ALLEGED SHIPMENT: On or about October 23, 1944, and January 15, March 15, and April 4, 1945, from the State of New York into the States of Missouri, Pennsylvania, and Florida.

NATURE OF CHARGE: *Premo Vasodrine Solution of Epinephrine Hydrochloride.* Adulteration, Section 501 (b), the article purported to be and was represented as "Solution of Epinephrine Hydrochloride," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from and its quality fell below the official standard since the drug had a potency ranging from 27 percent to 56 percent of the potency required by the United States Pharmacopoeia; and its difference in strength and quality from the official standard was not stated on the label. Misbranding, Section 502 (a), the label statement "Solution of Epinephrine Hydrochloride U. S. P. 1–1000" was false and misleading since it represented and suggested that the article consisted of Solution of Epinephrine Hydrochloride which conformed with the requirements of the United States Pharmacopoeia, and that it possessed a potency equivalent to that possessed by a solution containing 1 gram of U. S. P. Epinephrine Reference Standard in each 1,000 cc. The article did not conform with the requirements of the Pharmacopoeia for "Solution of Epinephrine Hydrochloride," and it possessed a potency equivalent to less than that represented.

Premo-Rub Liniment. Adulteration, Section 501(a)(4), the article contained for purposes of coloring only a coal-tar color, Butter Yellow, which color had not been listed for use in drugs in accordance with the regulations and was other than one from a batch that had been certified.

Premo Elixir Preminal. Adulteration, Section 501(a)(4), the article contained for purposes of coloring only a coal-tar color, Methyl Violet, which color had not been listed for use in drugs in accordance with the regulations and was other than one from a batch that had been certified.

DISPOSITION: Pleas of not guilty having been entered, the case came on for trial before the court on March 14, 1949. At the conclusion of the trial on March 17, 1949, the corporation was found guilty on all 6 counts of the information and was fined $1,200. The individual was found guilty on 5 counts of the information and not guilty on count 6 relating to the *Premo Elixir Preminal*, and he was fined $500.

2655. Adulteration of Cornocide (corn remedy). U. S. v. Denver Pharmaceutical Mfg. Co., Inc., and Samuel Garber, David Kaplan, and Samuel Sherman. Pleas of guilty. Fines of $600 against corporation, $50 each against defendants Garber and Kaplan, and $20 against defendant Sherman. (F. D. C. No. 21471. Sample Nos. 8580–H, 8581–H.)

INFORMATION FILED: September 17, 1948, Eastern District of New York, against the Denver Pharmaceutical Mfg. Co., Inc., Long Island City, N. Y., and against Samuel Garber, president, David Kaplan, treasurer, and Samuel Sherman, secretary.

ALLEGED SHIPMENT: On or about May 23, 1946, from the State of New York into the State of New Jersey.

NATURE OF CHARGE: Adulteration, Section 501 (a) (4), the article contained, for purposes of coloring only, coal-tar colors, Butter Yellow (Colour Index No. 19) and Sudan IV (Colour Index No. 258), which had not been listed for

use in drugs in accordance with the regulations, and were other than ones from batches that had been certified in accordance with the regulations.

DISPOSITION: On December 8, 1948, pleas of guilty were entered on behalf of all defendants. On January 13, 1949, the court imposed a fine of $600 against the corporation, and January 20, 1949, the court imposed fines of $50 each against defendants Garber and Kaplan and $20 against defendant Sherman.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

2656. Action to enjoin and restrain the interstate shipment of isotonic solution of sodium chloride, water for injection, epinephrine hydrochloride injection, aminophylline, sodium ascorbate and dextrose injection, sodium iodide and sodium salicylate, sodium iodide and sodium salicylate with colchicine, sodium cacodylate, and sodium thiosulfate. U. S. v. Bristol Laboratories, Inc. Tried to the court. Case dismissed. (Inj. No. 198.)

COMPLAINT FILED: On or about September 25, 1948, Northern District of New York, against Bristol Laboratories, Inc., Syracuse, N. Y. The complaint alleged that the defendant had been and was then shipping in interstate commerce drugs which were adulterated and misbranded.

NATURE OF CHARGE: Adulteration, Section 501 (b), the *isotonic solution of sodium chloride, water for injection, epinephrine hydrochloride injection, aminophylline, and sodium ascorbate and dextrose injection* purported to be and were represented as drugs, the names of which are recognized in the United States Pharmacopoeia, and the *sodium iodide and sodium salicylate, sodium iodide and sodium salicylate with colchicine, sodium cacodylate,* and *sodium thiosulfate* purported to be and were represented as drugs, the names of which are recognized in the National Formulary; and the purity and quality of the drugs fell below the official standards therefor since they were not and had not been substantially free of undissolved material which could be detected readily without magnification when tested in accordance with the method prescribed by the standards; and the differences of the drugs in quality and purity from the standards were not plainly stated, or stated at all, on their labels.

Misbranding, Section 502 (a), the names of the drugs, *isotonic solution of sodium chloride, water for injection, epinephrine hydrochloride injection, aminophylline, and sodium ascorbate and dextrose injection,* and the statement "U. S. P." appearing in the labeling of a number of such drugs, were false and misleading since such names and statement represented and suggested that the drugs conformed to the specifications of the United States Pharmacopoeia, whereas they did not conform to such specifications.

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

DISPOSITION: Pursuant to a motion filed on behalf of the defendant, the court on October 8, 1948, entered an order directing the Government to show cause why an order should not be made requiring it to answer the following interrogatories:

---

*See also No. 2654.

1. State when said drug was introduced into interstate commerce by the defendant in violation of the Federal statute as alleged in the complaint.

2. Where did the plaintiff obtain samples of said drug and on what date and from whom?

3. Was the sample obtained by the plaintiff contained in a vial or ampule?

4. What was the size of the vial or ampule in which the drug was contained?

5. What was the lot number or numbers on the label on the vial or ampule in which said drug was contained? If the plaintiff obtained more than one sample, state the number of samples it obtained of said drug, and if they where in different vials or ampules, state the size of each of the vials and ampules and the respective lot numbers shown on the labels.

6. State in detail what was done with each sample of said drug prior to their examination.

7. State when and where such examination was made and by whom made.

8. State in detail the qualifications of the person making such examination.

9. State in detail the method employed by such person in making the examination and attach copy of any report covering said examination made by said person.

10. If more than one examination was made by the same person, or if more than one person made the examination of said drug, state the names of all persons making the examination, the qualifications of said persons, and attach reports of all examinations made by either or all of said persons covering all samples of said drug.

11. State the nature, chemical, and physical properties, size and number of the undissolved particles found in each of said samples examined by the plaintiff.

12. Describe in detail any and all devices and techniques used in the examination of said drug during the examination.

13. How were the ampules or vials of each sample of said drug treated or handled by plaintiff before examination?

14. Set forth in detail each of the steps followed in making each of said examinations.

15. State how much time was consumed in the actual examination of each of said samples of said drug.

16. How many of such examinations were made on the dates above set forth by each of the persons whose names are above set forth?

17. What other work had been performed by each of said persons on each of said dates prior to examining said drugs?

18. How long after each of said persons began work on each of said dates was said drug examined?

19. What test had been made of the vision of each of the persons above named, and when was each of said tests made and by whom? What was the result of each such test?

20. What in detail, is the interpretation which plaintiff places upon the terms "substantially free" of "undissolved material," "detected readily," "without magnification," "without excessive magnification," and "normal vision"?

21. When was said interpretation adopted? Has said interpretation been changed at any time since 1942? If so, what were the changes in said interpretation, and when were said changes made?

22. What has been the care and treatment of each of said samples of said drugs which were examined since the date of each of said examinations?

23. If a 100 watt incandescent lamp was used, what was the rated voltage at the time it was being operated?

In addition, the order of October 8 directed the Government to show cause why an order should not be made requiring it to make discovery of (1) samples of each of the lots of the allegedly adulterated drugs named in the complaint; (2) the solution and the container used in testing each of the drugs; and (3) photostatic copies of any reports made showing the results of the test and a description of the manner in which the tests were made. A motion also was filed by the defendant to have the complaint made more definite and certain. On October 26, 1948, an answer to the motion was filed giving the information requested. On the same date, answers to certain of the interrogatories, together with information on certain of the matters requested by way of discovery, were filed by the Government, accompanied by objections to answering the other interrogatories and to making discovery of certain matters. The objections and briefs and arguments of counsel were taken under advisement by the court, and on November 13, 1948, the court handed down the following opinion:

BRENNAN, *District Judge:* "Several motions have been made in this action, all of which have been disposed of by the action of the parties, except the matter of answering certain interrogatories heretofore served upon the plaintiff by the defendant. The propriety of the interrogatories comes before this Court through the medium of an order to show cause, which was returnable on October 11, 1948. This decision is directed to that question alone.

"The defendant seeks to propound some twenty-three interrogatories, the answers to which defendant claims are required in order to prepare for trial properly.

"The plaintiff has already filed answer to interrogatories Nos. 1 to 8 inclusive, 13, 22 and part of 9, so that no discussion of same is made in this memorandum.

"This is an action in which the sale or introduction of certain drugs in interstate commerce is sought to be restrained by injunction, for the reason that same, as manufactured by the defendant, fails to meet the requirements of the Federal Food, Drug and Cosmetic Act. A proceeding looking to the granting of a temporary injunction has been commenced by the plaintiff, and same is held in abeyance since it is evident that a trial upon the merits may be had without undue delay.

"The test to which the drugs might be subjected in order to ascertain whether or not they comply with the provisions of law appears on its face to be capable of conflicting constructions, and its application will apparently become a basis of dispute in this litigation.

"It is unnecessary to discuss in detail the law applicable to the dispute arising upon this motion. The defendant relies upon Rule 33 of the Federal Rules of Civil Procedure, and the provisions of Rule 26, as referred to therein. Both rules have been many times subject to judicial interpretation, and it is sufficient to say that the weight of judicial precedents is that they shall be applied with liberality to the end that the parties may not be surprised upon the trial of the action. In deciding this motion the Court has in mind such a construction and application of the rule, and it also has in mind that the plaintiff, in applying for a temporary injunction, would be required to establish affirmatively a basis for that relief which would, in effect, give to the defendant a somewhat detailed basis of the action prior to the trial thereof. It would

seem, therefore, that no serious objection should be made to the answering of any interrogatory which calls for evidence which would be required to be produced upon the temporary injunction proceeding. The cases of U. S. vs. 300 Cans, etc., 7 F. R. D. 36, and U. S. v. 88 Cases, etc., 5 F. R. D. 503, have been considered.

"A consideration of the disputed interrogatories follows:

"Interrogatory No. 9. This interrogatory has been partially answered, and the plaintiff apparently objects to the attaching of a copy of any report covering the examination made by the plaintiff of the drugs manufactured by the defendant. No valid reason exists for such objection. The report would necessarily become part of the temporary injunction proceeding. It is the basis of the action. The interrogatory is allowed.

"Interrogatory No. 10 is allowed.

"Interrogatory No. 11 is disallowed, since the reports in Interrogatories Nos. 9 and 10 will cover the substance of the interrogatory, if, in fact, a record were made of the size and number of the undissolved particles.

"Interrogatory No. 12 is allowed. The information called for may possibly be covered in the answers to Interrogatories Nos. 9 and 10.

"Interrogatory No. 14 is allowed.

"Interrogatory No. 15 is allowed.

"Interrogatories Nos. 16, 17 and 18 are disallowed. They call for details which would seem to be unnecessary at this time. Their propriety may arise on cross examination.

"Interrogatory No. 19. This interrogatory assumes that tests have been made of the vision of the persons conducting the tests. As phrased it would seem to call for unnecessary details. It would seem, however, that the defendant is entitled to know, and the plaintiff is required to show, that the persons conducting the tests possessed and used normal vision, as that term is defined in the test prescribed. The interrogatory is re-framed as follows: 'What means or precautions were taken to establish as a fact that the person or persons at the times of making the tests possessed and used normal vision in the conduct thereof?' The interrogatory as re-framed, if accepted by the defendant, is allowed. The interrogatory as propounded is disallowed.

"Interrogatory No. 20. It is apparent that the expressions in the interrogatory 'without excessive magnification' was intended to read 'without accessory magnification.' The interrogatory is allowed as to all of the terms therein, except 'Detected readily,' 'without magnification' and 'without accessory magnification.' These three terms define themselves. The other terms in the interrogatory may be the subject of dispute which might arise from a difference in interpretation between a chemist and a manufacturer. Such dispute, if it exists, should be openly defined prior to the trial of the issues. The interrogatory is allowed, with the exception of the three expressions or terms excluded as above set forth.

"Interrogatory No. 21 is allowed.

"Interrogatory No. 23 is allowed.

"Order may be submitted accordingly."

Answers to the interrogatories were subsequently filed in accordance with the foregoing opinion. An answer to the complaint was filed on behalf of the defendant, denying that the products were adulterated or misbranded and alleging that the sections of the act involved were unconstitutional and void because (1) such sections attempted to delegate legislative power to persons

who publish or might publish the United States Pharmacopoeia or the National Formulary, (2) such sections set forth no standard for the guidance of the person to whom the legislative power was delegated, (3) such sections purported to require compliance with standards adopted after the effective date of such sections and failed to set forth any requirements for notice or hearing prior to adoption of the standards or for judicial review thereof, and (4) the drug standards involved in the case were vague, uncertain, arbitrary, and capricious. In addition the defendant's answer alleged that the drug standards were illegal and void, in that enforcement of the standards would be in violation of the Administrative Procedure Act because the defendant had neither notice nor opportunity for hearing prior to adoption of the standard and no opportunity for judicial review thereafter.

The case came on for trial on January 17, 1949, and at the conclusion of the testimony for the Government on January 25, 1949, the court granted the defendant's motion for dismissal of the case on the ground (1) that the standards involved were indefinite and (2) that the evidence was insufficient to show such violation of the Act as would warrant the granting of the relief prayed for.

2657. Action to enjoin and restrain the interstate shipment of Kamba or Kamba Tonic. U. S. v. John L. Denney. Tried to the court. Injunction granted. Action for violation of injunction tried to the court. Defendant placed on 6 months' probation. (Inj. No. 98.)

COMPLAINT FILED: May 25, 1944, Southern District of California, against John L. Denney, Fresno, Calif., alleging that the defendant was engaged in the manufacture, production, and sale of a product known as *Kamba* and *Kamba Tonic;* that the product was manufactured from a herb of the rose family, probably of *Chamaebatia foliolosa*, commonly known as bear grass or mountain misery; that it was prepared in three forms, a ground dried herb, the water extract of the herb preserved with sodium benzoate, and the distilled form which is the condensate obtained when boiling the herb with water in the preparation of the water extract of the herb.

The complaint alleged further that the defendant had been and was still shipping the products in interstate commerce under labeling which represented that the herb form was an antitoxin and antiseptic for internal and external use; that it was a tonic and would cure many conditions and diseases, especially arthritis; that the liquid preparation was an antiseptic for internal and external use and was effective as a treatment for disorders of the stomach and bowels, for constipation, hemorrhoids, and arthritis; that the herb and liquid products were capable of destroying poison and bacteria and were beneficial for internal and external troubles, carbuncles, skin diseases, arthritis, bronchial, lung, ear, and eye troubles, sinus and hay fever, scalds, burns, cuts, bruises, boils, athlete's foot, dandruff, constipation, female trouble, gall bladder, stomach ulcers, sleeping sickness, mastitis in cows, dysentery and pneumonia in calves and poultry, streptococcus in chickens and turkeys, and pneumonia and paralysis in chickens; that the products contained 24,000 International Units of vitamin A and "a lot of vitamin B_1"; that they were "preventive medicine accepted by the United States through the mails as being OK"; that they were recommended for eczema, poison oak and ivy, neuralgia, arthritis, and other rheumatisms, open sores, and all forms of skin diseases; that they would clear up the average case of arthritis in about 3 months; that they would kill poisons and cleanse the system; and that "most of the demand for the herb is for arthritis though it is wonderful for stomach ailments and in fact any ailment."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements in the labeling above referred to were false and misleading; Section 502 (b) (2), the labels failed to bear a statement of the quantity of the contents; and, Section 502 (e), the labels failed to bear a statement of the common or usual names of the active ingredients.

Adulteration, Section 501 (c), the strength of the articles differed from, and their quality fell below, that which they purported and were represented to possess since they were not "antitoxin" and "antiseptic," as represented.

PRAYER OF COMPLAINT: That the defendant be restrained and enjoined from shipping in interstate commerce the drugs "Kamba" or "Kamba Tonic."

DISPOSITION: On or about August 30, 1945, a default decree was entered granting the injunction. On September 26, 1945, the defendant filed a motion to set aside the default decree, which was granted on October 8, 1945.

On December 5, 1946, a decree for a permanent injunction was entered enjoining the defendant from introducing or causing to be introduced into interstate commerce any herb concoction, distillate, or other preparations under the name of "Kamba" or "Kamba Tonic" or any preparation made from the genus of herbs known as *Chamaebatia*. On December 27, 1946, the writ of injunction in accordance with said decree was issued.

On or about April 23, 1947, a complaint was filed charging violation of the writ of injunction. On October 3, 1947, the matter having been tried before the court, the defendant was found guilty of contempt and was sentenced to 6 months' imprisonment. The sentence was suspended, and the defendant was placed on probation for 6 months.

2658. Adulteration of Dr. E. R. Eatons Formula. U. S. v. 3 Boxes * * *. (F. D. C. No. 25770. Sample No. 9075–K.)

LIBEL FILED: September 21, 1948, District of New Jersey.

ALLEGED SHIPMENT: On or about August 2, 1948, by the C. F. Kirk Co., from New York, N. Y.

PRODUCT: 3 boxes, each containing 25 ampuls, of *Dr. E. R. Eatons Formula* at Teaneck, N. J.

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 for intravenous use and was contaminated with undissolved material, whereas an article intended for intravenous use should be substantially free of undissolved material.

DISPOSITION: March 28, 1949. Default decree of condemnation and destruction.

2659. Adulteration and misbranding of prophylactics. U. S. v. 5 Gross * * *. (F. D. C. No. 26120. Sample No. 3876–K.)

LIBEL FILED: December 7, 1948, District of Columbia.

ALLEGED SHIPMENT: On or about September 16, 1948, by the Blue Ribbon Co., from Baltimore, Md.

PRODUCT: 5 gross of *prophylactics* at Washington, D. C. The product was packed in 3-unit tins, 4 tins to the package and 12 packages to the carton. Examination of samples showed that 2.45 percent were defective in that they contained holes.