

DRUG FOR VETERINARY USE

3060. Misbranding of Smith's Preparation No. 1. U. S. v. Jennie L. Johnson (Nu Lac Yeaston Co.). Plea of nolo contendere. Fine of \$50, plus costs. (F. D. C. No. 28109. Sample No. 44928-K.)

INFORMATION FILED: January 4, 1950, Southern District of Iowa, against Jennie L. Johnson, trading as the Nu Lac Yeaston Co., Jefferson, Iowa.

ALLEGED SHIPMENT: On or about February 15, 1949, from the State of Iowa into the State of South Dakota.

PRODUCT: Analysis disclosed that the product consisted of copper sulfate 44.04 percent, magnesium sulfate 7.63 percent, potassium iodide 0.30 percent, and methylene blue 0.25 percent, and charcoal and plant material.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label and in order blanks accompanying the article were false and misleading. The statements represented and suggested that the article would be effective in the treatment of necro in hogs, whereas it would not be effective for such purpose.

DISPOSITION: April 22, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$50, plus costs.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3041 TO 3060

PRODUCTS

	N. J. No.		N. J. No.
Angelica seed.....	3049	Prostall.....	3054
Benadryl Capsules.....	3044	Prostate hypertrophy, prepara-	
Benzedrine Sulfate Tablets.....	3041-3043	tion for.....	3054
Colusa Natural Oil and Colusa		Quince seed.....	3050
Natural Oil Capsules.....	3045	Radio Therapeutic Instrument,	
Devices.....	3053, 3058, 3059	Drown.....	3059
Dexedrine Sulfate Tablets.....	3041, 3044	Ruko Aromatic Iodine Bath and	
Drown Radio Therapeutic Instru-		Ruko Double Strength Pine	
ment.....	3059	Needle Bath.....	3057
Mineral oil.....	3047	Salt solution, physiological.....	3052
Min-E-Vita, Improved.....	3055	Seconal sodium capsules.....	3043
Nembutal sodium capsules.....	3043	Sinuothermic device.....	¹ 3058
Nembutal suppositories.....	3051	Smith's Preparation No. 1.....	3060
Orris root.....	3048	Sodium pentobarbital capsules...	3042
Parenteral drugs.....	3052	Thyroid tablets.....	3042
Pentobarbital, sodium, capsules...	3042	Veterinary preparations.....	3060
Phenobarbital tablets.....	3042	Vitamin preparations... 3046, 3055, 3056	
Prophylactics.....	3053	Wheat germ oil capsules.....	3056

¹ (3058) Seizure contested. Contains opinions of the courts.

W.V.
E.R.S.
F.D.C.
D.H.T.
P.E.S.

FEDERAL SECURITY AGENCY

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]

3061-3080

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., August 16, 1950.

CONTENTS*

	Page		Page
Drugs actionable because of failure to bear adequate directions or warning statements.....	62	Drugs and devices actionable because of false and misleading claims.....	81
Drugs actionable because of contamination with filth.....	79	Drugs for human use.....	81
Drugs and devices actionable because of deviation from official or own standards.....	80	Drugs for veterinary use.....	84
		Index.....	87

*For presence of a habit-forming narcotic without warning statement, see Nos. 3064, 3065; omission of, or unsatisfactory, ingredients statements, Nos. 3062-3064, 3066; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3063-3066; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3063, 3064, 3066.

**DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE
DIRECTIONS OR WARNING STATEMENTS**

3061. Action to enjoin and restrain the interstate shipment of Colusa Natural Oil and Colusa Natural Oil Capsules. U. S. v. Chester Walker Colgrove (Colusa Remedy Co.), and Colusa Remedy Co., a corporation. Tried to the court; injunction granted. Action for violation of injunction tried to the court; verdict of guilty. Corporation fined \$5,000; individual fined \$4,000 and placed on probation for 5 years. Judgment affirmed on appeal. Petition for certiorari denied by United States Supreme Court. (Inj. No. 140.)

COMPLAINT FILED: November 20, 1946, Southern District of California, against Chester Walker Colgrove, trading as the Colusa Remedy Co., Los Angeles, Calif. The complaint alleged that the defendant had been and was then shipping in interstate commerce *Colusa Natural Oil* and *Colusa Natural Oil Capsules* which were misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labels of the articles failed to bear adequate directions for use in that the directions for use in the labeling were not adequate in any of the conditions for which the articles were recommended or suggested in their advertising sponsored by the defendant, the packager of the articles. The articles were held for sale to the public for medicine in the treatment of psoriasis, eczema, leg sores, leg ulcers, and athlete's foot.

PRAYER OF COMPLAINT: That a temporary restraining order issue, restraining the defendant from commission of the acts complained of; that pending final determination of the case, a preliminary injunction issue; and that after due proceedings, the preliminary injunction be made permanent.

DISPOSITION: On November 22, 1946, a temporary restraining order was issued against the defendant Colgrove, restraining him from introducing into interstate commerce the products known as *Colusa Natural Oil* and *Colusa Natural Oil Capsules*, until further order of the court. The temporary restraining order subsequently was dissolved, and the Colusa Remedy Co., a corporation, was added as a defendant in the action. The case came on for trial before the court on December 2, 1946. Upon the Government's motion for a preliminary injunction, and after consideration of the evidence submitted and the briefs of the parties, the court, on February 14, 1947, ordered that the defendants be enjoined pending determination of the action. On April 14, 1947, the court, with the consent of the defendants, entered a decree permanently enjoining the defendants from introducing *Colusa Natural Oil*, or any like product, into interstate commerce without a label containing adequate directions for the use of such product in the treatment of all conditions, ills, and diseases for which such product should be prescribed, recommended, and suggested in the advertising material disseminated or sponsored by or on behalf of the defendants, or either of them, which directions should include the quantity of the dose to be taken or applied in the treatment of each of such

conditions, ills, and diseases, as well as the frequency and duration of administration or application of such doses.

On October 3, 1947, an information was filed against both defendants, charging that they had made a number of shipments of *Colusa Natural Oil* and that the labels failed to bear adequate directions for use for certain conditions for which the drug was prescribed, recommended, and suggested in advertising material disseminated and sponsored by the defendants, in disregard of the requirements of the injunction. The matter came on for hearing before the court without a jury on or about December 19, 1947, and at the conclusion thereof, the court found the defendants guilty of contempt. On January 5, 1948, the court fined the Colusa Remedy Co. \$5,000 and Chester Walker Colgrove \$4,000, and sentenced the latter to two years in jail. The jail sentence was suspended, and the defendant was placed on probation for a period of five years, conditioned upon payment of the fine and compliance with all Federal, State, and local laws.

A notice of appeal to the United States Court of Appeals for the Ninth Circuit was filed by the defendants on January 13, 1948; and on August 8, 1949, after consideration of the briefs and arguments of counsel, the following opinion was handed down by that court:

HEALY, *Circuit Judge*: "This is an appeal from a judgment holding the appellants in criminal contempt of a preliminary and permanent injunction issued under 21 USCA Section 332 (a), a provision of the Federal Food, Drug and Cosmetic Act.

"The corporate appellant is controlled by the individual appellant Colgrove. For a number of years Colgrove has been marketing through this or other companies two products, Colusa Natural Oil and Colusa Natural Oil in capsules, and has advertised them on a national scale as remedies beneficial in the treatment of various skin diseases. His court experience in this respect is of significance. In a case decided in 1947, *United States v. 9 Bottles Colusa Natural Oil*, 78 F. Supp. 721, there were findings that the products are composed of crude petroleum oil and are of no value in the treatment of skin affections; and that their use in some circumstances may even be harmful. Numerous actions have been resorted to by the government in all parts of the country for the condemnation of the products because of the asserted illegal introduction of them in commerce, in most of which proceedings judgments for the complainant were taken by default.¹ In 1942 Colgrove and a corporation he controlled were convicted in the district court for the Northern District of California of violating the Act by the interstate shipment of misbranded drugs.²

"In 1945 appellants changed the labeling of the Colusa Oil preparations so that the labels failed to mention any maladies for which the drugs were recommended. However, they then proclaimed the worth of the products in the treatment of specified ailments extensively in newspaper advertisements. Early in 1947 the United States sought an injunction in the court below restraining the shipment of the products in interstate commerce without a label containing adequate directions for their use in the treatment of all conditions for which they were prescribed, recommended and suggested in the advertising material. The action was predicated on 21 USCA Section 352 (f) (1), which provides that a drug or device shall be deemed to be misbranded unless its labeling bears adequate directions for use.³ A preliminary injunction was

¹ Consult Federal Security Agency publications, "Notices of judgment under the Federal Food, Drug and Cosmetic Act, Nos. 1383 and 2087," dated April 1946 and December 1947, respectively.

² The conviction was set aside by this court because of rulings on evidence (136 F. 2d 868), and on remand there was a plea of nolo contendere and sentences of fine and imprisonment were imposed.

³ Interpretative regulations of the Federal Security Administrator, promulgated pursuant to 21 USCA Section 371 (a), provide that directions for use may be inadequate by reason of omission, in whole or in part, of directions for use "in all conditions for which such drug or device is prescribed, recommended, or suggested in its labeling, or in its advertising disseminated or sponsored by or on behalf of its manufacturer or packer. . . ." Section 2.106 (a), Title 21 Code of Federal Regulations 1943, Cum. Supp., p. 5224, as amended by 1946 Supp., p. 2952.

granted, after which the court issued a permanent injunction with appellants' consent. Appellants then devised a label on which it was stated that the products were intended for use in the treatment of four skin diseases, namely psoriasis, eczema, athlete's foot, and leg ulcers. Specific directions as to the method of use for these affections were incorporated in the label. The newspaper advertising was thereupon changed in such manner as to highlight these four diseases; but the advertising contained, in addition, reports of benefits derived in the treatment of other skin diseases not mentioned on the label, no adequate directions for use being given. Among the other skin affections referred to are poison ivy or oak, and acne, these conditions being mentioned in excerpts from testimonials received from doctors and druggists, and from letters from satisfied customers.

"Thereupon the government filed a contempt information containing nine counts, predicated on allegations of nine interstate shipments. The charge in each count is that appellants disregarded the injunctive orders in that the advertising material disseminated by them prescribed, recommended and suggested the use of the oil in the treatment of certain diseases in addition to the four mentioned on the label, and that adequate directions for using the remedy for those diseases were not printed on the label. The information is based on 21 USCA Section 332 (b). A jury and special findings were waived and upon trial to the court appellants were adjudged guilty on eight counts.

"Numerous arguments for a reversal are advanced, but few of which are worthy of discussion. The first point urged is that the court lacked jurisdiction of the subject matter and of the parties. There was no lack of jurisdiction of either. Appellants themselves appeared voluntarily. The Act prohibits the introduction into interstate commerce of any misbranded drug. 21 USCA Section 331 (a). A drug is deemed misbranded if its labeling bears inadequate directions for use, 21 USCA Section 352 (f) (1); and as appears in footnote 3 above the authoritative regulations declare directions inadequate if there is an omission of directions for use in all conditions for which the drug is prescribed, recommended or suggested in advertising matter sponsored by the manufacturer or distributor. The court's statutory authority for the issuance of the injunctions and for the trial of violations thereof is ample and has already been indicated.

"A large part of appellants' brief is devoted to collateral attacks on the injunctions, but since they were not appealed from and no modification was sought they are immune from challenge for mere error. It is settled law that unless an injunction is void its propriety must be tested by appeal and not by disobedience. *Clarke v. Federal Trade Commission*, 9 Cir., 128 F. 2d 542, and authorities there cited. Cf. also *United States v. United Mine Workers*, 330 U. S. 258, 293.

"As already seen, the injunctions prohibited appellants from introducing their Colusa Oil into commerce without a label containing adequate directions for use in the treatment of all conditions for which the product is 'prescribed, recommended and suggested' in their advertising material, that is to say, the key words in the orders were employed conjunctively, not disjunctively as they might have been under the administrative regulations. Colgrove was quick to seize upon the discrepancy, and he steered his course so as to sail as closely into the wind as he thought he safely could. His primary claim both below and here is that while the advertising matter relating to diseases other than the four mentioned on the label may be taken as 'recommending and suggesting' the use of the oil, its use is not therein 'prescribed' for the other diseases, hence the literal terms of the injunction were observed. We are of a contrary opinion.

"The advertisements address themselves to 'Skin Sufferers.' Photographs of the skin before and after treatment for eczema and leg ulcers are shown, and these two diseases, together with the remaining two mentioned on the labels, are named in large type. Following that, in small type, are columns headed 'summary of clinical reports on 28 cases,' 'thousands of doctors are Colusa customers,' 'excerpts from reports by druggists,' and 'thousands of users write letters of praise.' These subheadings refer indiscriminately, not only to the four diseases mentioned in the label, but also to acne and poison ivy or oak, and in the letters from lay users to a number of other skin conditions as well. We

append in the footnote excerpts from the material emanating from professional sources.⁴

"Little comment need be made on this advertising; it speaks for itself. Plainly the sponsor intended to be understood as adopting as his own the quoted statements of the doctors and professional dispensers of the preparation. That these would be taken by the lay reader as unqualifiedly prescribing the use of Colusa oil in the treatment of acne and poison ivy or oak, admits of no fair doubt.⁵ The term 'prescribe' is given the following definition by Webster: 'Med. To direct, designate, or order the use of, as a remedy.'⁶ The word 'designate,' in turn, is defined as 'to mark out and make known; to point out; to indicate.' Neither logic nor fairness requires a narrower definition of the term when employed in flamboyant advertising like the present. The word 'prescribe' of course includes recommending and suggesting.

"Other points urged are unworthy of specific attention.

"Affirmed."

The individual defendant filed a petition for certiorari with the United States Supreme Court on November 17, 1949, and this petition was denied on January 9, 1950.

3062. Misbranding of Powdr X. U. S. v. Lafayette M. Gray (L. M. Gray and Powdr-X Co.). Plea of not guilty. Tried to the jury. Verdict of guilty on counts 1 and 3 and not guilty on count 2. Fine of \$1,000 and costs. Judgment reversed by court of appeals and new trial ordered. Petition for certiorari denied by Supreme Court. Plea of nolo contendere. Fine, \$1,000. (F. D. C. No. 21482. Sample Nos. 43748-H, 43981-H, 44462-H, 52670-H.)

INFORMATION FILED: July 31, 1947, District of Minnesota, against Lafayette M. Gray, trading as L. M. Gray and the Powdr-X Co., Minneapolis, Minn.

ALLEGED SHIPMENT: Between the approximate dates of December 4, 1945, and March 23, 1946, from the State of Minnesota into the States of California and Indiana.

LABEL, IN PART: "Powdr X * * * Contents Silicon Dioxide, Aluminum Oxide, Ferric Oxide, Calcium Oxide, Magnesium Oxide, Sodium Oxide."

⁴ "SUMMARY OF CLINICAL REPORTS ON 28 CASES—

"A doctor who owns a hospital in Texas reported under oath that in a clinic of 20 cases of psoriasis, 16 cleared of all lesions completely in 30 days—4 were 70% clear and continued treatment; that out of 40 cases of eczema all but three were cleared of all lesions in 3 weeks to a month with prognosis of the three good for recovery; that out of 11 cases of athlete's foot all, save one who did not return for treatment, were completely cured—8 to 14 days for acute cases and 3 weeks for chronic cases; that out of three cases of leg ulcers complete healing resulted in all 3 of the cases in a month; and in 8 cases of poison ivy or oak, complete cures were effected in an average of 5 days.' His report states, 'not in a single case of this clinical group did I meet with toxic bad effects . . . Intolerance or flare-ups . . . Colusa may be used near the eyes without danger . . . it relieves itching quickly. A little of the oil covers large areas. It is non-irritating. Soothing to raw and denuded lesions and affected areas. Easily massaged into the skin.'

"Two other doctors make similar glowing clinic reports—one, a United States Government health physician reporting on 25 cases, and the other a Mexican Government health physician reporting on 43 cases.

"THOUSANDS OF DOCTORS ARE COLUSA CUTOMERS

EXCERPTS FROM A FEW OF THEIR REPORTS—

"New York—Dr. C.—practiced 10 years. . . . (Case b) 'Poison ivy on entire body. Intense itching and swelling, itching stopped almost immediately on application of Colusa prod. and had entirely cleared in 5 days.'

"Ohio—Dr. H.—practiced 44 years. . . . (Case b) 'acne, 3 cases, all improving.'

"EXCERPTS FROM REPORTS BY DRUGGISTS—

"Nebraska druggist—99% pleased customers. Stubborn cases: . . . 'Worked wonderfully acne.'"

⁵ In the stipulation of facts made on trial the appellants impliedly concede that the advertising prescribed the use of the oil for the four diseases mentioned on the label. Colgrove appears to make a like concession in his oral testimony. There is no valid ground for the attempts to distinguish between the language employed in references to these four diseases and that relating to others referred to by the doctors and druggists.

⁶ Webster's New International Dictionary, 1937 Ed. Unabridged.