2755. Misbranding of Brandenfels' Scalp and Hair Treatment. U. S. v. 43 Bottles, etc. (F. D. C. No. 21914. Sample Nos. 39009–H, 39010–H.)

LIBEL FILED: December 4, 1946, Eastern District of Michigan; amended libel filed May 3, 1948, Western District of Washington.

ALLEGED SHIPMENT: On or about November 7, 1946, by Carl Brandenfels, from St. Helens, Oreg.

PRODUCT: 43 16-ounce bottles and 43 8-ounce bottles of *Brandenfels' Scalp and Hair Treatment* at Detroit, Mich. Examination of the 16-ounce bottles of the product showed that the product consisted essentially of about ¼ gram of sulfanilamide in each 100 cc., water, and cornstarch, and that the product in the 8-ounce bottles consisted essentially of a perfumed emulsion of oil in water.

LABEL, IN PART: "Brandenfels' Scalp and Hair Treatment Formula A * * * Contents: 16 Ounces [or "Formula B * * * Contents: 8 Ounces"]."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Scalp and Hair Treatment" and "The Hair Farmer" were false and misleading since they represented and suggested that the articles when used as directed were effective in promoting the growth of hair, whereas the articles were not effective for such purposes.

Further misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use by reason of its failure to state all of the conditions for which the articles were intended, namely, growing hair in bald areas, curing dandruff, and stopping falling hair from continuing to fall out, as well as promoting the growth of hair; and, further, the labeling of the articles failed to bear adequate directions for use in the conditions, namely, growing hair in bald areas, curing dandruff, stopping falling hair from continuing to fall out, and promoting the growth of hair, for which they were prescribed, recommended, and suggested in their labeling and in their advertising disseminated and sponsored by and on behalf of their manufacturer and packer.

DISPOSITION: Carl Brandenfels, Inc., appeared as claimant and filed an answer denying the allegations of the libel. Thereafter, pursuant to stipulation by the parties, the case was removed for trial to the Western District of Washington on December 22, 1947. On March 16, 1949, the claimant having consented to the entry of a decree, judgment of condemnation was entered and the products were ordered destroyed.

DRUG ACTIONABLE BECAUSE OF THE PRESENCE OF A NONCERTIFIED COAL-TAR COLOR*

2756. Adulteration of Meth-O-Sol and alleged misbranding of Benz-Cal-Cin. U. S. v. Crescent-Kelvan Co., Jeremiah T. Roach, and George Duke Lambert. Pleas of not guilty. Tried to the jury. Verdict of guilty. Fine of $1.00 against company; each individual fined $500 and placed on probation for 2 years. Judgment of conviction reversed upon appeal and case retried upon pleas of not guilty. Count 2 dismissed and verdict of guilty returned on count 1. Fine of $1 against company, $100 against defendant Roach, and $150 against defendant Lambert.

*See also No. 2766.

Imposition of prison sentence suspended and each individual placed on probation for 1 year. (F. D. C. No. 15500. Sample Nos. 79916–F, 79919–F.)

INFORMATION FILED: March 7, 1946, Eastern District of Pennsylvania, against the Crescent-Kelvan Co., an association, Philadelphia, Pa., Jeremiah T. Roach, president, and George Duke Lambert, secretary-treasurer of the company.

ALLEGED SHIPMENT: On or about March 7 and June 22, 1944, from the State of Pennsylvania into the State of Maryland.

NATURE OF CHARGE: Adulteration, Section 501 (a) (4), and misbranding, Section 502 (e). The charges of adulteration against the *Meth-O-Sol* and misbranding against the *Benz-Cal-Cin* are given in the court opinion set forth below.

DISPOSITION: Pleas of not guilty having been entered, the case came on for trial before a jury, and at the conclusion of the trial on January 17, 1947, the jury returned a verdict of guilty. A motion for a new trial was made on behalf of the defendants, and on January 31, 1947, the motion was denied. On the same date, the court imposed a fine of $1 against the company and a fine of $500 against each individual and placed the individuals on probation for a period of 2 years. Notice of Appeal to the United States Court of Appeals for the Third Circuit was thereupon filed on behalf of the defendants, and on January 26, 1948, after consideration of the briefs and arguments of counsel, the following opinion was handed down by that court:

BIGGS, *Circuit Judge:* "The information in the case at bar charges Crescent-Kelvan Company and the individual defendants in two separate counts with violations of the Federal Food, Drug and Cosmetic Act of June 25, 1938, c. 675, Section 1 et seq., 52 Stat. 1040 (1938), 21 U. S. C. § 301 et seq. (Supp. 1946).

"The first count charges that the defendants caused to be shipped in interstate commerce a drug, known by the trade name of 'Methosol,' adulterated within the purview of Section 501 (a) (4) of the Act, 21 U. S. C. A. § 351 (a) (4) (Supp. 1946), in that it contained, for purpose of coloring only, a coal-tar color, 'Butter Yellow,' actually dimethylamino-azobenzene, which had not been certified for use in accordance with the regulations [1] promulgated under Section 504 of the Act, 21 U. S. C. A. § 354 (Supp. 1946). The defendants do not contend that the drug was not within the purview and prohibition of the statute. Their defenses lie on other grounds which will be dealt with hereinafter.

"The second count charges a violation of Section 502 (e) of the Act, 21 U. S. C. A. § 352 (e) (Supp. 1946), in that the defendants caused to be shipped in interstate commerce certain capsules in a bottle labeled in pertinent part as follows: '1000 (Capsules) BENZ-CAL-CIN, Trade Mark, Chemical Combination Benzoinated-Phenyl Cinchoninic Acid and Calcium. . . . Each capsule represents Phenyl cinchoninic acid approximately two grains.' The gravamen of the charge in the count is misbranding in that the drug, 'Benz-Cal-Cin,' a fabrication of two or more ingredients, was not designated solely by a name recognized in an official compendium, the label on the bottle failing to bear the common or used name of each active ingredient, viz., free cinchophen and cinchophen in chemical combination. The defendants contend that

[1] See 21 C. F. R. Cum. Supp., 135.1–15 (1944).

the name on the label 'phenylcinchoninic acid,' was a common or usual name of the drug.

"The facts as shown by the evidence are as follows: While the precise status of Crescent-Kelvan Company cannot be ascertained from the record, it is described in the information as 'an association existing as a business trust under the laws of the Commonwealth of Pennsylvania. . . .' The learned trial judge in his charge told the jury that it was an 'association,' and that an association 'simply means that they operate as a business trust, which they can properly do under the laws of the Commonwealth of Pennsylvania.' Exhibit G–7, a bill of the Crescent-Kelvan Company, states that it is 'A Trust,' and that the defendant Roach is its president and that the defendant Lambert is its secretary-treasurer, while M. W. Lambert is shown as 'Trustee.' It was stipulated by counsel that if the Prothonotary of the Court of Common Pleas, Philadelphia County, were to testify he would produce a certificate, June Term, 1941, C. P. No. 3, 475, signed by Roland J. Christy, dated August 27, 1941, registering under the fictitious name, Crescent-Kelvan Company, which was characterized as 'Chemists to the Medical Professions . . .' and filed by the defendant Lambert as treasurer. We think it may be assumed in the light of the foregoing that Crescent-Kelvan Company was registered under the Pennsylvania Fictitious Names Act, 54 PS Pa. § 21 (1930), and that it is a 'Massachusetts trust' of the sort referred to by the Supreme Court of Pennsylvania in Pennsylvania Company, etc., v. Wallace, 346 Pa. 532, 31 A. 2d 71. In any event it is clear that the defendant Roach purported to act as the president of Crescent-Kelvan Company and that the defendant Lambert purported to act as its secretary-treasurer; that the individual defendants were in charge of the books, records and premises of Crescent-Kelvan Company and that their acts on behalf of it are sufficient to bind the 'Trust.'

"In March, 1944, an inspector of the Philadelphia station of the Food and Drug Administration came to the plant of Crescent-Kelvan Company where the individual defendants were in charge, and inspected the premises. Wagner, the inspector, testified that the inspection was made to ascertain the use by Crescent-Kelvan Company of coal-tar colors in drug products and that he found in the plant a package labeled 'D & O,[2] 4 oz. color, No. 305, for technical use only.'; that he was informed that this coal-tar color was used in the defendant's product 'Methosol'; that he took a sample therefrom, without objection from the individual defendants, offering to pay for it, an offer which was refused.

"Wagner further testified that thereafter he inspected the shipping records of Crescent-Kelvan Company and found that Methosol had been shipped by it to a physician in Maryland, and that Benz-Cal-Cin capsules had been shipped to another doctor in the same State. The two doctors testified that they had received respectively from Crescent-Kelvan Company by parcel post Methosol and Benz-Cal-Cin capsules. There was further testimony by an agent of the Administration that samples of these drugs had been procured from the physicians. Chemists employed by the Administration testified that the Methosol thus procured contained the prohibited coal-tar coloring Butter Yellow and that the Benz-Cal-Cin capsules contained free cinchophen and cinchophen in chemical combination.

"The jury found all defendants guilty on the counts of the information and the court entered judgment of sentence imposing a fine on Crescent-Kelvan Com-

[2] The product was distributed by Dodge & Olcott of New York City.

pany and sentencing the individual defendants to both fine and imprisonment, the sentences of imprisonment, however, being suspended and the individual defendants being placed upon probation. All the defendants have appealed.

"Substantially all of the testimony offered by the United States [3] was subject to repeated objections by the defendants. This brings us immediately to a discussion of the first point raised by them as grounds for reversal. The inspector of the Food and Drug Administration entered the premises of Crescent-Kelvan Company without a search warrant. The defendants assert that they were deprived of the rights guaranteed to them by the Fourth Amendment of the Federal Constitution and that their effects were subjected to unreasonable search and seizure because the inspector made the inspection without a search warrant, because he obtained a sample of the prohibited coal-tar color and, above all, because he inspected the shipping records from which the names of the Maryland doctors were obtained. This inspection of course led ultimately to samples of Methosol and Benz-Cal-Cin capsules being introduced into evidence at the trial.

"Passing by the question as to whether or not the guarantees of the Fourth Amendment may be invoked by a 'Trust' such as that at bar, a question which we need not answer, we find it unnecessary to deal with the defendants' contentions at length for the following reasons. Section 704 of the Act, 21 U. S. C. A. § 374 (Supp. 1946), provides that officers designated by the Administrator, after first making a request and obtaining permission of the owner, or custodian are authorized to enter, at reasonable times, any factory in which drugs are manufactured, processed, packed or held, for introduction to interstate commerce; and to inspect, at reasonable times, such factory and all pertinent equipment, finished and unfinished materials, containers and labeling therein.

"It is not contended that the inspector came upon the premises at an unreasonable time or forced his way into Crescent-Kelvan Company's plant. It is clear from the testimony that whether the inspector expressly requested leave to enter and received such permission from the individual defendants who were in fact in charge of the premises, leave and permission to enter were tacitly granted to the inspector by the individual defendants. Under the statute the inspector had the right to examine the package containing the prohibited coal-tar color, Butter Yellow. But even if the inspector had no express right under the statute to take a sample of the coal-tar color, the individual defendants consented and acquiesced in that taking. It is manifest also that whether or not the statute conferred upon the inspector the right to examine the shipping records of Crescent-Kelvan Company, permission to make such an inspection was implicitly granted to them by the individual defendants then present [4] who had the right to bind the 'Trust.' We find

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[3] None was offered on behalf of the defendants.

[4] Comparing the provisions of Section 704 of the Act 21 U. S. C. A., § 374 (Supp. 1946), with those of Section 703, 21 U. S. C. A., § 373 (Supp. 1946), relating to the inspection of drugs in the possession of carriers engaged in interstate commerce, it should be noted that the right to inspect shipping records is expressly conferred upon officers of the Administration. Since the right to inspect shipping records is not expressly conferred upon inspectors making inspections of factories, it may be argued that an inspection of a factory under the latter section would not include an inspection of the factory's shipping records. On the other side, it may be argued that inspection of a "factory" includes the inspection of everything to be found therein relating to the business of the factory. The latter view seems to us to be more in accord with the canons of statutory construction but it is unnecessary to decide this question in the case at bar.

it unnecessary, therefore, to embark upon a discussion of the authority granted to the inspector by the statute.

"We entertain no doubt that Section 704 is constitutional. Its provisions are bottomed upon the police power of the United States as exercised under the Commerce Clause of the Constitution for the protection of the public health.[5] See McDermott v. Wisconsin, 228 U. S. 115, 128; Hipolite Egg Co. v. United States, 220 U. S. 45, 47, and Seven Cases v. United States, 239 U. S. 510. No constitutional right is violated by a statute, an ordinance or a regulation providing for the inspection of places of business, dealing with drugs or foods during business hours. See Keiper v. City of Louisville, 152 Ky. 691, 154 S. W. 18, State ex rel. Melton v. Nolan, 161 Tenn. 293, 30 S. W. 2d 601, and the authorities collected in 47 Am. Jur. pp. 508–510. By its express terms Section 704 provides for inspection of factory premises only after first obtaining permission from the custodian thereof. The section is patterned on Section 3601 of the Internal Revenue Code and the authority exercised under that statute has never been regarded as violative of the guarantees of the Fourth Amendment. See Cooper v. United States, 3 Cir., 299 F. 483; United States v. Vlahos, 19 F. Supp. 166 (Ore.); In re Meador, 16 F. Cas. No. 9375. See also United States v. Barnes, 222 U. S. 513, and McDermott v. Wisconsin, 228 U. S. 115. The inspector in examining the premises and the shipping records of Crescent-Kelvan Company did no act which constituted a violation of the Fourth Amendment.

"Other grounds asserted by the defendants, however, require reversal of the judgments of conviction and a new trial. These grounds go to the sufficiency of the charge. This subject requires a brief discussion of the offense laid in the second count of the information and of the terms of the statute alleged to have been violated.[6] As we already stated the second count of the information is based on an alleged violation of Section 502 (e) of the Act which provides that a drug shall be deemed to be misbranded 'If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears . . . in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient . . . .' The drug contained in the Benz-Cal-Cin capsules was not designated 'solely' by a name recognized in an official compendium since it was described by the name 'Benz-Cal-Cin,' a trade name, and also was designated as a chemical combination, 'Benzoinated-Phenyl Cinchoninic Acid and Calcium.' The evidence presented shows that Benz-Cal-Cin was fabricated from two or more ingredients. Therefore, under the terms of the statute the active ingredient or ingredients should have been designated by their respective 'common or usual' name. The evidence offered will support the view that the active ingredient in the capsules was cinchophen or, as it is sometimes called, phenylcinchoninic acid.[7] The question, therefore, was whether or not the label on the bottle containing the capsules designated the active ingredient by its common or usual name.

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[5] See Sen. Rep. No. 361, 74th Cong., 1st Sess., p. 26, and H. R. Rep. No. 2139, 75th Cong., 3rd Sess., pp. 2, 12.

[6] No comment respecting the sufficiency of the first count of the information or the charge of the court below thereon is necessary for reasons already apparent.

[7] Cinchophen or phenylcinchoninic acid apparently was the only active ingredient. Cinchophen or phenylcinchoninic acid are the same drug, sometimes also called phenyl-quinoline-carboxylic acid. See The National Formulary, 7th Edition, 1942, published by the American Pharmaceutical Association, at p. 95.

"What did Congress mean when it made use of the phrase 'common or usual name'? The adjective 'common' has a multiplicity of definitions, but the first and the usual definition is 'belonging or pertaining to the community at large . . . habitual or notorious . . . .'[8] The adjective 'usual' is ordinarily deemed to be synonymous with the adjective 'common.' We think, therefore, that Congress intended that drugs should be labeled with the name by which they are known to the community at large. Cinchophen is a powerful drug which has been used as a diuretic in gout and to relieve acute articular rheumatism.[9] Though we may assume that it cannot be procured without a prescription and that therefore it would come into the hands of a member of the public only when prescribed by a physician, none the less we are of the opinion that Congress did not intend to limit the designation of 'common or usual name' by some such further phrase as 'known to physicians or to druggists.' To hold to the contrary would be to amend the statute by judicial interpretation.

"Evidence was offered that the common or usual name of the active ingredient in the Benz-Cal-Cin capsules introduced by the defendants in interstate commerce was 'cinchophen.' The defendants, relying upon the provisions of Section 301 (a) of the Act, 21 U. S. C. A. § 331 (a) (Supp. 1946),[10] and specifically on those of Section 201 (g) and (j) of the Act, 21 U. S. C. A. § 321 (g) and (j) (Supp. 1946),[11] seem to take the position that if the drug contained in the Benz-Cal-Cin capsules was designated on the bottle's label by a name employed in the official The National Formulary,[12] they were relieved from the criminal sanctions of the Act. In this they are in error. While The National Formulary refers to the drug under consideration as 'Cinchophen,' 'Phenylcinchoninic Acid' and 'Phenyl-Quinoline-Carboxylic Acid,'[13] the employment of these names by The National Formulary must be treated only as evidence to be weighed by the jury, in addition to all the other evidence presented, as to what is the common or usual name of the drug. In other words, the question for the jury on this phase of the case is whether the descriptive term phenyl *cinchoninic acid* is the common or usual name of the drug, or whether the word *cinchophen* is its common or usual name as contended by the United States.

"The charge of the court below was insufficient in that it did not set out clearly and adequately this issue of fact. This was the vital issue presented by count 2 of the information and the evidence adduced thereunder. The failure of the trial court to charge the jury adequately on this point was error which requires reversal of the judgments of conviction on the second count.

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[8] See Webster's New International Dictionary, 2d Edition.

[9] See The American Illustrated Medical Dictionary, Dorland, 19th Edition. The drug has since been removed from some formularies by reason of its propensity to cause acute jaundice.

[10] Which provides: "The following acts and the causing thereof are hereby prohibited: (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." 52 Stat. 1042 (1938), 21 U. S. C. A. § 331 (Supp. 1946).

[11] As follows: "(g) The term 'drug' means (1) articles recognized in the . . . official National Formulary . . .; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals . . ." [and] "(j) The term 'official compendium' means the . . . official National Formulary . . .".

[12] The official "The National Formulary", 7th Edition, 1942, published by The American Pharmaceutical Association, p. 95, was introduced into evidence.

[13] The word "Cinchophen," when first employed in the nomenclature of The National Formulary, is in boldface type. The other names in the nomeclature are not. Throughout the article respecting the drug in The National Formulary the reference is usually to "Cinchophen."

"Referring now to the charge generally, we find further error. The learned trial judge stated: 'Jeremiah T. Roach and George Duke Lambert [the individual defendants] are responsible as individuals under the law, and under this information, as it is drawn, for the acts committed by the company contrary to the Federal law.' As we have said the status of the defendant, Crescent-Kelvan Company, is not entirely clear, but putting to one side any question as to the precise nature of the association or trust it is clear that the court below charged that the individual defendants were responsible for the acts committed by Crescent-Kelvan Company. But even if there is evidence to support a conclusion by the jury that the individual defendants were responsible 'for the acts committed by the company' the charge is erroneous none the less. The learned District Judge in fact charged the jury that the individual defendants *were* responsible for the acts committed by Crescent-Kelvan Company. In effect he gave binding instructions in this respect. The trial court should have charged the jury in the usual way that if they believed the evidence of the responsibility of the individual defendants for the acts of Crescent-Kelvan Company to be worthy of credence, then they could find that the individual defendants were responsible for Crescent-Kelvan Company's misconduct. This portion of the charge was erroneous and worked prejudice to the individual defendants and to Crescent-Kelvan Company as well.

"The trial court also, quite inadvertently we know, fairly consistently throughout its charge stated that the guilt of the defendants was to be proved, to quote a typical instance, 'by proving by preponderance of the evidence their wrongdoing'. This misstatement was called to the court's attention by counsel for the defendants at the close of the charge and the court then charged that the United States 'has the burden throughout the trial of establishing, beyond a reasonable doubt, every fact essential to the conviction of the defendants . . . ' Thereafter, counsel for the United States suggested to the court that it might explain to the jury 'the question of reasonable doubt, eliminate the words "preponderance of the evidence" and stick to "reasonable doubt" '. The court said to the jury in response to this suggestion, 'The question of reasonable doubt is the question that you are to determine. If you are satisfied beyond a reasonable doubt that in the first count of the information that there was an adulteration, that is sufficient; if you are satisfied on the second count beyond a reasonable doubt that this was misbranded, that is sufficient. Does that answer your question?—*that is the preponderance of the evidence.*' [14]

"We are of the opinion that viewed as a whole the charge respecting the necessity of the jury finding that the proof offered by the United States was sufficient to prove the defendants' guilt beyond a reasonable doubt, was not clear. The learned trial judge had probably cured the original defects of the charge in this respect until he added the final clause italicized above, 'that is the preponderance of the evidence.' This so confused what he had stated previously that, in our opinion, the jury may well have been misled. Under all the circumstances the charge must be deemed to have been erroneous in this respect. Compare the circumstances of Pomerantz v. United States, 3 Cir., 51 F. 2d 911, and of Thompson v. United States, 3 Cir., 283 F. 895. The defendants in a criminal case are entitled to a clear and unequivocal charge

[14] Italics added.

by the court that the guilt of the defendants must be proved beyond a reasonable doubt.

"In this connection we deem it desirable to call attention to Rule 30 of the Federal Rules of Criminal Procedure, 18 U. S. C. A., foll. Section 687 (Supp. 1946), which provides, *inter alia*, that, "The court shall inform counsel of its proposed action upon the requests [for charge] prior to their arguments to the jury . . .' We cannot say that the error in the charge respecting reasonable doubt would not have occurred had the trial court followed the provisions of Rule 30 and, therefore, we may not say that the defendants were prejudiced by the failure of the trial court to observe the rule. It is possible and even probable, however, that had the provisions of Rule 30 been observed, the court below might not have fallen into error in its charge respecting reasonable doubt. The provisions of the Criminal Rules should be observed.

"Another matter respecting the charge remains for consideration. As we have stated, there are three defendants and there are two counts in the indictment. The jury did not render separate verdicts as to the individual defendants in respect to their guilt on *each* of the two counts. The court did not charge the jury that they should find the respective defendants guilty or not guilty on *each* count of the information. That the jury did not render separate verdicts as to the guilt or innocence of the defendants on each of the two counts is demonstrated by the transcript of what took place in the court room upon the return of the jury with the verdicts. In other words, the jury found all of the defendants guilty without differentiation as to each count. The court then sentenced the defendants, as demonstrated by the respective judgments of conviction and the commitments, without differentiation as to the counts, imposing the respective sentences set out at an earlier point in this opinion.

"The error of the course pursued is, we think, immediately demonstrable by assuming a case in which the appellate tribunal sets aside a judgment of conviction or directs a verdict of acquittal on one of two counts of an indictment or information, the defendant having been found guilty on both counts and sentence having been imposed without regard to the separate counts. Under such circumstances how can the single sentence run against the defendant? He received one sentence on two counts. But the appellate tribunal found that there was enough evidence to support a conviction based on one count and that the trial court had properly charged the jury as to the law respecting that count; whereas, it found that though the evidence was sufficient to support the offense laid in the other count, the trial court had not properly charged the jury respecting the law applicable to that count. Under such circumstances a new trial would be necessary for upon remand the court below could not distinguish between the general verdict of the jury applicable to both counts. To state the matter in other words we say that where there are separate counts in an indictment or information, there must be separate verdicts by the jury, under proper instructions from the court, as to the guilt or innocence of each defendant on each count if a judgment of conviction is to stand where there is error in the record affecting one or more of the counts. The failure of differentiation in the case at bar is not important since the errors of the charge require reversal as to both counts in any event. The practice of separate verdicts on separate counts should be adhered to by the district courts of this circuit where more than one count is contained in an indictment or information.

"The judgments of conviction will be reversed."

The case was retried upon the defendants' pleas of not guilty, and at the conclusion of the testimony on January 4, 1949, and upon motion made on behalf of the defendants, the court ordered that count 2 of the information be dismissed. On the same day, a verdict of guilty on count 1 of the information was returned by the jury.

A motion for a new trial was made on behalf of the defendants, and on February 9, 1949, such motion was denied. On June 2, 1949, the court imposed a fine of $1 against the company, $100 against defendant Roach, and $150 against defendant Lambert. Imposition of prison sentences against the individuals was suspended, and the individuals were placed on probation for 1 year.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2757. Adulteration of Peptulcyl Ampoules. U. S. v. Solex Laboratories, Inc., and Nicholas Raimondi. Pleas of guilty. Fine of $1,000 against corporation and $750 against individual. (F. D. C. No. 21433. Sample No. 20284–H.)

INFORMATION FILED: March 17, 1947, Eastern District of New York, against Solex Laboratories, Inc., Brooklyn, N. Y., and Nicholas Raimondi, president of the corporation.

ALLEGED SHIPMENT: On or about April 18, 1945, from the State of New York into the State of Oklahoma.

LABEL, IN PART: (Carton) "Sterile Intramuscular Solution Peptulcyl Ampoules Formula A neutral solution of: Proteolytic Enzymes"; (ampul) "Peptulcyl Proteolytic Enzymes."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since it was represented to be sterile and to be suitable and appropriate for intramuscular injection, a use which requires a sterile product, whereas the article was not sterile and was unsuitable and inappropriate for intramuscular injection since it was contaminated with viable micro-organisms.

DISPOSITION: October 28, 1948. Pleas of guilty having been entered, the court imposed a fine of $1,000 against the corporation and a fine of $750 against the individual.

2758. Adulteration and misbranding of Obeto, Estrovar, and theobromine compound. U. S. v. Kenneth G. Ziegler (Ziegler Pharmacal Co.). Plea of guilty. Fine of $300 on each of 10 counts, plus suspended fine of $500 and suspended sentence of 1 year's imprisonment on each of remaining 2 counts. Defendant placed on probation for 1 year. (F. D. C. No. 25618. Sample Nos. 4894–K, 6105–K, 6361–K, 12967–K, 19271–K, 27405–K.)

INFORMATION FILED: March 11, 1949, Western District of New York, against Kenneth G. Ziegler, a member of the partnership of the Ziegler Pharmacal Co., Buffalo, N. Y.

ALLEGED SHIPMENT: On or about January 6, February 5, and March 11, 15, and 18, 1948, from the State of New York into the States of Massachusetts, Pennsylvania, Ohio, and Missouri.