5459. Wildunger herb tea. (F.D.C. No. 40302. S. No. 60–274 M.)

QUANTITY: 2 100-lb. drums at Detroit, Mich., in possession of Alfred A. Hofmann, t/a Botanical Mail-Order House.

SHIPPED: 2–25–57, from New York, N.Y.

LABEL IN PART: (4-oz. size container) "Wildunger Brand Herb Tea Contains: Bean Shells, Corn Silk, Birch Leaves, Cranberry Leaves, Shave Grass, Peppermint Leaves, Buchu Leaves, Licorice Root, Anise Seed * * * This well blended formula was originated in Bad Wildungen (Germany), one of the world's most famous spas * * * Prepared for and Distributed by Botanical Products, Detroit 19, Michigan U.S.A."

ACCOMPANYING LABELING: Leaflets entitled "Are You Dieting? Are You On A Salt-Fat-Starch or Sugar Restricted Diet?" "Note: Wildunger Brand Herb Tea contains 75% of the herbs mentioned in this reprint * * *," "General Dietetic Rules by Dr. Marc Royal Counselor and County Physician at Bad Wildungen, Germany * * *," "and "Wildunger Brand Herb Tea * * * It's Here At Last!"

RESULTS OF INVESTIGATION: The article in the drums was to be repacked by the consignee into containers holding 4 ozs. and labeled as described above. The accompanying labeling referred to above was used by the consignee in direct mail advertising to customers and prospective customers or was enclosed in packages mailed to customers.

LIBELED: 6–4–57, E. Dist. Mich.

CHARGE: 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was effective in the treatment of diabetes, diseases of the urinary organs, and for improving the health.

DISPOSITION: 7–29–57. Default—destruction.

5460. Dried herbs. (F.D.C. No. 39188. S. Nos. 78–147 L, 86–525/7 L, 88–082 L.)

INFORMATION FILED: 5–10–56, E. Dist. Mich., against Wyatt E. Brown, t/a, W. E. B. Chemical & Products Co., Detroit, Mich.

SHIPPED: Between 6–1–54 and 8–11–54, from Michigan to Minnesota, Ohio, and West Virginia.

LABEL IN PART: (Bag) "For Sugar Diabetes Vinca Major Urtica Dioica Directions Place one teaspoonful in a cup. Pour boiling water over. Let stand 12 hours ___ minutes. Strain and drink one cupful morning and night," "For Asthma * * * Symplocarpus Foetidus Eriodictyon Californicum Viburnum Apulus Directions Place one teaspoonful in a cup. Pour boiling water over. Let stand 12 hours ___ minutes. Strain and drink one cupful morning and night," "X–Special Blood Tonic Podophyllum Peltatum And Other Herbs * * * Dose: 1 Teaspoonful Morning and Night," "Special Nerve Tonic * * * Valeriana Officinalis, Scutellaria Lateriflora, Indian Sage, Lobelia Inflata, Mentha Piperita, Cypripedium, Pubescens, Serpentaria Aristolopia, Humulus, Lupulus, Kolanut, Lousewort, Nipta, Cataria Dose: 1 Teaspoonful Morning and Night," or "Prostate Gland Plantago Majoo Dose: 1 Teaspoonful Morning and Night."

CHARGE: 502(a)—the labeling of the articles, when shipped, contained false and misleading representations and suggestions that the articles would be adequate and effective in the treatment of diabetes, asthma, abnormal conditions of the blood, nervousness and other abnormal conditions affecting the

nerves, or abnormal conditions of the prostate gland, as indicated above; 502(b)(2)—the articles failed to bear labels containing an accurate statement of the quality of contents; and 502(e)(2)—the labels of the articles failed to bear the common or usual name of each active ingredient in the articles.

PLEA: Nolo contendere.

DISPOSITION: 1–27–57. $500 fine and probation for 2 years.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 5441 TO 5460

PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (5447) Seizure contested. Contains opinions of the court.
[2] (5455) Injunction issued.

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5461–5480

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent and (2) a criminal proceeding terminated upon a plea of guilty. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *May 6, 1959.*

CONTENTS*

*For omission of, or unsatisfactory, ingredients statements, see Nos. 5463, 5466, 5469; failure to bear a label containing an accurate statement of the quantity of the contents, No. 5463; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 5463.

502760—59

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 5461–5480

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, and its quality and purity fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength and quality differed from that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug; and (2) the drug was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient, including the proportion of alcohol contained therein; Section 502(f)(1), the labeling of the article failed to bear adequate directions for use; Section 502(f)(2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; Section 502(l), the article was, or purported to be, or was represented as, a drug composed partly of chlortetracycline, bacitracin, or any derivative thereof, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; Section 503(b)(4), the article was subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and, in another case, the article bore the caution statement quoted above, but the article was not one to which Section 503(b)(1) applies.

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

5461. Coron tablets. (F.D.C. No. 40677. S. No. 53–624 M.)

QUANTITY: 368 btls. at Bellaire, Tex.

SHIPPED: 7–31–57, from St. Louis, Mo., by Keith-Victor Pharmacal Co.

LABEL IN PART: "100 No. 501 Tablets Coron Each Tablet contains: Cobalt Gluconate 25 mg. Ferrous Gluconate 200 mg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 2.91 mg. of cobalt (equivalent to 24 mg. of cobalt gluconate) per tablet.

LIBELED: 10–3–57, S. Dist. Tex.

CHARGE: 502(j)—when shipped, the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Dosage: One or two tablets after each