of organic iron and that when used as directed, it would supply the consumer thereof with therapeutically important doses of organic iron; whereas it did not contain a substantial amount of organic iron and when used as directed, it would not supply the consumer with therapeutically important doses of organic iron since it contained but an inconsequential amount of iron, either organic or inorganic. It was alleged to be misbranded further in that certain statements in the labeling, regarding its curative and therapeutic effects, falsely and fraudulently represented that it was effective as a treatment for iron-poor blood; effective to benefit the nerves and blood, to improve the digestion, to alleviate nervous fatigue, restless sleep, mental depression, irritability, and headaches when associated with secondary anemia and vitamin B_1 deficiency; effective to increase resistance, to help the blood in case of iron-poor anemia, to relieve many nervous symptoms of secondary anemia, to assist in producing a favorable rise in the hemoglobin and red blood cell count, and to insure improvement in appearance and in the state of well-being; effective to be of great benefit to adolescent girls at the onset of menstruation; and effective as a general tonic in convalescence.

On February 15, 1940, pleas of guilty having been entered on behalf of the defendants, the court imposed fines in the total amount of $1,200, i. e., $400 against each defendant.

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

30998. Adulteration and misbranding of Oralsulin. U. S. v. Lafayette Pharmacal, Inc., and Bern B. Grubb. Pleas of nolo contendere. Corporation fined $50 and costs. Bern B. Grubb fined $25 without costs. (F. & D. No. 42546. Sample Nos. 21735–C, 48552–C, 53661–C.)

The labeling of two of the three shipments of this product bore false and fraudulent statements regarding its curative and therapeutic effectiveness in the treatment of diabetes mellitus; that of a third shipment bore a device conveying the same false and fraudulent implication. The article was also labeled to indicate that it consisted of insulin or an insulin-like substance which was enclosed in a capsule that would resist the action of the gastric juices and protect the product from disintegration in the stomach but which would be dissolved in the intestinal tract; whereas it was not insulin nor did it possess the properties of insulin, its coating was soluble in gastric juices, and the product would dissolve in the stomach. A sample from one shipment was found to contain ginger and that from a second shipment was found to contain starch.

On January 11, 1939, the grand jurors of the United States within and for the Northern District of Indiana presented an indictment against Lafayette Pharmacal, Inc., Lafayette, Ind., and Bern B. Grubb, president of the corporation at the time of the shipments mentioned hereinafter, alleging shipment in violation of the Food and Drugs Act as amended, on or about January 2, January 6, and September 16, 1937, from the State of New York into the States of Louisiana and Maryland, of quantities of Oralsulin which was adulterated and misbranded.

Analyses of the product showed in each instance that it consisted essentially of powdered animal tissues including a small proportion of an enzyme such as is found in pancreas tissue. A sample was found to contain starch and another was found to contain powdered ginger. Biological tests of the samples showed no evidence of insulin activity following oral administration, also that the coating dissolved in the stomach and that the contents disintegrated in the stomach.

The shipment of January 2, 1937, was alleged to be adulterated in that the strength and purity of the article fell below the professed standard and quality under which it was sold in that it was represented to consist of "Enterocap Oralsulin," namely, insulin or an insulin-like substance intended for oral administration, enclosed in a specially devised and perfected capsule which actually protected against gastric action and dissolved in the intestinal canal; whereas it was not insulin, did not contain insulin or any insulin-like substance, it did not possess the properties of insulin, was not enclosed in a capsule which protected it against gastric action and dissolved in the intestinal canal since the capsule was soluble in gastric juice and the said article would disintegrate in the stomach when administered orally. The said shipment was alleged to be misbranded in that the following statements appearing in the labeling, (circular) "In the treatment of Diabetes Mellitus extreme interest was aroused by the introduction of Insulin. As in the case of anything original or novel in therapeutics, many claims were made; and results anticipated have been modified

to a considerable degree as a result of practical use. Naturally enough, the advent of Insulin stimulated investigation and research having for its object the development of an Oral Medication, rather than the use of the hypodermic method. The main handicap was of course recognized to be the factor of gastric digestion or modification; because medicinal animal substances contain endocrine as well as chemical substances of a protein character. The introduction of these into the stomach unprotected, immediately exposes them to modification or even destruction. Can such substances be adequately protected? The answer to this vitally important question is found in the form of Enterocap Oralsulin. Pronounced En'-ter'-o-cap O'-ral'-su-lin. Oralsulin is a desiccation of the pancreas of young food animals, together with interdependent gland desiccations. This is enclosed in a specially devised and perfected capsule or Enterocap, which actually protects against gastric action and dissolves in the intestinal canal," (carton) "Oralsulin Enterocap * * * A Perfect Seal," and (bottle) "Enterocap Oralsulin," were false and misleading for the reasons indicated hereinbefore. It was alleged to be misbranded further in that certain statements in the labeling regarding its curative and therapeutic effects falsely and fraudulently represented that it was effective as a treatment for diabetes mellitus.

The shipment of January 6, 1937, was alleged to be adulterated in that the strength and purity of the article fell below the professed standard and quality under which it was sold in that it was represented to consist of "Enterocap Oralsulin," namely, insulin or an insulin-like substance intended for oral administration and enclosed in a specially devised and perfected capsule which actually protected against gastric action and dissolved in the intestinal canal; to contain a hormone secreted by and peculiar to the pancreas, namely, insulin; and to consist entirely of special desiccation of the pancreas of young food animals, together with interdependent gland desiccations; whereas it was not insulin, it contained no insulin nor any insulin-like substance, it did not possess the properties of insulin, it was not enclosed in a capsule which protected against gastric action and dissolved in the intestinal canal since said capsule was soluble in gastric juice and the article would disintegrate in the stomach when administered orally, it did not contain a hormone secreted by and peculiar to the pancreas, namely, insulin, and it did not consist entirely of a special desiccation of the pancreas of young food animals, together with interdependent gland desiccation since it consisted in part of ginger. The said shipment was alleged to be misbranded in that the following statements in the labeling, (circular) "Diabetes Therapy In the treatment of Diabetes Mellitus extreme interest was aroused by the introduction of Insulin. As in the case of anything original or novel in therapeutics, many claims were made, and results anticipated have been modified to a considerable degree as a result of practical use. Without in any way disparaging the use of Insulin, and encouraging its use as an emergency agent certain considerations attending its use must of necessity have to be considered by the practical physician in general practice. In the first place, the use of Insulin has to be more or less continuous or constant in the average case of diabetes. It is not a question of the administration of a few doses and subsequent arrest of the disease. Many and continuous injections have to be employed and the natural result is that the method of administration becomes irksome and repulsive, in fact, not infrequently, patients complain that the remedy is worse than the disease. Then again there is the question of expense, for the cost of these frequent injections amounts in most cases to a severe strain on the average person's financial resources. Naturally enough, the advent of Insulin stimulated investigation and research having for its object the development of an Endocrine Hormone effect, rather than direct chemical action. It was of course, important to find not only an agent but a method of administering that agent by the mouth instead of by the needle. The main handicap was of course recognized to be the factor of gastric digestion or modification; because medicinal animal substances contain endocrine as well as chemical substances of a protein character. The introduction of these into the stomach unprotected, immediately exposes them to modification or even destruction. Can such substances be adequately protected? The answer to this vitally important question is found in the form of Enterocap Oralsulin. Pronounced En'-ter'-o-cap O'-ral'-su-lin. Oralsulin is a hormone treatment prepared by a special desiccation of the pancreas of young food animals, together with interdependent gland desiccations. This is enclosed in a specially devised and perfected capsule or Enterocap, which actually protects against gastric action but

just as actually dissolves in the intestinal canal," (carton) "Oralsulin * * * Enterocap * * * A Perfect Seal," and (bottle) "Enterocap Oralsulin," were false and misleading for the reasons indicated hereinbefore. It was alleged to be misbranded further in that certain statements in the labeling regarding its therapeutic and curative effects falsely and fraudulently represented that it was effective as a treatment for diabetes mellitus.

The shipment of September 16, 1937, was alleged to be adulterated in that its strength and purity fell below the professed standard and quality under which it was sold in that it was represented to consist of "Enterocap Oralsulin," namely, insulin or an insulin-like substance intended for oral administration and enclosed in an "enteric investure" which released the medicament in the bowel beyond stomach or gastric digestive functioning and to consist entirely of a desiccated pancreas substance the raw materials of which were derived from animals; whereas it was not insulin, did not contain insulin or any insulin-like substance, it did not possess the properties of insulin, was not enclosed in an "enteric investure" which released the medicament in the bowel beyond stomach or gastric digestive functioning in that the said "investure," namely, capsule, was soluble in gastric juice and said article would disintegrate in the stomach when administered orally and said article did not consist entirely of desiccated pancreas substance, the raw materials of which were derived from animals, but did consist in part of starch. The said shipment was alleged to be misbranded further in that the following statements in the labeling, (circular) "Enterocap Oralsulin is an enteric investure of desiccated pancreas substance * * * The raw materials used are from animals," and "Enterocap is the offer of a method to attempt the release of the medicament in the bowel beyond stomach or gastric digestive functioning," (carton) "Oralsulin," and "Enterocap * * * A Perfect Seal," and (bottle) "Enterocap Oralsulin," were false and misleading for the reasons indicated hereinbefore. The said shipment was alleged to be misbranded further in that the letters "Oralsulin," borne on the bottle, carton, and in the circular constituted a device regarding the therapeutic and curative effects of the article and meant to purchasers of said article that the article was effective in the treatment of diabetes mellitus when used as directed in the circular—the device having acquired such meaning through former representations and claims recommending and claiming that the article was efficacious for such purpose—which were made by the defendants in certain circulars enclosed with previous consignments of the article; and said device and statements were false and fraudulent in that they represented falsely and fraudulently that the article was effective as a treatment for diabetes mellitus.

On December 11, 1939, the Lafayette Pharmacal, Inc. entered a plea of nolo contendere as to all the charges aforesaid and the court imposed a fine of $50 and costs against the corporation. On the same date the defendant Bern B. Grubb entered a plea of nolo contendere to the counts charging false and fraudulent curative and therapeutic representations and was fined $25 without costs.

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

30999. Misbranding of Catalyn. U. S. v. (Dr.) Royal Lee (Vitamin Products Co.). Tried to the court and a jury. Verdict of guilty. Fine, $800. Judgment affirmed by Circuit Court of Appeals. Writ of certiorari denied. (F. & D. No. 32917. Sample Nos. 45216–A, 45217–A.)

The labeling of this product bore false and fraudulent representations regarding its curative and therapeutic effectiveness and false and misleading representations regarding its vitamin content.

On December 26, 1934, the United States attorney for the Eastern District of Wisconsin, acting upon a report by the Secretary of Agriculture, filed in the district court an information against Dr. Royal Lee, trading as Vitamin Products Co., Milwaukee, Wis., alleging shipment on or about October 23 and November 2, 1933, from the State of Wisconsin into the State of California of quantities of Catalyn which was misbranded in violation of the Food and Drugs Act as amended.

Analysis showed that the article consisted essentially of a mixture of milk sugar, wheat starch, cellulose, nitrogenous matter, fatty acids, saponifiable oil, and mineral matter including small quantities of compounds of iron, aluminum, calcium and sodium, and phosphates. Biological examination showed that the article contained no detectable quantities of vitamins A, C, and D; and no significant quantities of vitamins B and G.