reaction occur, discontinue use immediately and consult your physician. Use only as directed," created the misleading impression that the only potentially harmful effect the article might have was the causing of a visible or otherwise recognizable reaction on the small area of the body treated, and the statement was also misleading because it failed to reveal the fact, material in the light of the representation, that use of the article might sensitize the user to sulfonamides so as to preclude their subsequent use, including their use in serious disease conditions, and that such sensitization might not be recognized by the user. The legend "A Sulfa Drug Compound," appearing in the labeling of the article, was misleading since it created the impression that sulfanilamide was the only pharmacologically active component of the preparation, whereas the preparation also contained carbolic acid and mineral oil, which are pharmacologically active.

Further misbranding, Section 502 (e) (2), the label of the article failed to bear the common or usual name of the active ingredient, carbolic acid; Section 502 (f) (1), the following label statements on some packages did not constitute adequate directions for the use of the article in the treatment of impetigo: "Directions This preparation is intended * * * to soothe * * * irritation and discomfort resulting from such skin diseases as * * * Impetigo * * * Shake well before using and then apply locally by a gentle finger massaging of affected parts," and "Impetigo: Wash affected area with warm water and mild soap. Dry skin thoroughly. Apply solution and massage gently. Open blebs and drain. Repeat application as often as necessary to keep the skin lubricated"; and, Section 502 (f) (2), the labeling of the article failed to warn that its use should be discontinued if the skin condition under treatment became worse, if a new rash appeared, or if the patient developed a fever or any other indication of illness, and it also failed to warn that the article might sensitize the user to sulfonamides so as to preclude their subsequent use, including their use in serious disease conditions.

DISPOSITION: May 28, 1945. The Nu-Basic Product Co., Royal Oak, Mich., claimant, having admitted the facts of the libels, and the cases having been consolidated for trial in the Northern District of Illinois, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1566. Misbranding of Pso-Ridisal. U. S. v. 1,233 Dozen Bottles of Pso-Ridisal (and 2 other seizure actions against Pso-Ridisal). Consent decree of condemnation. Product ordered released under bond. (F. D. C. Nos. 13314, 13415, 13627. Sample Nos. 81350–F, 81385–F, 81399–F.)

LIBELS FILED: Between the approximate dates of August 11 and September 11, 1944, Western District of Missouri; amended libels filed on or about September 12, 1944.

ALLEGED SHIPMENT: Between the approximate dates of April 19 and August 29, 1944, by the Nu-Basic Product Co., from Royal Oak, Mich.

PRODUCT: 1,302½ dozen bottles of *Pso-Ridisal* at Kansas City, Mo. Analyses of samples disclosed that the product consisted essentially of sulfanilamide, carbolic acid, mineral oil, and water.

NATURE OF CHARGE: Misbranding, Section 502 (a). The legend "A Sulfa Drug Compound" and the designation "Pso-Ridisal," appearing on the label of the article, were false and misleading since they implied that the article would be effective for ridding the user of psoriasis, by reason of its content of sulfanilamide, whereas it would not be so effective. The label statement, "This preparation is intended * * * to soothe the * * * irritation and discomfort resulting from such skin diseases as Psoriasis, Dermatitis, Eczema, * * * Athlete's Foot and Dandruff, and to assist in removing * * * unsightly lesions, was false and misleading because the article would not be effective to soothe the irritation and discomfort resulting from psoriasis, dermatitis, eczema, athlete's foot, and dandruff, or to assist in removing unsightly lesions. The label statement, "Warning Initial application should be confined to a small area of the body to permit comparison between treated and untreated parts. Should undesirable reaction occur, discontinue use immediately and consult your physician. Use only as directed," created the misleading impression that the only potentially harmful effect the article might have was the causing of a visible or otherwise recognizable reaction on the small area of the body treated, and it failed to reveal the fact, material in the light of such representation, that use of the article might sensitize the user to sulfonamides so as to preclude their subsequent use, including their use in serious disease

conditions, and that such sensitization might not be recognized by the user. The legend appearing on the label, "A Sulfa Drug Compound," was misleading since it created the impression that sulfanilamide was the only pharmacologically active component of the preparation, whereas the preparation also contained carbolic acid and mineral oil, which are pharmacologically active.

Further misbranding, Section 502 (e) (2), the label of the article failed to bear the common or usual name of the active ingredient, carbolic acid; Section 502 (f) (1), its labeling failed to bear adequate directions for use in the treatment of impetigo, for which purpose the article was offered, since the label statement, "Directions This preparation is intended * * * to soothe * * * irritation and discomfort resulting from such skin diseases as * * * Impetigo * * * Shake well before using and then apply locally by a gentle finger massaging of affected parts," did not constitute adequate directions for use of the article in the treatment of impetigo; and, Section 502 (f) (2), the article contained sulfanilamide and its labeling failed to bear a warning that its use should be discontinued if the skin condition under treatment became worse, if a new rash appeared, or if the patient developed a fever or any other indication of illness, and that the article might sensitize the user of sulfonamides so as to preclude their subsequent use, including their use in serious disease conditions.

DISPOSITION: The Nu-Basic Product Co. appeared as claimant and filed a motion to dismiss on the ground that a libel proceeding was pending in another district based upon the same misbranding as alleged in the instant actions, and that there had been no prior judgment in favor of the Government which would authorize multiple seizures of the product. The motion was subsequently overruled with the filing of amended libels which incorporated the allegations that the labeling had been found by the Commissioner of the Food and Drug Administration to be in a material respect misleading to the injury or damage of the purchaser or consumer of the product, and that an article of like composition and substance to the product, and labeled and branded almost exactly, had been previously the subject of a libel action which resulted in the condemnation of the article for having been misbranded. Thereafter, the cases were consolidated and removed for trial to the Northern District of Illinois, and on May 28, 1945, the claimant having admitted the facts in the libels, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

1567. Adulteration of wild cherry bark. U. S. v. 1 Drum of Wild Cherry Bark. Default decree of condemnation and destruction. (F. D. C. No. 13091. Sample No. 77432-F.)

LIBEL FILED: July 28, 1944, Eastern District of New York.

ALLEGED SHIPMENT: On or about October 4, 1943, by S. B. Penick and Co., from Jersey City, N. J.

PRODUCT: 1 100-pound drum of *wild cherry bark* at Long Island City, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the product consisted in whole or in part of a filthy substance by reason of the presence of insects, insect parts, insect larva capsules, mites, rodent hair fragments, cat hair fragments, human hair fragments, and feather fragments; Section 501 (a) (2), it had been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth; and, Section 501 (b), it purported to be and was represented as *wild cherry bark*, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was not substantially free from extraneous animal material and animal excreta, as required by the standard.

DISPOSITION: July 25, 1945. The sole intervener having withdrawn his claim, judgment of condemnation was entered and the product was ordered destroyed.

1568. Adulteration of Lobelia herb. U. S. v. 4 Bales of Lobelia Herb. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 12977. Sample No. 68461-F.)

LIBEL FILED: July 17, 1944, Southern District of Ohio.

ALLEGED SHIPMENT: On or about August 5, 1943, from Asheville, N. C.