine menstrual cycle; that it was effective to maintain or restore health, vitality, or pep; to correct over-

weight or underweight conditions; to influence health; to give pep to one's step or elasticity or tone to one's muscles; to favorably influence pathological conditions; to adjust devitalized conditions of the body; to correct overstimulation or increased activity of the thyroid; to prevent or remedy the accumulation of toxins in the body, the acceleration or retardation of the action of the glands, the unbalancing of the functioning of the endocrine system or metabolism of the body; effective to correct mental or physical sluggishness due to insufficient glandular substances; to regulate fat metabolism; to remedy underweight, weakness, or emaciation due to deficiency of elements supplied by the glandular system; to remedy obesity, headaches, and despondency, renew energy and vitality; to relieve the pain and suffering accompanying menstruation, to promote digestion and assimilation of food, to effect regaining of strength, to increase weight or maintain normal weight; to remedy toxic goiter or fibroid tumor; to correct atrophy and loss of function of the sex glands; to effect improvement in the health and physical and mental condition of men and women who have reached the age of forty; to cause ill persons to recover; to make practically all people healthy; to prevent attacks of hay fever and asthma; to correct painful menstrual periods; to increase resistance against disease and bacteria; to correct overweight or underweight; and that it was effective in normalizing the functions of the endocrine glands.

The Acid Eliminating Powder was alleged to be misbranded in that the statement "Acid Eliminating Powder," borne on the label, was false and misleading since the article was not an acid eliminant as so understood. It was alleged to be misbranded further in that representations in the labeling regarding the curative and therapeutic effects of the article falsely and fraudulently represented that it was effective to eliminate indigestion; to help nature neutralize the toxic acid of the system; to avert or correct active or passive liver congestion; to prevent abscess of the liver or cirrhosis of the liver; to increase the resistance of the body; to correct habitual constipation; to eliminate chronic constipation; to prevent the development of conditions requiring surgical intervention; to improve digestion; to remedy female weaknesses, painful menstruation, vaginal irritation, hot flashes and other symptoms of the menopause, leucorrhea (whites), sexual frigidity, hay fever, or asthma; to increase resistance against disease and bacteria; to correct menstrual irregularities; to cause the annoying symptoms of the menopause to disappear; to correct constipation, hives, acidosis, or skin eruptions; and to prevent heart congestion, gall-bladder congestion, liver and kidney congestion, poor digestion, mental depression, fatigue, and rheumatism or arthritis.

The Formula No. DP 64 Duodenin and Pancreas Substance Tablets were alleged to be misbranded in that the statements in the labeling, "Contains Duodenin and Pancreas Substance" and "Formula No. DP 64 Duodenin-Pancreas Tablets," were false and misleading in that they represented that the article contained duodenin and pancreas and that it was active and effective because of the presence of duodenin and pancreas; whereas it consisted of inert animal material resembling glandular substance and milk sugar. It was alleged to be misbranded further in that the statement "Useful in Diabetes Mellitus," regarding its curative and therapeutic effect, was false and fraudulent in that the said statements represented that the article was medicinally effective in the treatment of diabetes mellitus; whereas it was not.

The Formula No. RS 63 Useful in Secondary Anemia was alleged to be misbranded in that the statement "Rich in calcium salts and iron," appearing in the labeling, was false and misleading in that it represented that each tablet of the article contained proportionately and relatively large quantities of calcium salts and iron; whereas each tablet contained not more than 0.28 grain (0.018 gram) of combined calcium and not more than 0.0027 grain (0.00017 gram) of combined iron. It was alleged to be misbranded further in that the statement "Useful in Secondary Anemia," appearing in the labeling, regarding its curative and therapeutic effects, was false and fraudulent in that the said statement represented that the article was of medicinal effectiveness in the treatment of secondary anemia; whereas it was not.

On September 20, 1939, pleas of guilty were entered by the defendants and the court imposed a fine of \$240 for all defendants.

GROVER B. HILL, *Acting Secretary of Agriculture.*