

3381. Alleged misbranding of Nutrilite Food Supplement. U.S. v. 91 Packages, etc. (and 9 other seizure actions). Claimant files answers denying product misbranded. Court denies claimant's motion to consolidate and remove libels to Southern District of California for trial; libels ordered removed and consolidated for trial in Northern District of California. Consent decrees entered providing for delivery of product to charitable institutions. (F. D. C. Nos. 25789, 25810, 25975, 26068, 26085, 26123, 26141 to 26144, incl. Sample Nos. 875-K, 7496-K, 9082-K, 9083-K, 9095-K, 9096-K, 9113-K, 15250-K, 20745-K, 25560-K, 37758-K, 40671-K.)

**LIBELS FILED:** Between the dates of September 30, 1948, and January 14, 1949, in the District of New Jersey, Southern and Western Districts of New York, Southern District of Florida, District of Nebraska, District of Minnesota, Eastern and Western Districts of Washington, and Northern District of Illinois.

**ALLEGED SHIPMENT:** Between the dates of July 25 and December 15, 1948, by Mytinger & Casselberry, Inc., from Long Beach, Calif.

**PRODUCT:** 180 packages of *Nutrilite Food Supplement* and 34 packages of Nutrilite Capsules No. 5 at Belleville, N. J., accompanied by a number of copies of a 58-page edition and a 36-page edition of a booklet entitled "How to Get Well and Stay Well" and a number of copies of booklets entitled "NutriLife Vol. 1 No. 1" and "NutriLife Vol. 1 No. 3"; 19 packages of *Nutrilite Food Supplement* at New York, N. Y., accompanied by a number of copies of a 58-page edition of the booklet "How to Get Well and Stay Well" and a number of booklets entitled "Sales Manual"; 12 packages of *Nutrilite Food Supplement* at Eggertsville, N. Y., accompanied by a number of copies of a 58-page edition of the booklet "How to Get Well and Stay Well"; 20 packages of *Nutrilite Food Supplement* and 6 boxes of Nutrilite Mineral Tablets at St. Petersburg, Fla., accompanied by a number of copies of a 42-page edition of the booklet "How to Get Well and Stay Well" and a number of copies of leaflets entitled "NutriLife Vol. 1 No. 1 [or "No. 3"]"; 654 packages of *Nutrilite Food Supplement*, accompanied by a number of copies of a 36-page edition of the booklet "How to Get Well and Stay Well," and 51 sales kits each containing 2 copies of the 36-page edition of the booklet "How to Get Well and Stay Well" and 3 vials of alfalfa leaves, order blanks, and other printed matter at Minden, N. J.; 200 packages of *Nutrilite Food Supplement* at Clarkfield, Minn., accompanied by a number of copies of a 42-page edition of the booklet "How to Get Well and Stay Well"; 35 packages of *Nutrilite Food Supplement* at Seattle, Wash., accompanied by a number of copies of a 42-page edition of the booklet "How to Get Well and Stay Well"; 19 packages of *Nutrilite Food Supplement* at Spokane, Wash., accompanied by a number of copies of a 42-page edition of the booklet "How to Get Well and Stay Well"; and 78 packages of *Nutrilite Food Supplement* at Oak Park, Ill., accompanied by a number of copies of the 58-page edition and the 42-page edition of the booklet "How to Get Well and Stay Well."

Each package of *Nutrilite Food Supplement* contained 2 bottles of Nutrilite Multiple Vitamin Dietary Supplement Capsules and 1 box of Nutrilite Mineral Tablets.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements in the labeling were false and misleading since the product was not effective to accomplish the results stated and implied. (A description of the labeling and excerpts therefrom and the charges set out in the libels based on the labeling are indicated in the complaint for injunction filed by the Government in the Southern District of California to enjoin Mytinger and Casselberry, Inc., and others from introducing the product *Nutrilite Food Supplement* in interstate commerce under labeling which misbranded it, as reported in notice of judgment No. 3383.)

**DISPOSITION:** Mytinger & Casselberry, Inc., Long Beach, Calif., entered its appearance as claimant in all actions and filed answers denying that the product was misbranded as alleged in the libels. On April 6, 1948, the claimant moved to consolidate and remove the cases to its home district, the Southern District of California. Decision on the motion was held in abeyance pending the termination of the injunction proceedings filed by the claimant to enjoin the Government from making multiple seizures of the claimant's product, as reported in notice of judgment No. 3382.

Upon termination of the injunction suit against the Government, the motion for removal of the seizure actions to the Southern District of California was denied, and the libels were ordered consolidated and removed to the Northern District of California. The court delivered the following opinion:

**FAKE, Chief Judge:** "The issues here arise on motions to consolidate and remove some ten libel actions instituted by the United States in divers jurisdictions about the country. They involve the same parties and substantially the same issues bearing on alleged violations of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. 301 et seq.

"The above act expressly provides for the seizure of drugs in interstate commerce for violations of the act, the seizures to be made by libels as in admiralty. It further provides that when such libel proceedings are pending in two or more jurisdictions, a claimant may apply to the Court of one such jurisdiction for an order consolidating such proceedings for trial in one district, and in the words of the statute that district shall, in the absence of 'good cause to the contrary,' be 'a district of reasonable proximity to claimant's principal place of business.' The weight of authority is that 'a district of reasonable proximity to claimant's principal place of business' excludes the district of claimant's place of business. *United States v. 29 Bottles* \* \* \* *Ocean Lax*, 44 Fed. Supp. 317; *United States v. Six Dozen Bottles* \* \* \* *Dr. Peter's Kuriko*, 55 Fed. Supp. 458; *United States v. 600 Units* \* \* \* *Neu-Ovo*, 60 Fed. Supp. 144; *United States v. 26 Dozen Bottles* \* \* \* *Wheatamin Brand Cevigards*, 60 Fed. Supp. 626.

"I conclude that under this statute, the district of reasonable proximity for the trial of the actions considered here is the United States District Court for the Northern District of California, Southern Division.

"Claimants argue that Title 28 U. S. C. A. 1404 (a) is applicable. That statute is directed toward Change of Venue and provides:

For the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought.

"There is no doubt but that the actions under consideration are civil actions, *Ex Parte Collett*, 337 U. S. 55, but are they such actions as might have been brought in any other districts than those in which they were brought? The answer is no, because they were brought as actions in rem, and as such could be commenced only where the res was found at the time. 28 U. S. C. A. 1395 (b). *United States v. 11 Cases* \* \* \* *Ido-Pheno-Chon* (Civil Action 5145, District Court of the United States, District of Oregon, opinion by Chief Judge Fee, filed August 31, 1950, as yet unreported).

"An order of consolidation will be entered for trials in the Northern District of California, Southern Division."

On April 10, 1951, upon stipulation of the parties that the cases presented no questions for adjudication for the reasons that (1) the products under seizure may have become below label potency and therefore unmarketable by reason of lapse of time and that (2) the use of the labeling involved had been covered by a final consent decree entered in the Southern District of California in the injunction suit referred to hereinbefore, the court ordered that the products be delivered to charitable institutions, with the explanation that the products may be below label potency, and that any literature in possession of the marshal be sent to Mytinger & Casselberry, Inc., Long Beach, Calif., to be disposed of in accordance with the said decree.

**3382. Suit for injunction to restrain prosecution of pending seizures of Nutrilite Food Supplement; to enjoin institution of additional seizures; and to test constitutionality of Section 304 (a) of the Act and administrative action taken thereunder. Mytinger & Casselberry, Inc., v. Oscar R. Ewing, Paul B. Dunbar, Charles W. Crawford, Louis D. Elliott, George P. Larrick, and Tom C. Clark. Motion for dismissal denied; defendants' petition to Supreme Court for writ of prohibition denied. Tried before three-judge court. Decree of permanent injunction; decree reversed upon appeal to Supreme Court.**

**COMPLAINT FILED:** On December 30, 1948, Mytinger & Casselberry, Inc., of Long Beach, Calif., filed in the District of Columbia a complaint for temporary and permanent injunction and temporary restraining order against Oscar R. Ewing, Administrator, Federal Security Agency; Paul B. Dunbar, Commissioner, Charles W. Crawford, Associate Commissioner, Louis D. Elliott, Assistant Commissioner, and George P. Larrick, Assistant Commissioner, Food and Drug Administration; and Tom C. Clark, Attorney General of the United States.

**NATURE OF COMPLAINT:** The complaint alleged that the plaintiff, Mytinger & Casselberry, Inc., had established a large and lucrative business in the distribution of *Nutrilite Food Supplement*, which is an encapsulated concentrate of alfalfa, parsley, and water cress, fortified with vitamins and minerals; that distribution was made by direct contact with consumers through field agents who used a sales booklet entitled "How to Get Well and Stay Well"; and that the booklet contained a general discussion of nutrition, the need for vitamins and minerals, and the consequences of the lack of such factors in the diet, but contained no statements that were false, fraudulent, or misleading.

The complaint recited a history of the firm's contacts with the Food and Drug Administration, which allegedly resulted in elimination of all false labeling claims, and stated that, nevertheless, an indictment had been returned against the firm.

The complaint alleged further that the defendants had caused to be initiated a number of libel actions against, and had been instrumental in having a number of state and local embargoes placed upon, the products of the plaintiff; that additional libel actions were in contemplation; that all such seizure for condemnation actions involved the same issues of law and fact, and that one such case would result in determination of the validity of the claims made by the plaintiff; and the multiple seizure actions had tied up large amounts of *Nutrilite*, which was subject to deterioration and loss of potency with the passage of time, and would be of no value to the plaintiff when the cases had been determined; that no necessity existed for harassing the plaintiff with numerous actions; that the business and good will of the plaintiff were threatened by the arbitrary and illegal actions of the several defendants; and

that the prosecution of such libels in various parts of the United States was unnecessarily oppressive and expensive to the plaintiff since plaintiff's business would be destroyed before an adjudication on the merits could be made.

The complaint alleged also that multiple seizure actions were not authorized by Section 304 (a) of the Act because (1) there had been no prior judgment in favor of the United States; (2) the product was not dangerous to health; and (3) no finding had been served upon the plaintiff to the effect that the labeling of the product was fraudulent or would be in a material respect misleading, to the injury or damage of the purchaser or consumer. The complaint alleged also that the application to its product of a finding which had been made without hearing and which had not been served upon it would deprive it of property without due process of law; that the Food and Drug Administration refused to stipulate or approve a stipulation so as to permit removal of the libels to the Southern District of California, where witnesses were available, thus depriving plaintiff of an opportunity adequately to defend the case; that the defendant officials of the Federal Security Agency were pursuing a course of enforcement over and beyond their prescribed statutory duties, with a design to harass and ruin plaintiff prior to any adjudication on the merits; that the Administrative Procedure Act provides for judicial review of any finding that may have been made as a basis for multiple seizures; and that the finding should be reviewed and set aside because it was an arbitrary, capricious, and unreasonable exercise of discretion in that it was not founded upon fact, and in the circumstances of the case, deprived plaintiff of property without due process of law in violation of the Fifth Amendment.

#### MOTION TO DISMISS

Following the filing of the complaint, a motion for dismissal of the action and for summary judgment was filed on behalf of the defendants. The motion was based on the grounds that (1) the defendant officials of the Federal Security Agency had no control over the litigation and no power to comply with the prayers of the complaint; (2) the recommendations of multiple seizure actions were made in accordance with Section 304 (a) of the Act, and the findings on which the recommendations were based were not subject to judicial review; (3) the complaint failed to state a claim upon which relief could be granted against the Attorney General; (4) the complaint sought relief which was beyond the Court's authority; (5) the complaint failed to state a claim for equitable relief; and (6) the public interest precluded temporary injunctive relief.

After consideration of the briefs and arguments of counsel, Judge Pine of the United States District Court for the District of Columbia, on January 26, 1949, denied the motion without prejudice on the ground that since the initial determination of probable cause had been made by the Food and Drug Administration defendants acting under delegated authority, rather than by the Federal Security Administrator, the determinations were improper.

On January 28, 1949, the Acting Federal Security Administrator, J. Donald Kingsley, made determinations of probable cause. The defendants' motion to dismiss was then renewed. On March 4, 1949, Judge Pine granted defendants' motion to dismiss, with leave to the plaintiff to amend to attack the constitutionality of Section 304 (a) of the Act.

#### AMENDED COMPLAINT

An amended complaint to present the constitutional question was thereupon filed by the plaintiff on the same day, i. e., March 4. The amended complaint

alleged substantially the same facts as were alleged in the original complaint, and, in addition, alleged that Section 304 (a) was repugnant to the due process clause, as it failed to afford plaintiff an opportunity for a hearing prior to the determinations of probable cause.

On March 7, 1949, upon plaintiff's motion for a temporary restraining order, Judge Tamm of the United States District Court of the District of Columbia entered such order to restrain the defendants from instituting and prosecuting any further and additional libel for condemnation actions against plaintiff's product, known as *Nutrilite Food Supplement*, based upon alleged misbranding of the product. In addition it was ordered that the temporary restraining order should remain in force until a hearing and determination of plaintiff's application for an interlocutory injunction could be made by a three-judge statutory court to be appointed to hear and determine such matters.

#### THREE-JUDGE COURT

On March 15, 1949, Judge Bennett C. Clark of the United States Court of Appeals for the District of Columbia and Judges T. Alan Goldsborough and Edward A. Tamm of the United States District Court for the District of Columbia were designated to serve as members of the three-judge statutory court to hear and determine the action. A motion for dismissal of the action was filed on behalf of the defendants, and on April 6, 1949, argument on the motion was heard before the three-judge court. At this time, the court informally directed counsel for the parties to stipulate that the restraining order should be continued in effect, to prepare for a pretrial conference, and to prepare for a trial on the merits as to whether the labeling was materially misleading. The defendants' counsel refused to stipulate, and the court thereupon denied the motion to dismiss. On the same day, the three-judge court, without hearing evidence and without making findings of fact or conclusions of law, entered an order in the nature of a temporary injunction, directing that the defendants be restrained and enjoined temporarily pending final judgment, from continuing or causing to be continued the prosecution of any of the pending libel actions referred to in the complaint, other than the first libel action referred to therein, and from instituting and causing to be instituted further libel actions against, or seizures of, *Nutrilite Food Supplement* until final judgment in the instant case.

#### PRETRIAL CONFERENCE

On April 13, 1949, a pretrial conference was held. During the course of this conference, counsel for the defendants objected to the trial (1) because Judge Pine's ruling was the law of the case on everything but the constitutional issue and (2) because the court was without jurisdiction to go into the question of misleading labeling in that the Act vests exclusively in the Federal Security Administrator the function of determining "whether there is probable cause to believe that the labeling involved in this case is materially misleading to the injury or damage of the purchaser or consumer," as a preliminary to the institution of multiple libel actions. Defendants' counsel also requested the court to vacate its temporary restraining order and preliminary injunction of April 6 for the reason that findings of fact and conclusions of law had not been issued. The defendants' objections having been overruled, the case was scheduled for trial on May 9, 1949. With reference to the issue to be tried, Judge Tamm stated as follows: "The issue before the court fundamentally, insofar as testimony is concerned, will be the question of misleading

labeling in the use of the book 'How to Get Well and Stay Well \* \* \*.' There are two questions before the court, one, a question of fact as to whether the labeling is misleading and, two, the question of whether the action which the defendant in the case took violated the constitutional rights of the plaintiff." Discussion also was had at the conference in regard to the filing by the defendants of an answer to the complaint, and, in accordance with the understanding then reached, such answer was filed on April 21, 1949. The answer (1) challenged the court's jurisdiction to try the issue as to whether the labeling is materially misleading; (2) asserted that the suit was in substance and effect against the United States, which had not consented to be sued; (3) admitted some and denied others of the allegations of the amended complaint, the essential defense being that the defendants acted under Section 304 (a) in requesting the institution of 10 suits against 10 shipments of an allegedly misbranded drug; and (4) denied that the defendants acted to harass the plaintiff or that they acted in excess of their statutory authority.

#### SUBPOENAS DUCES TECUM

Following the conference, the plaintiff served upon the defendant officials of the Federal Security Agency subpoenas duces tecum calling for the production of all records of the Federal Security Agency relating to the plaintiff. The defendants moved to quash the subpoena with respect to defendant Kingsley, on the ground that the subpoena was too vague, broad, and unreasonable, and that it constituted unauthorized probing of the Administrator's mental processes in making his decisions. On April 19, 1949, argument on the motion was heard before Judge Clark.

On April 29, 1949, the court entered an order denying the motion and directing the defendants to produce all records in the case insofar as they related to the decisions of probable cause made in the case. The order excluded the records that related to the criminal action then pending in the United States District Court for the Southern District of California, against Lee S. Mytinger and William S. Casselberry, secretary and president, respectively of Mytinger & Casselberry, Inc. It was ordered also that the defendants should have the right to inspect all documents in possession of the plaintiff or any of its officials or employees, relating to the product involved in the case.

#### PETITION FOR WRITS OF PROHIBITION AND MANDAMUS

On or about May 9, 1949, a petition for writs of prohibition and/or mandamus was filed in the Supreme Court on the ground that the three-judge court proposed action in excess of its jurisdiction in undertaking a trial de novo on the issue as to whether the plaintiff's labeling was materially misleading. The Supreme Court heard oral argument on the petition on May 16, 1949. On the same day, the court denied the petition.

#### PRETRIAL PROCEEDINGS

A motion for a pretrial order to specify the issues to be tried was filed by the defendants with the 3-judge court. On June 14, 1949, the court entered the following statement of the issues:

#### ISSUES TO BE TRIED

"1. The constitutionality, under the due process clause of the Fifth Amendment to the Constitution as applied to the facts in this case, of that provision of Section 304 (a) of the Food, Drug, and Cosmetic Act under which the

defendants have taken the libel and seizure actions without affording to the plaintiff a hearing for the purpose of establishing that the plaintiff's labeling was not, in a material sense, misleading to the injury or damage of the purchaser or consumer.

"2. Whether the defendants, in violation of the Fifth Amendment to the Constitution, acted arbitrarily, unlawfully, oppressively, and capriciously in determining, under Section 304 (a) of the Food, Drug, and Cosmetic Act, that the labeling of the plaintiff's product was, in a material respect, misleading to the injury or damage of the purchaser or consumer, without affording the plaintiff a hearing."

Subsequent to June 14, 1949, answers were made to the plaintiff's request for admissions, to the plaintiff's written interrogatories, and to the defendants' written interrogatories.

#### TRIAL

Following the service of such answers, the case was tried before the three-judge court from October 17 to 27, 1949. At the conclusion of the trial, the court held in an oral decision that the particular provision of the law involved in the case relating to multiple seizures was unconstitutional and that the defendants, in initiating multiple libel proceedings against the plaintiff without first affording to them a hearing upon the issue of whether the labeling upon the plaintiff's product was misleading, acted arbitrarily, oppressively, and capriciously; and on December 14, 1949, the court handed down findings of fact and conclusions of law to that effect.

On the same day, December 14, the court entered a decree of permanent injunction against the defendants, pursuant to which the defendants were permanently enjoined from continuing or causing to continue the prosecution of any of the libel for condemnation actions pending against *Nutrilite Food Supplement*; and from instituting or causing to be instituted any further or additional libel for condemnation actions, or any other actions against *Nutrilite Food Supplement*, under the provisions of the Act which had been held to be unconstitutional.

#### APPEAL

The defendants appealed directly to the United States Supreme Court from the decision of the three-judge court. On May 29, 1950, the following opinion reversing such decision was handed down by the Supreme Court:

Mr. JUSTICE DOUGLAS: "This is an appeal<sup>1</sup> from a three-judge District Court specially constituted on appellee's application for an injunction to restrain enforcement of a portion of an Act of Congress for repugnance to the Due Process Clause of the Fifth Amendment.<sup>2</sup>

"Section 304 (a) of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. § 334 (a), 52 Stat. 1044, as amended, 62 Stat. 382, 21 U. S. C. Supp. III § 334 (a), permits multiple seizures of misbranded articles 'when the Administrator has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Agency that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer.'<sup>3</sup>

<sup>1</sup> 28 U. S. C. §§ 1253, 2101, 62 Stat. 928, 961.

<sup>2</sup> 28 U. S. C. §§ 2282, 2284, 62 Stat. 968.

<sup>3</sup> The provision of which the quoted portion is a part reads as follows: "Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: Provided, however, That no libel for condemnation shall be instituted under this Act, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon

"Appellee is the exclusive national distributor of Nutrilite Food Supplement, an encapsulated concentrate of alfalfa, water cress, parsley, and synthetic vitamins combined in a package with mineral tablets. There is no claim that the ingredients of the preparation are harmful or dangerous to health. The sole claim is that the labeling was, to use the statutory words, 'misleading to the injury or damage of the purchaser or consumer' and that therefore the preparation was 'misbranded' when introduced into interstate commerce.

"This was indeed the administrative finding behind eleven seizures resulting in that number of libel suits, between September and December, 1948. The misbranding, it was found, resulted from the booklet which accompanied the preparation.' Shortly thereafter the present suit was instituted to have the multiple seizure provision of § 304 (a) declared unconstitutional and to dismiss all libel cases except the first one instituted. The District Court held that appellants had acted arbitrarily and capriciously in violation of the Fifth Amendment in instituting multiple libel suits without first affording the appellee a hearing on the probable cause issue; that the multiple seizure provision of § 304 (a) was unconstitutional under the Due Process Clause of the Fifth Amendment; and that appellants should be permanently enjoined from instituting any action raising a claim that the booklet accompanying the preparation was a misbranding since it was not fraudulent, false, or misleading. 87 F. Supp. 650.

"First. The administrative finding of probable cause required by § 304 (a) is merely the statutory prerequisite to the bringing of the lawsuit. When the libels are filed the owner has an opportunity to appear as a claimant and to have a full hearing before the court.<sup>5</sup> This hearing, we conclude, satisfies the requirements of due process.

"At times a preliminary decision by an agency is a step in an administrative proceeding. We have repeatedly held that no hearing at the preliminary stage is required by due process so long as the requisite hearing is held before the final administrative order becomes effective. See *Lichter v. United States*, 334 U. S. 742; *Inland Empire Council v. Millis*, 325 U. S. 697; *Opp Cotton Mills v. Administrator*, 312 U. S. 126.

the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitation shall not apply (1) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this Act, or (2) when the Administrator has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Agency that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer."

"The booklet, *How to Get Well and Stay Well*, is used by salesmen in soliciting prospective customers. A version of the booklet in use in 1947 represented that Nutrilite had "cured or greatly helped" such "common ailments" as "Low blood pressure, Ulcers, Mental depression, Pyorrhea, Muscular twitching, Rickets, Worry over small things, Tonsillitis, Hay Fever, Sensitiveness to noise, Underweight, Easily tired, Gas in Stomach, Cuts heal slowly, Faulty vision, Headache, Constipation, Anemia, Boils, Flabby tissues, Hysterical tendency, Eczema, Overweight, Faulty memory, Lack of ambition, Certain bone conditions, Nervousness, Nosebleed, Insomnia (sleeplessness), Allergies, Asthma, Restlessness, Bad skin color, Poor appetite, Billiousness, Neuritis, Night blindness, Migraine, High blood pressure, Sinus trouble, Lack of concentration, Dental caries, Irregular heartbeat, Colitis, Craving for sour foods, Arthritis (rheumatism), Neuralgia, Deafness, Subject to colds." This version is the basis for an indictment now pending in the Southern District of California charging Lee S. Mytinger and William S. Casselberry with the misbranding of Nutrilite in violation of the Federal Food, Drug, and Cosmetic Act.

After a hearing prior to the indictment, appellee revised the booklet. Direct curative claims were eliminated. But pages 41-52 of the revised booklet were devoted to case histories explaining that Nutrilite brought relief from such ailments as diabetes, feeble-mindedness, stomach pains, sneezing and weeping. Appellant Crawford, Associate Commissioner of Food and Drugs, concluded that there was probable cause to believe and that he did believe that this version of the booklet was misleading. On September 28 and 30, 1948, he recommended seizures of Nutrilite shipments.

Appellee thereafter ordered its salesmen to remove pages 37-58 which contained the case histories. The pages which remained pointed to the dangers and prevalence of illness, described the discovery of Nutrilite, and recommended the booklet to those who wanted to get well and stay well. On December 2, 1948, appellant Larrick, Assistant Commissioner of Food and Drugs, made a probable cause determination on these pages of the booklet and recommended seizure.

Six new pages were thereafter added to the booklet. On December 9, 1948, appellant Dunbar, Commissioner of Food and Drugs, made a probable cause determination on that version of the booklet and recommended further seizures.

<sup>5</sup> § 304 (b) provides in part: "The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury."



"But this case does not go as far. Here an administrative agency is merely determining whether a judicial proceeding should be instituted. Moreover, its finding of probable cause, while a necessary prerequisite to multiple seizures, has no effect in and of itself. All proceedings for the enforcement of the Act or to restrain violations of it must be brought by and in the name of the United States. § 307. Whether a suit will be instituted depends on the Attorney General, not on the administrative agency. He may or may not accept the agency's recommendation. If he does, seizures are made and libels are instituted. But the seizures and suits are dependent on the discretion of the Attorney General.

"It is said that these multiple seizure decisions of the administrator can cause irreparable damage to a business. And so they can. The impact of the initiation of judicial proceedings is often serious. Take the case of the grand jury. It returns an indictment against a man without a hearing. It does not determine his guilt; it only determines whether there is probable cause to believe he is guilty. But that determination is conclusive on the issue of probable cause. As a result the defendant can be arrested and held for trial. See *Beavers v. Henkel*, 194 U. S. 73, 85; *Ex parte United States*, 287 U. S. 241, 250. The impact of an indictment is on the reputation or liberty of a man. The same is true where a prosecutor files an information charging violations of the law. The harm to property and business can also be incalculable by the mere institution of proceedings. Yet it has never been held that the hand of government must be stayed until the courts have an opportunity to determine whether the government is justified in instituting suit in the courts. Discretion of any official may be abused. Yet it is not a requirement of due process that there be judicial inquiry before discretion can be exercised. It is sufficient, where only property rights are concerned, that there is at some stage an opportunity for a hearing and a judicial determination. *Phillips v. Commissioner*, 283 U. S. 589, 596-597; *Bowles v. Willingham*, 321 U. S. 503, 520; *Yakus v. United States*, 321 U. S. 414, 442-443.

"One of the oldest examples is the summary destruction of property without prior notice or hearing for the protection of public health. There is no constitutional reason why Congress in the interests of consumer protection may not extend that area of control. It may conclude, as it did here, that public damage may result even from harmless articles if they are allowed to be sold as panaceas for man's ills. A requirement for a hearing, as a matter of constitutional right, does not arise merely because the danger of injury may be more apparent or immediate in the one case than in the other. For all we know the most damage may come from misleading or fraudulent labels. That is a decision for Congress, not for us. The decision of Congress was that the administrative determination to make multiple seizures should be made without a hearing. We cannot say that due process requires one at that stage.

"Second. The District Court had no jurisdiction to review the administrative determination of probable cause.

"The determination of probable cause in and of itself had no binding legal consequence any more than did the final valuation made by the Interstate Commerce Commission in *United States v. Los Angeles & S. L. R. Co.*, 273 U. S. 298. It took the exercise of discretion on the part of the Attorney General, as we have pointed out above, to bring it into play against appellee's business. Judicial review of such a preliminary step in a judicial proceeding is so unique that we are not willing easily to infer that it exists.

"Judicial review of this preliminary phase of the administrative procedure does not fit the statutory scheme nor serve the policy of the Act. Congress made numerous administrative determinations under the Act reviewable by the courts.<sup>6</sup> But it did not place the finding of probable cause under § 304 (a) in that category. This highly selective manner in which Congress has provided for judicial review reinforces the inference that the only review of the issue of probable cause which Congress granted was the one provided in the libel suit. Cf. *Switchmen's Union v. Board*, 320 U. S. 297, 305-306.

"The purpose of the multiple seizure provision is plain. It is to arrest the distribution of an article that is dangerous, or whose labeling is fraudulent

<sup>6</sup> Review of an order of the Administrator refusing to permit an application for a new drug to become effective or suspending the effectiveness of an application is authorized in § 505 (h), 21 U. S. C. § 355 (h). Orders of the Administrator in connection with issuing, amending, or repealing regulations under §§ 401, 403 (j), 404 (a), 406 (a) and (b), 501 (b), 502 (d), 502 (h), 504, 604 are expressly made reviewable by § 701 (e) and (f), 21 U. S. C. § 371 (e) and (f).

or misleading, pending a determination of the issue of adulteration or misbranding. The public therefore has a stake in the jurisdictional issue before us. If the District Court can step in, stay the institution of seizures, and bring the administrative regulation to a halt until it hears the case, the public will be denied the speedy protection which Congress provided by multiple seizures. It is not enough to say that the vitamin preparation in the present case is not dangerous to health. This preparation may be relatively innocuous. But the statutory scheme treats every 'misbranded article' the same in this respect—whether it is 'dangerous to health,' or its labeling is 'fraudulent,' or materially 'misleading to the injury or damage of the purchaser or consumer.'<sup>7</sup> What we do today determines the jurisdiction of the District Court in all the cases in that category. If the court in the present case can halt all multiple seizures but one, so can the court in other cases. The means which Congress provided to protect consumers against the injurious consequences of protracted proceedings would then be seriously impaired. Congress weighed the potential injury to the public from misbranded articles against the injury to the purveyor of the article from a temporary interference with its distribution and decided in favor of the speedy, preventive device of multiple seizures. We would impair or destroy the effectiveness of that device if we sanctioned the interference which a grant of jurisdiction to the District Court would entail. Multiple seizures are the means of protection afforded the public. Consolidation of all the libel suits so that one trial may be had<sup>8</sup> is the relief afforded the distributors of the articles.<sup>9</sup>

"Reversed.

"Mr. Justice Burton concurs in the result.

"Mr. Justice Clark took no part in the consideration or decision of this case."

Mr. JUSTICE JACKSON (dissenting): "The Court does not deal at all with what appears to be the ultimate issue decided by the court below.

"The trial court of three judges wrote no opinion but made forty-three detailed findings of fact which would require twenty of these printed pages to reproduce and which summarize a 1,500-page record of a long trial. Those findings are made largely on undisputed evidence and on evidence from government sources. This Court does not criticize or reverse any of them.

"The substance of these is to find that the Government instituted a multiplicity of court actions, with seizures in widely separated parts of the country, with a purpose to harass appellee and its dealers and intending that these actions and the attendant publicity would injure appellee's business before any of the issues in such cases could be tried. This, the court held, was justified by no emergency the product being, at worst, harmless and having been marketed for years with knowledge of the Department.

"Assuming as I do that the Act on its face is not constitutionally defective, the question remains whether it has been so misused by refusal of administrative hearing, together with such irreparable injury in anticipation of judicial hearing, as to deny appellee due process of law or to amount to an abuse of process of the courts.

"The Government has sought and received from this Court protection against a multiplicity of suits under circumstances where injury was less apparent than in this. *Landis v. North American Co.*, 299 U. S. 248. The holding of the court below and the contention of the appellee here that the

<sup>7</sup> See § 304 (a) note 3, supra.

<sup>8</sup> Sec. 304 (b) provides in part: "When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby."

<sup>9</sup> Congress has granted distributors, through the provision for consolidation of all libel suits, the measure of relief which courts at time grant through a stay of multiple actions. See *Landis v. North American Co.*, 299 U. S. 248.

Government is not entitled to so apply the statute as to bring multiple actions designed to destroy a business before it can be heard in its own defense is not frivolous, to say the least.

"I am constrained to withhold assent to a decision that passes in silence what I think presents a serious issue."

Mr. JUSTICE FRANKFURTER (dissenting): "While I agree with the Court as to the constitutional and statutory issues canvassed in its opinion, I am unable to answer Mr. Justice Jackson's dissent, and I must therefore yield to it.

"Of course Congress may constitutionally vest judicially unreviewable discretion in an executive agency to initiate multiple suits in order to stop trafficking in pernicious drugs or even in those that are harmless, where efficacy is misrepresented. I agree that it has done so in the Federal Food, Drug, and Cosmetic Act of 1938. 52 Stat. 1040, 21 U. S. C. § 301 *et seq.* But it does not at all follow that Congress has thereby cut off the right of access to the courts to prove that the enforcing agency has not acted within the broadest bounds of fair discretion, rare as the occasion may be for such an attempt and however improbable its success.

"Such I understand to be the nature of the proceedings below and such the basis of the District Court's decree. Unless we can say, as I cannot, that the findings in support of it have no support in the evidence, we should not hold that the court below was without jurisdiction to entertain the suit.

"The limited claim which the District Court sustained falls precisely within the qualification left open by this Court in a leading case sustaining the power of Congress to vest unreviewable discretion in executive agencies. When the Court was urged to deny this power of Congress and 'extreme cases' were put showing 'how reckless and arbitrary might be the action of Executive officers,' the Court made this answer:

It will be time enough to deal with such cases, as and when they arise. Suffice it to say, that the courts have rarely, if ever, felt themselves so restrained by technical rules that they could not find some remedy, consistent with the law, for acts, whether done by government or by individual persons, that violated natural justice or were hostile to the fundamental principles devised for the protection of the essential rights of property. *Monongahela Bridge Co. v. United States*, 216 U. S. 177, 195.

Mr. Justice Harlan, speaking for the Court, cast its thought in the language current at the time. But the thought behind the words is not outmoded and controls, I believe, the case before us."

The plaintiff filed a petition for rehearing in the Supreme Court, together with a motion for a stay of the mandate. On June 14, 1950, Mr. Justice Douglas denied the motion for a stay of the mandate. A motion was filed in the District Court on July 5, 1950, to stay the entry of an order on the mandate in that court until the Supreme Court had had an opportunity to act upon the petition for rehearing. On July 21, 1950, Judge Tamm denied the motion for a stay and, in compliance with the mandate of the Supreme Court, ordered that the decree of permanent injunction of December 14, 1949, be dissolved and vacated. A petition to the three-judge court to review Judge Tamm's action was filed on behalf of the plaintiff on July 22, 1950. On October 16, 1950, the Supreme Court denied the petition for rehearing. On November 15, 1950, the three-judge court entered an order denying the petition for review of Judge Tamm's action.

**3383. Action to enjoin and restrain interstate shipment of Nutrilite Food Supplement. U. S. v. Mytinger & Casselberry, Inc., Nutrilite Products, Inc., Lee S. Mytinger, William S. Casselberry, and Carl F. Rehnborg. Consent decree granting injunction. (Inj. No. 214.)**

**COMPLAINTS FILED:** The original complaint was filed on September 22, 1949. On October 23, 1950, the following amended complaint was filed:

"The United States of America, plaintiff herein, by and through Ernest A. Tolin, United States Attorney for the Southern District of California, Central Division, files this Amended Complaint for Injunction and respectfully represents unto the Honorable Court as follows:

"1. This proceeding is brought under section 302 (a) of the Federal Food, Drug, and Cosmetic Act [21 U. S. C. 332 (a)], hereinafter referred to as 'the Act,' specifically investing the several United States District Courts with jurisdiction to enjoin and restrain violations of section 301 of said Act [21 U. S. C. 331] as hereinafter more fully appears.

"2. The defendants, Nutrilite Products, Inc., a California corporation having its principal place of business at Buena Park, California, and Carl F. Rehnberg, an individual who resides at Buena Park, California, are the manufacturers and packers of an article of drug designated by name as Nutrilite Food Supplement. The defendants, Mytinger & Casselberry, Inc., a California corporation having its principal place of business at Long Beach, California, and Lee S. Mytinger and William S. Casselberry, individuals residing at Long Beach, California, are the exclusive national distributors of the drug.

"3. 'Nutrilite Food Supplement' is prepared and distributed in three dosage forms designated as 'Nutrilite Food Supplement XX,' 'Nutrilite Food Supplement X,' and 'Nutrilite Food Supplement Junior.' Each is comprised of an encapsulated multi-vitamin preparation with a base of an extract of alfalfa, dried watercress, and dried parsley, combined in a package with multi-mineral and vitamin tablets. Nutrilite XX and Nutrilite X differ in the package content of vitamin capsules; Nutrilite XX contains 62 capsules, two per day are recommended, and the price is \$19.50 per package, whereas Nutrilite X contains 31 capsules, one per day is recommended, and the cost is \$12.00 per package. Nutrilite Junior also contains 31 capsules, one per day is recommended, the price is \$7.50 per package, and it differs from Nutrilite X in that the potency of Vitamins A, D, and B<sub>1</sub> in each capsule is one-half that of each capsule of Nutrilite X.

"4. The label of the drug 'Nutrilite Food Supplement XX' is, in part, as follows:

[Front Panel]

The NUTRILITE BASE is a highly concentrated extract of specially grown alfalfa and selected watercress and parsley, processed by methods known only to NUTRILITE chemists, and obtainable only in NUTRILITE products. To the base are added crystalline vitamins and vitamin concentrates.

This package contains multiple vitamin capsules and mineral tablets.

Suggested Use: One capsule and three tablets twice daily.

Two capsules and six tablets supply the following amounts and proportions of minimum daily adult requirements:

Vitamin A	25,000	USP Units	625%	Calcium	950	Mgs.	125%
Vitamin D	2,500	USP Units	625%	Phosphorus	562	Mgs.	75%
Vitamin B <sub>1</sub>	20	Mgs.	2000%	Iodine	0.4	Mgs.	400%
Vitamin B <sub>2</sub>	10	Mgs.	500%	Iron	20	Mgs.	200%
Vitamin C	200	Mgs.	666%	Copper	2	Mgs.	xx
Vitamin B <sub>6</sub>	4	Mgs.	x	Manganese	2	Mgs.	x
Vitamin K	1	Mg.	xx	Zinc	2	Mgs.	x
Vitamin E	10	Int. Units	x	Cobalt	0.2	Mgs.	x
Inositol	20	Mgs.	x	Nickel	0.2	Mgs.	x
Folic Acid	1	Mg.	x	Fluorine	0.2	Mgs.	x
Rutin	1	Mg.	x	Niacinamide	25	Mgs.	xx
Para-aminobenzoic Acid	20	Mg.	x	Pantothenic Acid	8	Mgs.	x

(x) Need in human nutrition not established — (xx) Requirement not established.

The labels on Nutrilite X and Nutrilite Junior suggest one capsule and six tablets daily, and the statements of amounts of vitamins and minerals supplied correspond to that dosage. Recent shipments of Nutrilite XX bear labeling which represents that it contains in addition to the ingredients listed above 5 micrograms of Vitamin B<sub>12</sub> and 20 micrograms of Biotin in two capsules (the recommended daily intake).

"5. The drug is not marketed through customary retail channels but is sold by distributors who directly solicit consumers to obtain written contracts (called programs) for delivery of one package of Nutrilite each month. These distributors, who also are purchasers of Nutrilite, are sponsored by other distributors in the defendant Mytinger & Casselberry, Inc. organization who are called 'potentate,' 'high potentate,' or 'exalted potentate' according to the volume of sales produced by his sponsored group.

"6. The distributors in the past have used and at the present time use numerous items of written, printed and graphic matter supplied by the defendants Mytinger & Casselberry, Inc., and Lee S. Mytinger and William S. Casselberry in their distributional scheme.

"7. One item of such written, printed and graphic matter is a booklet entitled 'How to Get Well and Stay Well.' Distributors use and have used this booklet upon their initial approach to prospective consumers. The booklet, which discusses the relationship between vitamins, nutrition and disease, is left with the prospective purchaser for perusal at his leisure and is picked up by the distributor at the time he undertakes to complete the sale. The booklet has been through at least four revisions, each precipitated by governmental action, but the defendant Mytinger and Casselberry, Inc., has contended each time that the earlier booklet made no false or misleading claims for Nutrilite Food Supplement.

"8. The edition of 'How to Get Well and Stay Well' in use until May 1948 represented without qualification that Nutrilite is an effective therapeutic agent in 'almost every case' and is a cure of 'common ailments,' among which the following were specifically listed: low blood pressure, ulcers, mental depression, pyorrhea, muscular twitching, worry over small things, tonsillitis, hay fever, sensitiveness to noise, easily tired, gas in stomach, faulty vision, headache, constipation, boils, lack of ambition, nervousness, nosebleed, insomnia, (sleeplessness), allergies, asthma, restlessness, bad skin color, biliousness, migraine, high blood pressure, sinus trouble, lack of concentration, dental caries, irregular heartbeat, flabby tissues, hysterical tendency, eczema, overweight, faulty memory, colitis, craving for sour foods, arthritis (rheumatism), neuralgia, deafness, subject to colds. At another point the booklet implied that 'cancer, diabetes, heart trouble, high blood pressure, constipation, tuberculosis, arthritis, neuritis' and numerous other diseases would respond to Nutrilite treatment. This booklet also contained testimonial letters by means of which the drug Nutrilite was represented as an effective treatment for many diseases. Said representations were false and misleading in that Nutrilite is not effective in the treatment and cure of such conditions and diseases.

"9. After the firm had been given an opportunity to show cause why a contemplated criminal proceeding should not be instituted against it, it undertook a revision of the booklet. Acting upon the advice of an attorney that they should eliminate the names of all diseases and use instead descriptions of symptoms manifested by persons who had sought relief through Nutrilite, the defendant Mytinger & Casselberry, Inc., devised a 58-page edition of 'How to Get Well and Stay Well.' The principal effects of revision were the elimination of specific disease names, but this edition included a number of case histories explaining to the prospective purchaser how other persons had obtained relief and freedom from such ailments and symptoms of disease as: low vitality, over-fatigue, insomnia, poor appetite, gastro-intestinal distress, recurrent vague aches and pains, weak eyes, defective teeth, nervousness, heart disease, stomach pains, disease conditions requiring surgery, feeble-mindedness, diabetes, hemorrhage connected with the menopause, indigestion, sneezing, weeping, anemia, leukemia, sinus trouble, constipation, tuberculosis, headache, dizziness, vomiting, and all deficiency diseases.

"In order to convey to the public the false and misleading impression that Nutrilite Food Supplement will cure every ailment and disease afflicting mankind, and yet avoid mentioning any specific disease names, the defendants Mytinger & Casselberry, and Lee S. Mytinger and William S. Casselberry, with this revision, inaugurated a subterfuge which they call a 'new language.'

In the 'new language' every ailment or illness is referred to as a state of 'non-health.' This unhappy state is claimed to be a result of body chemical imbalance. When the body is in 'chemical balance,' it is said to be free from all illness and in a state of health. The use of Nutrilite Food Supplement is claimed to bring the body into chemical balance, and thus to bring about the condition of health. The 'new language' insists that Nutrilite will cure nothing—the patient merely gets 'well through the use of Nutrilite.'

"Examples of this, found in the 58-page booklet, follow:

Page 30 - Your body is a chemical machine, and always the chemical balance must be maintained. When your body gets out of chemical balance, you are ill. When you get into chemical balance and stay there, you are well.

Page 40 - Remember that NUTRILITE never cures anything. NUTRILITE provides the body with needed nutrilites and other vital micro-food factors. The body takes these and rebuilds. In the process of rebuilding, the inner cause of the deficiency ailment disappears, and consequently the symptoms cease to bother. Then the person is well, and he *got well through the use of NUTRILITE*, but nothing was cured.

"The 'Sales Manual,' authored and distributed by defendants Mytinger & Casselberry, instructs their salesmen in the use of the 'new language,' in passages such as the following:

Pages 30, 30 - You should capitalize on this new approach and lean over backwards to keep away from the medical procedure. Stay in this newer field, which is the adjustment, through the use of a food supplement, of chemical imbalance resulting from vitamin-mineral deficiency.

Pages 30, 31 - WE NUTRILITE DISTRIBUTORS NEED TO THINK ONLY IN TERMS OF HEALTH AND NOT-HEALTH, and we should FORGET ALL ABOUT PARTICULAR AILMENTS, AND THEIR MEDICAL NAMES. FOR THE COMMON CONCEPTION OF SPECIFIC AILMENTS WITH MEDICAL NAMES, WE MUST SUBSTITUTE IDEAS OF FULL NUTRITION, CHEMICAL BALANCE AND HEALTH.

"When the 58-page edition of the booklet became involved in litigation arising under the Federal Food, Drug, and Comestic Act, the defendants Mytinger & Casselberry, Inc., and Lee S. Mytinger and William S. Casselberry, made further revisions by eliminating the case histories and by substituting new pages, the final result of which was a 42-page edition of the booklet.

"10. The 42-page edition of 'How to Get Well and Stay Well,' when read as a whole, as well as through specific claims, conveys to the reader the false and misleading impression that:

(a) Almost everyone in the United States is either ill or about to become ill;

(b) Almost every common illness including those most responsible for premature death is due to vitamin deficiencies;

(c) The average American diet is deficient in certain vital food factors, including both known and unknown vitamins and minerals which are called 'nutrilites' by all chemists;

(d) These dietary deficiencies are attributable to depleted soil, processing practices and storage methods which make it impossible to obtain in the diet the food factors that are essential to health;

(e) That the common illnesses may be prevented and cured through putting these food factors into the body to bring it into chemical balance;

(f) Illness is merely the result of chemical imbalance, and health is the result of chemical balance; and

(g) Chemical balance and thus getting well and staying well may be achieved through the use of Nutrilite which contains not only the known vitamins and minerals but also, because of its secret and concentrate base, the unknown vitamins and minerals.

"11. Some typical statements used to develop these impressions in the 42-page edition of the booklet 'How to Get Well and Stay Well' as as follows:  
Foreword: What we have tried to do in this book is show the average American, ill with the usual American deficiency ailments in the customary chronic

manner, what may be the cause of his illness, and how he should proceed to get well and stay well.

Page 6 - Your study of yourself, the members of your family, your relatives and friends has shown you that almost *everyone* is more or less ill.

Page 10 - . . . The result is that almost all members of our families have bodies which are malnourished, and show evidences of the malnutrition which causes most of our common deficiency ailments.

\* \* \* \* \*

So the purpose of this book—and the objective of the person who lent you this book—is to bring you to the point where you will recognize the fact clearly that your illness and the illness of your family is, in almost every case, the result of a failure to supply your body and the bodies of the members of your family with the vital food factors.

Page 11 - And remember your reward—a good chance for the relief of deficiency ailments if you have any (and most of our current and common ailments result from deficiencies) and their prevention if you are now lucky enough to be free from them.

Page 22 - Now, be sure to remember this: the American diet is deficient in nutrilites, the protective food factors. Why is this true? Why are we sick and ailing in this land of plenty? Why *don't* we get all the vitamins and minerals need?

Page 23 - English Academy of Medicine, LANCET, states: "99% of common illnesses are due to or are superimposed on vitamin deficiencies."

Page 28 - The flat wheel you develop as a result of diet deficiencies may show itself as one of the common or not so common deficiency diseases, including those most responsible for death in our 40's and 50's, whereas we *should* live in good health and vigor, and with full possession of our faculties, to the age of 90 or 100.

\* \* \* \* \*

. . . Most of the ills and diseases of human beings are unnecessary—they are the result of chemical starvation of our bodies for substances vitally necessary to life.

Page 33 - According to a recent study made by a large and well-known eastern college, only one in a thousand is not suffering from deficiency—from malnutrition. This means that no one can safely say: "I am perfectly healthy and my body is sound and well nourished."

Think of our population, and think of all the common ailments. Pick up any newspaper and you read of prominent citizens dying in early middle age of the various diseases that claim the lives of so many. Think of the people you know who are ill right now, and suffering, without relief.

This would certainly make it look as though each of us might have a body containing many imitation bricks, so that we look reasonably well, we can get around and do some work, but either we are now experiencing some deficiency disease, or we are ready to come down with one.

Page 40 - The sufferer with dietary deficiencies and deficiency ailments has the problem of getting into his body all the basic food factors which either were never in his food to start with or which have been partially removed in some way. If you are such a sufferer, how can these basic food factors be added to your food? We believe that NUTRILITE Food Supplement is at least one answer.

The man, woman or child who is reasonably well, and who wishes to stay that way and if possible improve, has also the problem of keeping his body supplied with all the vital food factors. If you are in this group you too have a problem, in this civilized age of devitalized and imitation food. And here again, you can turn to—NUTRILITE Food Supplement.

"12. Notwithstanding the effort by defendants Mytinger & Casselberry, Inc., Lee S. Mytinger and William S. Casselberry to avoid mention of diseases by name, the 42-page edition of 'How to Get Well and Stay Well' refers to a number of specific diseases, symptoms and conditions for which the product Nutrilite Food Supplement is offered as a preventive, treatment and cure:

Page 1 - Weak and lacking in energy; trouble digesting food; stomach pains; decaying teeth; trouble with heart and other important organs; aches, pains and discomfort in various parts of the body;

Page 2 - Difficulty seeing, hearing;

Page 3 - Partial inability to move the various parts of the body, (stroke or paralysis); partial breakdown of the thought processes (confused thinking); difficulty seeing, hearing, or failure of other sense organs; extreme personality changes; any illness, breakdown or invalidism; any weakness or incapacitated body racked with aches and pains:

Pages 5, 6 - Tuberculosis; spinal curvature;

Page 30 - Allergies;

Page 35 - Old age;

Page 38 - Psychological disturbances.

In addition the booklet, at page 3, represents and suggests that Nutrilite Food Supplement will nourish and rebuild the brain, the heart and the glands. These statements, claims, and representations are false and misleading.

"13. In addition to the statements referred to in paragraphs 11 and 12, there are many instances in the booklet in which defendants Mytinger & Casselberry, Inc., and Lee S. Mytinger and William S. Casselberry, have attempted to fortify certain false claims by use of 'facts' which are inaccurately presented and from which the defendants draw false and misleading conclusions. First, on pages 3 and 4 there is a fragmentary and incomplete quotation from a New York Times article for June 29, 1945, which indicates a rather high rejection rate for women applying for the W. A. C. The booklet 'How to Get Well and Stay Well' attributes these rejections to vitamin and mineral deficiencies, despite the fact that the complete New York Times article lists the specific causes of such rejection, and vitamin and mineral deficiencies are not included. Second, on page 4 there appears a statement that a survey by a large eastern college showed that only 2 out of 2,511 persons studied in Pennsylvania were receiving the vitamins, minerals and proteins they needed. The official report of that survey does not support this claim. Third, on page 6 appears the statement that 32% of draftees in World War II were rejected and that 52½% had some disability. These statements are presented in a context to force the reader to conclude that these rejections and disabilities were the result of vitamin and mineral deficiencies. Official selective service statistics show that vitamin and mineral deficiencies accounted for a negligible percentage of such rejection.

"Fourth, on pages 7, 8, and 9 false statements are made that Carl Rehnberg, the discoverer of Nutrilite, 'majored in biochemistry in an eastern university'; that he 'specialized in the chemistry of foods'; that he took part in 'early vitamin research experiments'; and that he 'returned to the United States in 1927' and 'began a six-year period of intensive study and experimentation.'

"14. Though the defendants, Mytinger & Casselberry, Inc., and Lee S. Mytinger and William S. Casselberry assert that the interstate distribution of the booklet 'How to Get Well and Stay Well' has been discontinued, the booklet remains in the hands of distributors who use it in their sales presentation. Even this alleged discontinuance of interstate distribution was made with the assertion that use of the booklet did not violate the Federal Food, Drug, and Cosmetic Act.

"15. In addition to the booklet 'How to Get Well and Stay Well,' the defendants Mytinger & Casselberry, Inc., and Lee S. Mytinger and William S. Cassel-



berry, have distributed and now distribute and have caused to be distributed to the sales force of Mytinger & Casselberry, Inc., certain other written, printed, and graphic matter consisting of a booklet entitled 'Sales Manual—Nutralite Food Supplement,' a book entitled 'The National Malnutrition' by D. T. Quigley, a book entitled 'Man Alive, You're Half Dead!' by Daniel C. Munro (New York, 1950), weekly issues of a sales publication entitled 'Nutralite News,' and various reprints from popular publications including but not limited to the following:

- 'Modern Miracle Men' by Rex Beach, S. Doc. No. 264, 74th Cong., 2d sess. (1941).
- 'We Feed our Hogs Better than our Children' by Fred Bailey, American Magazine (October 1947).
- 'Nutrition and Pregnancy' by Bruce Bliven, reprinted from *Ladies' Home Journal* (November 1947).
- 'The Miracle of Dr. Spies' by Dickson Hartwell, reprinted from *Colliers* (January 31, 1948).
- 'Vitamins are not Drugs!' by Dr. Simon Bensen, reprinted from *The Apothecary* (June 1946), by Lee Foundation for Nutritional Research.
- 'The Latest on Vitamin Pills' by Clarence Woodbury, *Woman's Home Companion* (January 1949).
- 'What Makes You Healthy?' by Winifred Raushenbush, *Ladies' Home Journal* (March 1949).
- 'Bangs Disease and Undulant Fever are Due to Nutritional Deficiencies' by J. F. Wischhusen, *American Feed and Grain Dealer*, Minneapolis, Minnesota (July 1948).
- 'A Practical Way to Avoid Malnutrition' by Royal S. Lee, Lecture Delivered at American Academy of Applied Nutrition reprinted by Lee Foundation for Nutritional Research (April 17, 1948).
- 'Are We Starving to Death' by Neil M. Clark, reprinted from *Saturday Evening Post* (1945).
- 'Soil, A Foundation of Health' by Arnold P. Yerkes, International Harvester Co. (Chicago, 1946).
- 'Cancer, a Nutritional Deficiency' by J. R. Davidson, reprinted from *Question Mark* (February 1943).
- 'Uncle Sam Against Cancer.'
- '—for Heart Disease: Vitamin E' by J. D. Ratcliff, reprinted from *Coronet* (October 1948).
- 'How to Get Well and Stay Well' reprinted from General Church Edition.
- 'Health is on the Downgrade' by Henry Trautman, M. D. reprinted from *Life Today* (December 1949).
- '"Food" for Thought' by Rev. Henry Retzek, reprinted from *Priest Magazine* (December 1945).
- 'The Prevention of Recurrence in Peptic Ulcer' by D. T. Quigley, Lee Foundation for Nutritional Research.
- 'The Need for Vitamins' by L. Stambovsky, Lee Foundation for Nutritional Research.
- 'Talking about Food' by George Tyner, reprinted from *Journal of the American Academy of Applied Nutrition* (Autumn, 1947).
- 'You Can't Build a Live Body with Dead Food.'
- 'Why Should You Use Nutralite?'
- 'Living Should be Fun' by Carlton Fredericks. (Institute of Nutrition Research, Inc.)

The said defendants also supply the sales force with a number of motion-pictures, including but not limited to the following:

American Living with Nutralite  
On the Other Side of the Fence  
Hidden Hunger  
Strange Hunger  
Hunger Signs

and with recorded 'sales presentations.'

"16. The said written, printed and graphic matter is used in the defendants' scheme of marketing said articles of drugs for the purposes of educating the distributors (who also are users of the article of drug) as to the conditions for which 'Nutralite Food Supplement' is claimed to be useful and for the purpose of supplying these distributors with information and material that

they may employ in educating the prospective customers as to their probable need for 'Nutrilite Food Supplement.' The 'Sales Manual' directs that salesmen read and study the material referred to in paragraph 15 in order to learn about vitamins and minerals and the benefits that vitamins and minerals generally, and 'Nutrilite Food Supplement' specifically, will accomplish. The distributors are instructed to quote from 'The National Malnutrition' by D. T. Quigley to bring the prospective customer to the realization that he is malnourished and that his ailments, whatever they may be, are due to malnutrition which 'Nutrilite Food Supplement' will correct. The news letter 'Nutrilite News' suggests that the book 'Man Alive, You're Half Dead' by Daniel C. Munro and the various reprints and motion pictures referred to in paragraph 15 be obtained through Mytinger & Casselberry, Inc., at reduced rates and placed in the hands of, or shown to, prospective purchasers of 'Nutrilite Food Supplement' and that the statements in such written, printed, and graphic matter be used as 'ammunition' in sales presentations, all for the purpose of inducing sales of 'Nutrilite Food Supplement.'

"The films referred to in paragraph 15, when taken as a whole, emphasize the impoverishment of soil and its effect on the nutritive content of plants, and this is claimed to result in improper diets in humans leading to illnesses and malformations. 'American Living with Nutrilite' portrays Nutrilite Food Supplement as the best solution to the problem of widespread malnutrition which is graphically presented in the other films. Typically, the distributor calls on the potential customer and makes a sales presentation in which 'Nutrilite Food Supplement' is offered as an effective agent for the prevention and cure of 'ill-health' or 'chemical imbalance.' This presentation is documented by quotations from the written, printed, and graphic matter specified above. The distributor is encouraged to, and does, make use of testimonials obtained locally. He relates to the prospective customer the details of miraculous improvements' in the health of persons living in the community that are claimed to have resulted from 'Nutrilite Food Supplement.' This presentation includes representations that 'Nutrilite Food Supplement' has been effective in the treatment of cancer, heart disease, ulcers, arthritis, tuberculosis, spastic colitis, Parkinson's disease—to name only a few. The distributor points to passages in the written, printed, and graphic matter to show that almost every disease and ailment known to mankind is due to a deficiency of vitamins and minerals and that vitamins and minerals will be an adequate treatment, preventive and cure of such diseases and ailments.

"17. In the setting in which they are used, the books 'The National Malnutrition' by D. T. Quigley and 'Man Alive, You're Half Dead' by Daniel C. Munro represent and suggest that all of the symptoms, conditions and diseases which beset the human body result from dietary deficiencies and that, excepting accidental injuries, all such symptoms, conditions and diseases can be prevented and adequately treated by the use of 'Nutrilite Food Supplement,' which said representations and suggestions are false and misleading.

"18. Typical of these false and misleading representations are:

'The National Malnutrition' by D. T. Quigley (Lee Foundation for Nutritional Research)—

Page 1 - In the life of the ordinary person, the most common disease-producing factors are from food deficiencies.

Page 3 - Coincident with the introduction of these foods [marmalade and other sweets, candies, cookies, and products made with white flour and sugar], the school children [of the Outer Hebrides] showed a large incidence of tooth decay, adenoids, diseased tonsils, arthritis, tuberculosis, and other diseases that go with deficiency diets. The people in the back part of the Island of Lewis and the people of the other islands who were not exposed to the diets of the more highly civilized English and Scotch suffered no deficiency disease. They continued to live to be near one hundred years of age without tuberculosis, arthritis, heart disease, diseases of digestion, or tooth decay.

Page 7 - We have been afflicted by mass diseases for so many decades that the average layman and the average doctor, and quite obviously the average dentist, does not know what is normal.

Page 12 - No one vitamin prevents old age.

Page 13 - Only by a judicious combination of all vitamins, combined with sufficient minerals, do we have the answer to the problem of old age.

Page 30 - The small child on a deficient diet becomes afflicted with chronic tonsillitis. The school child may develop tuberculosis. The youth is pimply and anemic. All have bad teeth. Many have permanently crippled hearts due to rheumatic infections. Seventy percent have rickets. A large proportion have digestive diseases and constipation. All these handicaps are the results of errors in diet.

Page 36 - Clinical tests on the nutrition of persons suffering neuroses, irritability and other forms of nerve and mental disease show that a great number of them may be improved by taking nicotinic acid, which is considered the specific treatment for pellagra. This indicates that many cases of insanity are on a deficiency basis, and that the persons who are insane from pellagra are not the only group suffering insanity because of inadequate diet.

Page 41 - Perhaps the most common infections are those connected with the upper respiratory tract—the diseases ordinarily known as colds, grippe, flu, and pneumonia. These diseases are largely diseases of the human animal, and undoubtedly affect humans because of the difference between human and animal diets.

Page 43 - The chronic gastritis and hyperacidity and stomach and duodenal ulcers are deficiency diseases the same as scurvy, beriberi, and rickets, and may be cured just as certainly and just as permanently by diet and proper mineral and vitamin intake.

Page 46 - Arthritis is undoubtedly due to infection built up on a deficiency basis, and may or may not have some connection with virus diseases . . .

Disease of the brain is well known to result from food deficiencies as in the case of the insanity accompanying pellagra. The insanities following attacks of flu, and the insanities which have been known to be cured after the removal of abscessed teeth are low grade brain infections which have been made possible by nutritional deficiency.

Page 49 - The evil effects of vitamin and mineral deficiencies here depicted, involving as they do diseases of the digestive organs, lung, heart, brain, and blood vessels, present a truly depressing picture.

Page 54 - A study of the requirements for normal nutrition and a study as to how well the average dietary meets these requirements leads to the conclusion that the average diet of the average civilized person of the present time is a deficient diet.

Page 55 - The largest diseased group in school children in the grade schools is that group which have severe colds, rheumatic fever, and rheumatic heart disease. In the high school group, the greatest disease producer is tuberculosis. The heart disease victim is the victim of some chronic focal infection. The victim of tuberculosis is also a victim of lowered resistance against disease, due to dietary deficiency. The problem of these diseased children is simply a problem of right and proper diet.

Page 67 - On the clinical side, many internists and some surgeons have come to consider vitamin C as a cure for stomach ulcers. Here they are recognizing a truth, but only a part of the whole truth—lack of vitamin C is undoubtedly one of the predominant causes of stomach ulcer (and stomach cancer). A complete treatment would mean a treatment with all other vitamins and minerals lacking in the individual's diet, as well as with Vitamin C.

Page 76 - The change that might be brought about by the adoption of scientific diet would be a very spectacular and decided change. Somewhere from 70 to 80 per cent of the disease that now afflicts the human animal would be eliminated. The average age of the average human being could be extended from somewhere around sixty to well over one hundred years.

Page 82 - Stomach or duodinal [sic] ulcer is as surely a dietary deficiency disease as is scurvy or pellagra.

Page 86 - That the doctors suffer equally with the lay public in deficiency diseases is quite evident. Mortality records show that doctors die from heart and blood vessel diseases in as great numbers as does the general population. The average doctor has as much pyorrhea and tooth decay as the average layman. The average doctor is as often crippled by neuritis and arthritis and has as much appendicitis, gall bladder disease, stomach ulcer and cancer as the layman. The need for educating doctors is very great. The reception of new ideas such as these is slow in the medical profession.

Page 96 - The great mass of people suffering from digestive disorders, heart symptoms, rheumatic pains and aches, and fatigue will notice improved health conditions very soon after the beginning of such a regime.

Pages 100, 101 - Then comes the school period with its sinus disease, children's febrile diseases and tonsilitis. The major part of the school child's diet is composed of refined carbohydrates, sugar and white flour. Remove them from the diet, and the incidence of sinus disease and tonsilitis will decrease to the vanishing point. Putrid tonsils and rotten teeth are logically removed. The cause is left. The result is a child who will grow to adulthood accumulating the usual mass of such diseases as Tuberculosis, Rheumatic Fever, Peptic ulcers, Heart diseases, susceptibility to every infection that comes along, fatigability—ALL CONDITIONS WHICH WOULD BE NON-EXISTENT IF THE DIET WERE CORRECT.

There are a number of mental and nervous diseases which can be treated successfully by adequate attention to nutrition. Even the treatment of venereal disease can be improved and painful conditions like arthritis and neuritis are more successfully treated if nutrition is made a first consideration.

'Man Alive, You're Half Dead!' by Daniel C. Munro (New York, 1950)—

Page 4 - The research of selfless scientists, who have devoted their lives to the banishment of disease, has demonstrated that much of this ill-being is due to wrong eating; . . . .

Page 14 - Directly and definitely, according to modern scientific findings, vitamin and mineral deficiencies have a specific bearing upon these great afflictions that beset mankind:

The common cold, pneumonia and other respiratory diseases; ulcers of the stomach, the duodenum and the intestine; heart trouble and hardening of the arteries; headaches; goitre; colitis (the general term for inflammation of the colon); deafness and the degenerative diseases of middle age; prostatic disturbances in men; uterine disturbances in women, and many others.

Page 17 - Every reader of this book can doubtless name many friends and acquaintances who have died of thrombosis, angina, cerebral hemorrhage (stroke), and kindred diseases—most of them the dreadful results of starvation—not a lack of food in *quantity*, but starvation of some essential food element.

Page 25 - Appendicitis, on final analysis, is a deficiency disease, infection appearing only after deficiencies in the diet have caused degeneration.

Page 26 - If you are below par, suffer from indigestion, frequent colds and other minor ailments, the information contained in the pages which follow may point the way to the banishment of all these ills.

If you wish to forestall those chronic diseases which make old age unhappy, often prematurely, and wish to live so that your fifties and sixties will be your age of major opportunities in business and social activities, you will find in these pages information of the utmost importance.

Page 40 - The idea of taking tablets or capsules to supplement your diet may seem strange to you who are in apparent good health. Actually it is the soundest kind of health insurance. If you really are not deficient in food factors, (but I believe all adults *are* deficient) such procedure will do you no harm whatever.

Page 42 - There is a definite correlation between a moderate diet (which however *must* contain all the necessary food factors) and longevity.

Page 85 - Gall bladder disease, ulcers of the stomach and intestine, pyelitis, colitis or degenerative disease of the heart and blood vessels, all are, in the primary stage, deficiency diseases. The best protection against such diseases is obtained by adequate intake of all the nutritional factors which produce perfect balance and metabolism.

Page 86 - There is a group of diseases striking with deadly effect among middle-aged and older people where the deficiency of Vitamin A plays an important part.

One of them is the heart disease, coronary thrombosis, in which a thrombus or clot forms in the coronary artery, one of the arteries that supply the heart muscles with nutrition in the form of blood.

I have no doubt that one reason for our being an eyeglass wearing nation is a deficiency of Vitamin A.

Pages 100, 101 - I am convinced that many of our mental diseases are deficiency diseases.

\* \* \* \* \*

Let me here call attention to the similarity in the pathology (tissue degeneration) of three distinct disease entities.

Spastic colitis.

Angina Pectoris.

Migraine headache.

In spastic colitis there is a spastic contraction of a tube of involuntary muscle—the colon.

In angina pectoris there is a spastic contraction of a tube of involuntary muscle—the coronary artery, supplying blood to the heart muscle itself. In migraine headache there is a spastic contraction of a tube of involuntary muscle—an artery wall in the brain.

In these three cases the essence of the pathology is the same—a disturbance of the nerve muscle relationship. These are typical cases of deficiency of Vitamin B Complex. Angina pectoris is much more serious than the other two because it affects a vital part, the heart.

. . . The Vitamin B Complex deficiency is even more important in producing heart degenerative disease . . . . I believe that this is the underlying story of the sudden deaths in middle life of so many of our prominent business men!

Nicotinic acid, one of the chemically isolated fractions of Vitamin B, has given wonderful results, in recent studies, in curing psychosis and mental

disease. Still another study has shown that in some early cases of deafness, due to degeneration of the auditory nerve, nicotinic acid has restored the function of hearing.

Page 110 - One great secret of body chemistry is vitamin cooperation and "balance." When the dietary intake is in perfect balance, with an adequate supply of all essentials, then good body metabolism occurs and we maintain full health.

Page 119 - *I believe that the deficiency of Vitamin C is the most common cause of coronary thrombosis.*

Page 126 - Clinicians in hospital practice have used Vitamin E with good results in cases of habitual abortion and threatened abortion.

In women, single massive doses of Vitamin E abolished the symptoms of uterine tenderness, cramps, hemorrhages and sacral backache and averted the impending toxæmia and interruption of pregnancy in some cases. In the human male, Vitamin E has been used successfully in a case of undescended testicle, in a case of impotence and gross atrophy of the testicles, and in a case for the production of normal spermatozoa.

Page 128 - And mineral deficiencies are deplorably common in the typical American diet, mineral deficiencies and the ills they bring are deplorably prevalent in American bodies.

Page 132 - It is the combination of vitamin-and-calcium deficiency that causes most of the world's low resistance to colds, susceptibility to dental caries, endocrine imbalance, and so on.

"The reprints and films referred to in paragraph 15, when taken as a group, expound the same false and misleading theme as does the booklet 'How to Get Well and Stay Well,' namely, that everyone suffers from dietary deficiencies due to (1) the influence of our devitalized and demineralized soil on the nutritive value of food, (2) food processing, (3) storage and transit delays, and (4) improper preparation and cooking. The said reprints, as does 'How to Get Well and Stay Well,' also emphasize the conclusion which is stated directly and succinctly on page 7 of the reprint 'Soil—A Foundation of Health' by Arnold P. Yerkes, (International Harvester Co.) Chicago, 1946: The fact is there is only one major disease, and that is malnutrition. All ailments and afflictions to which we may become heir are directly traceable to this major disease.

In addition to general statements of this character, the reprints specifically name certain 'ailments and afflictions' which are claimed to be the result of vitamin and mineral deficiencies. These are:

Cancer, heart disease, tuberculosis, mental disease, arthritis, rheumatism, influenza, osteomyelitis, paralysis, meningitis, pneumonia, myopia, hyperopia, nephritis, thyroid disease, abortion, gingivitis, hepatitis, orchitis, oophoritis, cystitis, diabetes, gastric ulcers, allergies, diarrhea.

in addition, dietary deficiencies in children are claimed to cause lowered resistance to:

Measles, scarlet fever, bronchopneumonia, middle ear disease, rheumatism, rheumatic disease, heart disease

and an increased tendency to:

Nasal catarrh, septic tonsils, adenoids, inflamed eyes, defective vision, nervous instability and cardiovascular derangements.

"When the said reprints are used by distributors in the manner specified above, 'Nutrilite Food Supplement' is falsely and misleadingly represented and suggested as an effective treatment and cure and preventive for the conditions and diseases enumerated above. In addition, the weekly newsletter, 'Nutrilite News,' includes brief summaries of written articles describing the beneficial effects of vitamins and minerals. The information contained in these newsletters is used by distributors in the sale of the product to convey the false and misleading impression that all illnesses are due to vitamin and

mineral deficiencies and that 'Nutrilite Food Supplement' is an adequate treatment, preventive, and cure for such illnesses.

"19. Prior to 1945, the product 'Nutrilite Food Supplement' had little or no interstate market. In 1945 the defendants, Mytinger and Casselberry, Inc., and Lee S. Mytinger and William S. Casselberry, were given the exclusive right to promote and distribute this product. At that time a variation of the present labeling was introduced and the defendants' interstate business has steadily increased. At this time defendants have agents and distributors in almost every state of the union and profess to gross \$500,000 per month from the sale of 'Nutrilite.'

"20. The defendants have had sufficient warnings to put them on notice that the labeling of their product Nutrilite Food Supplement is violative of the Federal Food, Drug, and Cosmetic Act. On June 18, 1947, pursuant to Section 305 of the Act [21 U. S. C. 335], a Notice of Hearing was sent to Mytinger and Casselberry, then a partnership, informing them that the booklet 'How to Get Well and Stay Well' and other labeling matter was false and misleading. In response to this notice there appeared, on July 15, 1947, at the office of the Los Angeles District of the United States Food and Drug Administration, Lee S. Mytinger, William S. Casselberry and Lee J. Myers, attorney, representing Mytinger and Casselberry. There also appeared at this hearing, Carl F. Rehnberg and Lester L. Lev, representing Nutrilite Products Co. At this hearing, Mr. Myers, attorney for Mytinger and Casselberry, stated that he personally would revise all the labeling to bring it into compliance with the Act. Inconsequential changes in the labeling were made at this time. On September 16, 1947, a Notice of Hearing was sent to Lee S. Mytinger, William S. Casselberry, and Carl F. Rehnberg, as individuals, and to Nutrilite Products Company. Written responses were received and Mr. Myers informed the Food and Drug Administration that the booklet, 'How to Get Well and Stay Well' had been entirely revised to comply with the Act. Printers proofs of the products' labels were submitted for approval but no proofs of the allegedly revised booklet or other labeling were received. The booklet as it finally appeared contained some changes in wording but as a whole it was still false and misleading. On September 20, 1948, a Grand Jury sitting in the jurisdiction of the United States District Court for the Southern District of California, Central Division, returned a true bill indicting Mytinger and Casselberry, a partnership, and Lee S. Mytinger, William S. Casselberry and Carl F. Rehnberg, as individuals, for violations of the Federal Food, Drug, and Cosmetic Act. This case is still pending. [This action was dismissed following the entry of the consent decree in this proceeding.] Because of its seriously misbranded condition, the United States Government, under section 304 (a) of the Act [21 U. S. C. 334 (a)], has instituted 11 seizure actions against the product, Nutrilite Food Supplement, in various United States district courts. These cases have not been tried. The only labeling changes effected by defendants as a result of the institution of these actions has been the deletion of the more obvious falsehoods and their replacement with more artful wording and the 'new language' designed to convey to the consumer the same information.

"21. The plaintiff believes that this product is seriously misbranded and constitutes a threat to the health of the consuming public. The booklet 'How to Get Well and Stay Well' as a whole, when used in the manner alleged herein, is calculated to convince the lay reader that the body can overcome every illness if 'Nutrilite Food Supplement' is added to the diet, despite the advice in several places that people should visit their medical doctors. The 'Sales Manual' specifically instructs the Nutrilite salesman to quote D. T. Quigley's book 'The National Malnutrition' at page 95 where it is stated:

To make up for past dietary sins, concentrated vitamins should be taken for six months to two years, in order that the individual may reach a point where, with his reserves restored, he can carry on a balanced diet.

The booklet, 'How to Get Well and Stay Well,' on page 20 contains these statements:

Actually, then, when a person has an ache or pain, a weakness, wasting, unsatisfactory feeling, a lesion, a symptom, or loss of physical capacity—in short, when he is ill, there are three courses of action open to him.

(1) He can reason that since his body needs all necessary building and regulating materials anyway, whether ill or well, he must make sure his body is getting all these essential items for proper rebuilding and regulating, and he will add these to his diet. Then he can wait long enough to give the body a chance to rebuild, and see if that is all he needs.

And on page 21 :

This procedure should be acceptable to all concerned. First, if the ailment is chronic rather than acute, no harm can come from the use of the process of rebuilding through food and the nutrilites, since the ailment has likely been plaguing the person for considerable time and the sufferer is still alive. A few months devoted to rebuilding the body can hardly make things worse.

This advice if followed with respect to all illnesses may easily result in irreparable injury to health or even death. A delay of 6 months to 2 years in treating a chronic condition of cancer, heart disease or tuberculosis may well result in death. That 'Nutrilite Food Supplement' is sold for the treatment and cure of such serious ailments is evidenced also by the memorandum entitled 'ACTION! YOUR CHANCE TO HELP,' which was sent to all Nutrilite distributors along with the weekly edition of 'Nutrilite News' on or about March 17, 1949. This memorandum solicits the aid of all Nutrilite distributors in securing users of Nutrilite to testify as to the efficacy of this drug in the treatment and care of: Cancer, tuberculosis, gallstones, prostate trouble, arthritis, heart trouble, liver trouble and kidney trouble and of any other 'reasonably serious ailment.'

"22. The plaintiff believes that the misbranding of this product has resulted and will continue to result in, injury and damage to the welfare of the consuming public, in that the defendants are attempting to and are in fact inducing consumers to purchase this product in reliance on representations made by and on behalf of the defendants that it will be effective in the treatment, cure and prevention of all diseases and conditions enumerated above, whereas this product will be ineffective when used for the treatment, prevention and cure of such diseases and conditions.

"23. The defendants, Nutrilite Products, Inc., and Carl F. Rehnberg are in active concert and participation with the defendants Mytinger & Casselberry, Inc., and Lee S. Mytinger and William S. Casselberry, by manufacturing the drug 'Nutrilite Food Supplement' and by acting as scientific advisors in the distributional scheme and by making public appearances before distributor groups to explain that 'Nutrilite Food Supplement' contains a secret base of unusual therapeutic value and is the answer to man's search for health, which said explanations are false and misleading.

"24. Delay in enforcement action has resulted from an injunction granted by a three-judge court in the District of Columbia, 87 F. Supp. 650. The Supreme Court of the United States has recently reversed the lower court on the ground that it acted without jurisdiction, 339 U. S. 594.

"25. As successive regulatory steps have been taken by the United States, the defendants have increased their word of mouth promotion and decreased the written, printed, and graphic matter in the distribution scheme. While defendants are contending that their written, printed, and graphic promotional material is innocuous, and merely offers Nutrilite Food Supplement as a dietary supplement, their distributors and agents are utilizing the information contained in this material and in fact are selling Nutrilite Food Supplement to the public as an effective treatment, preventive, and cure for all the common ailments. The plaintiff alleges that if defendants are forced by an injunction to discontinue their offensive labeling they will, unless enjoined, continue the merchandising of 'Nutrilite Food Supplement' through oral representations made by their distributors. In that case, the said drug would be misbranded within the meaning of 21 U. S. C. 352 (f) (1), in that its labeling would fail to bear adequate directions for use.

"26. The plaintiff is informed and believes that unless restrained by the court, the defendants will continue to introduce and deliver for introduction into interstate commerce the said article of drug misbranded within the meaning of 21 U. S. C. 352 (a) and 352 (f) (1). The plaintiff also is informed and believes that unless restrained by the court, the said defendants will con-



tinue to cause the said article of drug to be misbranded within the meaning of 21 U. S. C. 352 (a) and (f) (1) while held for sale after shipment in interstate commerce by directing the distributors to use oral and written testimonials obtained locally and by directing the said distributors to use written, printed, and graphic matter obtained locally to explain that 'Nutrilite Food Supplement' is useful in the treatment, prevention, and cure of all of the ills that beset mankind.

**PRAYER:** "That the defendants, Mytinger & Casselberry, Inc., a corporation, and Nutrilite Products, Inc., a corporation, and Lee S. Mytinger, William S. Casselberry, and Carl F. Rehnberg, individuals, and each and all of their officers, agents, representatives, servants, employees, and attorneys, and all persons in active concert or participation with any of them be perpetually enjoined from directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction in interstate commerce the article of drug designated as 'Nutrilite Food Supplement,' or the same article by any other designation, or any similar article, (1) misbranded within the meaning of Section 502 (a) of the Act [21 U. S. C. 352 (a)] by virtue of the use of the aforesaid false and misleading written, printed, and graphic matter, or any other false or misleading written, printed, and graphic matter, in the manner aforesaid, or (2) misbranded within the meaning of Section 502 (f) (1) [21 U. S. C. 352 (f) (1)] in that the labeling of said article fails to bear adequate directions for the uses for which the said article is intended, in violation of Section 301 (a) of said Act [21 U. S. C. 331 (a)];

"That the aforesaid defendants and all persons in active concert or participation with them be perpetually enjoined from directly or indirectly doing or causing to be done any act, whether oral, written, or otherwise, in the manner aforesaid, or in any other manner, with respect to the aforesaid article, or similar article, while held for sale after shipment in interstate commerce which results in said article being misbranded, (1) within the meaning of Section 502 (a) [21 U. S. C. 352 (a)] in that the said written, printed or graphic matter is false and misleading or (2) within the meaning of Section 502 (f) (1) [21 U. S. C. 352 (f) (1)] in that the labeling of said article fails to bear adequate directions for the uses for which the said article is intended, in violation of Section 301 (k) of the Act [21 U. S. C. 331 (k)]; and

"That the defendants be required to tender to all purchasers of Nutrilite Food Supplement, past and present, a refund of all amounts collected by said defendants from said purchasers, as the sale price of said article; and that the plaintiff be given judgment for its costs herein and for such other and further relief as to the court may deem just and proper."

**DISPOSITION:** On November 16, 1950, the following motions were filed on behalf of the defendants: (1) a motion to drop Lee S. Mytinger and William S. Casselberry as defendants on the grounds that they were not necessary nor proper parties defendant; that a judgment against the corporation would bind them; that the defendants were not engaged in any of the acts complained of; and that the defense would impose upon said defendants great and unnecessary expense; (2) a motion to drop the Nutrilite Products, Inc., and Carl F. Rehnberg as defendants, on the ground that they were neither indispensable nor proper parties defendant; (3) a motion to dismiss the complaint on the ground that the complaint failed to state a claim for relief; (4) a motion to strike certain allegations from the complaint on the grounds that they were redundant, immaterial, impertinent, and scandalous; and (5) a motion for a more definite statement on the grounds that the complaint was vague and ambiguous. The motions were considered by the court on briefs filed by the parties, and on December 19, 1950, the court denied all of the said motions.

The defendants' answers to the complaint were filed on December 29, 1950. On or about this date, the defendants served requests for admission, which were in part answered and in part objected to by the Government. Subsequently, the court overruled certain of the Government's objections and

sustained the others; the Government then filed an amended answer to the request for admission. On January 10, 1951, the defendants filed a demand for a jury trial, which, however, was vacated on or about January 29, 1951, on motion of the Government.

On January 18, 1951, the Government filed a motion to strike portions of the defendants' answers to the complaint, on the grounds that they were immaterial and insufficient as a defense to this action. This motion was overruled in part and granted in part in an oral ruling from the bench.

On January 31, 1951, a motion was filed on behalf of the defendants, praying that the proceedings in the injunction suit be stayed pending the outcome of the case involving 10 actions against certain quantities of *Nutrilite Food Supplement*, which had been seized by process of libel in various Federal districts and which had been removed to the Northern District of California and consolidated for trial at San Francisco (reported in N. J. No. 3381). The defendants' motion for stay of proceedings was denied on February 2, 1951.

On February 14, 1951, the defendants moved, in the Northern District of California, for an order and injunction restraining the United States and its officers and the Honorable Ben Harrison, Judge for the Southern District of California, from proceeding with the trial of the injunction suit until disposition of the consolidated seizure actions, which motions were denied.

On February 9, 1951, the Government filed a motion to compel Carl F. Rehnberg to answer certain questions which he had refused to answer upon oral examination and to require the production of documents and records by Bernard Bailey, Lee S. Mytinger, and William S. Casselberry. The court ruled, on February 26, 1951, that Mr. Rehnberg need not answer the questions objected to by him on the grounds of self incrimination. The court further ruled that the records of the corporations may be subpoenaed and should be produced, and that the secret process for the identity of a solvent used in manufacturing could be inquired into by examination of other witnesses.

On February 14, 1951, the Government filed requests for admission. No answers were filed to these requests, and on April 6, 1951, the following consent degree of injunction was entered:

HARRISON, *District Judge*: "Upon the consent of all parties, and before any testimony has been taken, and without any finding by the Court on any issue of fact or law, it is

#### I

"ORDERED, ADJUDGED, AND DECREED that this Court has jurisdiction of the subject matter hereof and of all the parties herein; and it is further

#### II

"ORDERED, ADJUDGED, AND DECREED that the defendants, and each of them, and their officers, agents, distributors, representatives, servants, employees, attorneys, and all persons in active concert or participation with any of them who receive actual notice of this decree by personal service or otherwise be and hereby are perpetually enjoined from directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce the article designated as 'Nutrilite Food Supplement XX'; 'Nutrilite Food Supplement X'; 'Nutrilite Food Supplement Junior,' or the same article by any other designation or any vitamin and/or mineral product whether it contains or does not contain any plant or animal material in addition to the vitamins and minerals therein, accompanied by the following written, printed, or graphic matter or accompanied by any written printed, or graphic matter substantially to the same effect:

"How To Get Well and Stay Well"—any edition; 'Sales Manual—Nutralite Food Supplement'—any present and past editions; 'Agent's Manual'—any present or past editions; 'The National Malnutrition' by D. T. Quigley, M. D.; 'Man Alive, You're Half Dead!' by Daniel C. Munro, M. D.; 'You Can Live Longer Than You Think' by Daniel C. Munro, M. D.; 'Nutralite News'—any past issue; 'Southern California News,'—any past issue; 'Modern Miracle Men' by Rex Beach, S. Doc. No. 264, 74th Cong. 2d Sess. (1941)—M. & C. Reprint No. 1; 'We Feed Our Hogs Better Than Our Children' by Fred Bailey, *American Magazine* (October, 1947), M. & C. Reprint No. 2; 'Nutrition and Pregnancy' by Bruce Bliven, reprinted from *Ladies' Home Journal* (November, 1947), M. & C. Reprint No. 3; 'The Miracles of Dr. Spies,' by Dickson Hartwell, reprinted from *Colliers* (January 31, 1948), M. & C. Reprint No. 4; 'Vitamins Are Not Drugs!' by Dr. Simon Benson, reprinted from *The Apothecary* (June, 1946) by Lee Foundation for Nutritional Research, M. & C. Reprint No. 5; 'The Latest on Vitamin Pills' by Clarence Woodbury, *Woman's Home Companion* (January, 1949), M. & C. Reprint No. 6; 'What Makes You Healthy?' by Winifred Raushenbush, *Ladies Home Journal* (March, 1949), M. & C. Reprint No. 7; 'Bang's Disease and Undulant Fever Are Due to Nutritional Deficiencies' by J. F. Wischhusen, *American Feed and Grain Dealer*, Minneapolis, Minnesota, (July, 1948), M. & C. Reprint No. 8; 'A Practical Way to Avoid Malnutrition' by Royal S. Lee, Lecture delivered at American Academy of Applied Nutrition, reprinted by Lee Foundation for Nutritional Research (April 17, 1948), M. & C. Reprint No. 9; 'Quotations on Vitamins,' M. & C. Reprint No. 10; 'Are We Starving to Death' by Neil M. Clark, reprinted from *Saturday Evening Post* (1945); 'Health Is On The Downgrade' by Henry Trautman, reprinted from *Life Today* (December, 1949); '"Food" For Thought' by Rev. Henry Retzek, reprinted from *Priest Magazine* (December, 1945); 'Living Should Be Fun' by Carlton Fredericks; 'Your Career as a Nutralite Distributor'—past issues; 'Your Body Will Thank You'; 'What's Wrong with You?' 'Fun After Forty'; 'Carl—Answers Some Questions'; 'Health From the Ground Up'; 'NutriLife, Vol. 1, No. 1, Give Your Body a Chance'; 'NutriLife, Vol. 1, No. 2, Arthritis and Nutralite'; 'NutriLife, Vol. 1, No. 3, What's Wrong with You'; 'Success Course Number 1—the Sales Manual'—past issues; 'Success Course Number 2—The Quigley Quiz'; 'Success Course Number 4—Health From the Ground Up'; 'On the Other Side of the Fence' (Film—in its present form);

"Provided that any information derived from the foregoing publications used in devising new labeling shall not be prohibited if it conforms to all of the provisions of the Federal Food, Drug, and Cosmetic Act.

### III

and it is further

"ORDERED, ADJUDGED, AND DECREED that the defendants, and each of them, and their officers, agents, distributors, representatives, servants, employees, attorneys, and all persons in active concert or participation with any of them who receive actual notice of this decree by personal service or otherwise be and hereby are perpetually enjoined from directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce the article designated as 'Nutralite Food Supplement XX,' 'Nutralite Food Supplement X,' 'Nutralite Food Supplement Junior,' or the same article by any other designation or any vitamin and/or mineral product whether it contains or does not contain any plant or animal material in addition to the vitamins and minerals therein, accompanied by any written, printed, or graphic matter which states, represents, or implies, directly or indirectly, that such article will or may be effective to prevent or adequately treat or cure any of the following named diseases and conditions: Arthritis, rheumatism, high blood pressure, abnormal blood count, Buerger's disease, cancer, leukemia, tumor, cerebral hemorrhage, stroke, apoplexy, diabetes, deafness, infection of ear, middle ear disease, astigmatism, cataract, near-sightedness, gall bladder trouble, hemorrhage connected with menopause, premature menopause, dysmenorrhea, prostate trouble, impotence in males, sterility, uterine cramps, uterine hemorrhages, angina pectoris, coronary occlusion, coronary thrombosis, heart disease, hypertensive heart disease, rheumatic heart disease, infantile paralysis, poliomyelitis, cystitis, kidney congestion, kidney stone, nephritis, pyelitis, cirrhosis of the liver, hepatitis, sclerosis of the liver, multiple sclerosis, palsy, paralysis,

Parkinson's disease, scarlet fever, measles, meningitis, pneumonia, smallpox, ulcers (duodenal, peptic, stomach, gastric), varicose veins, or any other symptom, disease or condition that is not within the allowable claims specified in paragraph V, including subparagraph 31. Nothing in this paragraph III shall prohibit the defendants, their officers, agents, distributors, representatives, servants, employees, attorneys and all persons in active concert or participation with any of them who receive actual notice of this decree by personal service or otherwise from selling or offering for sale Nutrilite Food Supplement solely as a food supplement to supplement or fortify the diet of any person who may have any of the diseases or conditions above mentioned.

#### IV

"ORDERED, ADJUDGED, AND DECREED that the defendants, and each of them, and their officers, agents, distributors, representatives, servants, employees, attorneys, and all persons in active concert or participation with any of them who receive actual notice of this decree by personal service or otherwise be and hereby are perpetually enjoined from directly or indirectly introducing or causing to be introduced and delivered or causing to be delivered for introduction in interstate commerce the article designated as 'Nutrilite Food Supplement XX,' 'Nutrilite Food Supplement X,' 'Nutrilite Food Supplement Junior,' or the same article by any other designation or any vitamin and/or mineral product whether it contains or does not contain any plant or animal material in addition to the vitamins and minerals therein, accompanied by any written, printed, or graphic matter which states, represents, or implies, directly or indirectly that:

"1. There is only one major disease and that is malnutrition; and every ailment or affliction which the public is currently suffering or to which they may become heir is directly traceable to malnutrition.

"2. Most of the ills and diseases of human beings are the result of chemical starvation of our bodies for vitamins and/or minerals.

"3. Physicians are trained in medicine, not nutrition, and are therefore not prepared to accept the proposition that many people's complaints may be, and probably are, caused by deficiencies of microfood factors; the 'medical approach' of doctors in ascribing illness and disease to poisons and germs is old fashioned.

"4. When a person has an ache or pain, a weakness, wasting, unsatisfactory feeling, a lesion, a symptom, or loss of physical capacity, in short, when he is ill, he can reason that since his body needs all necessary building and regulating materials anyway, whether ill or well, he will add a vitamin and mineral food supplement to his diet, then he can wait long enough to give the body a chance to rebuild and see if that is all he needs.

"5. Deficiencies of vitamins and/or minerals in the diet may show itself as one of the common or not so common deficiency diseases, including those most responsible for death in our 40's and 50's, whereas we should live in good health and vigor, and with full possession of our faculties, to the age of 90 or 100.

"6. Diagnosis of disease is not necessary because whatever the trouble or its medical name a vitamin and mineral food supplement will cause it to disappear.

"7. The use of a vitamin and mineral food supplement will bring about a condition of health.

"8. Every illness is the result of chemical imbalance and health is the result of chemical balance, and a vitamin and mineral food supplement will bring the body into chemical balance.

"9. The terms 'health nuisances,' 'chemical imbalance,' 'not-health,' 'poor nutrition,' 'malnutrition,' 'deficiency disease,' 'dietary deficiency,' 'deficiency ailment,' or 'dietary deficiency ailment' have the same meaning as every and all ailments, illnesses or sicknesses.

"10. The accessory food factors necessary to good health are called nutrilites in the text books of the bio-chemists; the term 'nutrilites' means vitamins, chlorophyll, bios, inositol and many others.

"11. All vitamins and other accessory food factors originate in plant material.

"12. A food supplement which is capable of protecting against the ravages and pain of deficiency diseases must contain all the vitamins, including those

which cannot be bought in the drug store, together with the nutrilites and minerals so often lacking in our diet.

"13. A significant proportion of military service rejections during World Wars I and II were due to malnutrition or vitamin and/or mineral deficiencies in the diet.

"14. Distributors should use the process of elimination in selling a vitamin and mineral food supplement, through which it is reasoned that all diseases and incapacities except those due to germ invasions and accidents, are attributed to faulty nutrition.

"15. Any other representation not within the allowable claims specified in Paragraph V including subparagraph 31, which does not conform to the Federal Food, Drug and Cosmetic Act.

## V

and it is further

"ORDERED, ADJUDGED AND DECREED that the allowable claims that may be made as to the need for, or usefulness of, Nutrilite Food Supplement XX, Nutrilite Food Supplement X, and Nutrilite Food Supplement Junior, shall be limited to the following:

"1. These articles, when taken as directed, will supply to the user's diet the vitamins and minerals stated on the labels in the amounts and proportions of the minimum daily requirements stated on their labels.

"2. The need in human nutrition has been established for the following vitamins and minerals contained in Nutrilite Food Supplement:

Vitamin A	Calcium
Vitamin D	Phosphorus
Vitamin B-1 (Thiamin)	Iodine
Vitamin B-2 (Riboflavin)	Copper
Vitamin C (Ascorbic Acid)	Iron
Vitamin K	
Vitamin B-6	
Niacinamide	

but the need in human nutrition has not been established for the following vitamins and minerals contained in Nutrilite Food Supplement:

Vitamin E	Manganese
Inositol	Zinc
Folic Acid	Cobalt
Rutin	Nickel
Para-aminobenzoic Acid	Fluorine
Pantothenic Acid	
Vitamin B-12	
Biotin	

"3. That a prolonged deficiency in the intake of any vitamin or mineral for which the need in human nutrition has been established (except Vitamin D, which may also be derived from exposure to sunlight) produces pathological conditions known as vitamin or mineral deficiency diseases, whereas the daily intake of a certain minimum quantity of such substances prevents the onset of such conditions.

"4. That a 'clinical deficiency disease' is one which is capable of being diagnosed by qualified physicians from generally recognized symptoms.

"5. That a 'sub-clinical deficiency condition' is one, the symptoms of which are not sufficiently definite or apparent, as to be capable of diagnosis.

"6. That 'sub-clinical deficiency conditions' do exist in the United States.

"7. All of the B-Complex vitamins for which the need in human nutrition has been established, viz: vitamin B<sub>1</sub> (thiamine), vitamin B<sub>2</sub> (riboflavin), niacin, and vitamin B<sub>6</sub> (pyridoxine), are contained in Nutrilite.

"8. If any representations are made to sell the need for Nutrilite Food Supplement, they shall not relate to the vitamins and minerals for which the need in human nutrition has not been established, other than statements which conform to all provisions of the Food, Drug and Cosmetic Act and are based upon reliable scientific evidence of the value of these substances.

"9. If any representations are made to sell the need for food supplementation with Nutrilite Food Supplement, such representation shall be that supplementation may be needed only if the user's diet is deficient in one or more of

the vitamin and mineral nutrients for which the need in human nutrition has been established.

"10. If the non-specific symptoms specified in the following paragraphs are mentioned, it shall be explained that if any such symptom persists it may be a danger signal for serious disease having no relationship to a vitamin or mineral deficiency.

"11. If clinical vitamin and mineral deficiency diseases (xerophthalmia, rickets, osteoporosis, beriberi, ariboflavinosis, scurvy, or pellagra) are discussed, it shall be explained that such diseases are rare in the United States.

"12. If a claim is made that death may result to human beings from a vitamin and/or mineral deficiency, there shall be associated with it a statement that this occurs only after prolonged and severe deficiencies of the vitamins and minerals needed in human nutrition and that such deaths are rare in the United States.

"13. If a claim is made that a symptom may be due to a sub-clinical vitamin or mineral deficiency, there shall be associated with the claim a qualification that Nutrilite Food Supplement would be of benefit only if the symptom resulted from a deficiency of one or more of the vitamins or minerals contained in Nutrilite Food Supplement.

"14. The vitamins and minerals for which the need in human nutrition has been established are needed in certain minimum daily amounts for the proper growth and vigor of children.

"15. If a claim is made that a deficiency of vitamin A may cause nutritional night blindness, or lowered resistance to infection of the mucous membranes of the eye or other organs, it shall be explained (1) that these symptoms could occur only when the daily intake of vitamin A has been less than the minimum daily requirement over a prolonged period, and (2) that these are non-specific symptoms in that they may be caused by any of a great number of conditions or may have functional causes; and (3) that such non-specific symptoms do not of themselves prove a nutritional deficiency.

"16. If the claim is made that persons suffering from chronic diarrhea require greater amounts of Vitamin A, it shall be explained that this is due to the evacuation of the vitamin before it can be absorbed by the body.

"17. If any claim is made to the effect that a deficiency of vitamin B<sub>1</sub> (thiamine), vitamin B<sub>2</sub> (riboflavin), and/or niacin may be the cause of nervousness, loss of appetite, neuritis, loss of muscle tone, digestive upsets, diarrhea, vague aches and pains, fatigue, irritability, headache, dizziness, dryness of the hair or skin, mental depression, insomnia, indigestion, loss of weight, constipation, weakness, reddening of the lips, or sores about the angles of the mouth, swelling and redness of the tongue, or inflammation of the mouth, it shall be explained (1) that these symptoms could occur only when the daily intake of vitamin B<sub>1</sub>, vitamin B<sub>2</sub>, and niacin is less than the minimum daily requirement over a prolonged period; (2) that these are non-specific symptoms in that they may be caused by any of a great number of conditions or may have functional causes; and (3) that such non-specific symptoms do not of themselves prove a nutritional deficiency.

"18. Vitamin B<sub>1</sub> (thiamine) tends in some cases to relieve the neuritis of alcoholism and the neuritis of pregnancy.

"19. If it is claimed that a deficiency of vitamin C leads to dental caries, anemia, defective teeth and gums, sponginess of the gums, soreness and bleeding of the gums, pyorrhea, some gum infections, loss of appetite, and local hemorrhages of the mucous membranes of the nose, mouth, gums and about the face, it shall be explained (1) that these symptoms could occur only when the daily intake of vitamin C is less than the minimum daily requirement over a prolonged period, (2) that these conditions, while they may be concomitant signs of a vitamin C deficiency, do not of themselves prove a vitamin C deficiency, and (3) that these symptoms are non-specific and may be caused by any of a great number of conditions or may have functional causes.

"20. It may be claimed that a deficiency of vitamin D (whether dietary or not) or a deficiency of calcium in the human diet may produce rickets in infants or osteoporosis in adults; that vitamin D aids in the utilization of calcium and phosphorus, and is effective when adequate amounts of these minerals are present in the diet. It may be claimed that vitamin D promotes the utilization of calcium and phosphorus in the human body; that a deficiency of vitamin D (less than 400 units per day) or calcium, (less than 750 milligrams per day) over a prolonged period may cause poor bone and tooth development

in the growing child; and that during pregnancy and lactation there is an increased need for calcium, phosphorus, and iron. It may be claimed that an adequate daily supply of vitamin D (whether obtained from the diet, from dietary supplementation, or from exposure of the body to sunlight) may be useful in preventing or arresting dental caries in children when calcium and phosphorus are liberally supplied and the diet is adequate with respect to other nutrients.

"21. It may be claimed that calcium is one of the essential factors in the proper coagulation of the blood; and that in some cases the administration of calcium to pregnant women will relieve muscular soreness, muscular spasms, muscular numbness, tingling of the muscles.

"22. That where whole wheat bread forms an important part of the diet, the need for calcium is increased.

"23. It may be claimed that a deficiency of iron in the diet may cause iron deficiency anemia and that an adequate supply of iron is one of the essential factors in blood building. If it is claimed that a deficiency of iron in the diet may cause lack of energy or palpitation of the heart, it shall be explained (1) that these symptoms could occur only when the daily intake of iron is less than the minimum daily requirement over a prolonged period; (2) that these symptoms do not of themselves prove an iron deficiency; and (3) that these symptoms are non-specific and may be caused by any of a great number of conditions or may have functional causes.

"24. It may be claimed that a deficiency of iodine in the human diet will cause simple goiter.

"25. It may be claimed that a deficiency of vitamin K in the human body leads to a tendency to excessive bleeding from minor wounds.

"26. That the need for vitamin B<sub>6</sub> (pyridoxine) in human nutrition was established during the year 1950.

"27. That a deficiency of copper does not produce any known clinical disease, but copper is necessary for the utilization of iron in the human system.

"28. Alfalfa, parsley, and watercress in the Nutrilite Base contribute small amounts of some of the vitamins and minerals for which the need in human nutrition has been established.

"29. It may be claimed that diets may be lacking in the vitamins and minerals for which the need in human nutrition has been established, by reason of poor dietary habits, the improper selection of foods, unbalanced menus and the loss of a portion of the water-soluble vitamins through excessive cooking, storage, and processing.

"30. It may be claimed that many physicians who practice obstetrics supplement the diets of expectant mothers with vitamins and minerals known to be needed in human nutrition.

"31. That the specifications of the foregoing allowable claims shall not preclude the making of other claims or representations which conform to all the provisions of the Federal Food, Drug and Cosmetic Act including representations based upon generally accepted scientific facts in the field of nutrition; nor shall the foregoing specifications preclude the making of statements or representations which are supported by reliable scientific opinion, although not supported by the consensus of scientific opinion, provided the statements or representations are qualified by an explanation that a difference of reliable scientific opinion respecting the same does exist; and in the event of conflict between the provisions of this subparagraph 31 and any other provision of this decree the provisions of this subparagraph 31 shall prevail.

## VI

and it is further

"ORDERED, ADJUDGED, AND DECREED that the defendants, and each of them, and their officers, agents, distributors, representatives, servants, employees, attorneys, and all persons in active concert or participation with them who receive actual notice of this decree by personal service or otherwise be and hereby are perpetually enjoined from directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction in interstate commerce the article designated as 'Nutrilite Food Supplement,' or the same article by any other designation or any vitamin and/or mineral product whether it contains or does not contain any plant or animal material in addition to the vitamins and minerals therein, unless its labeling

states and enumerates all the purposes and conditions for which the article is intended (by the person who introduced it or caused it to be introduced or who delivered it or caused it to be delivered for introduction into interstate commerce) when introduced into interstate commerce to be used.

## VII

and it is further

"ORDERED, ADJUDGED, AND DECREED that the defendants, and each of them, and their officers, agents, distributors, representatives, servants, employees, attorneys, and all persons in active concert or participation with any of them who receive actual notice of this decree by personal service or otherwise be and hereby are perpetually enjoined from doing or causing to be done any of the following acts or any acts substantially to the same effect, whether oral, written or otherwise, with respect to the aforesaid article, or any vitamin and/or mineral product whether it contains or does not contain any plant or animal material in addition to the vitamins and minerals therein, while held for sale after shipment in interstate commerce:

"1. The use, in the sale of Nutrilite Food Supplement, of any of the written, printed, or graphic matter enumerated in paragraph II, or of any other written, printed, or graphic matter substantially to the same effect, including but not limited to the following, none of which was shipped in interstate commerce by defendants herein: 'Soil, A Foundation of Health' by Arnold P. Yerkes, International Harvester Co. (Chicago, 1946); 'Cancer, a Nutritional Deficiency' by J. R. Davidson, reprinted from *Question Mark* (February, 1943); '— for Heart Disease: Vitamin E' by J. D. Ratcliff, reprinted from *Coronet* (October, 1948); 'The Prevention of Recurrence in Peptic Ulcer' by D. T. Quigley, Lee Foundation for Nutritional Research; 'The Need for Vitamins' by L. Stambovsky, Lee Foundation for Nutritional Research; 'Talking about Food' by George Tyner, reprinted from *Journal of the American Academy of Applied Nutrition* (Autumn, 1947); 'Why We Need Vitamin E' by August Pacini; 'You Can't Build a Live Body with Dead Food' and 'Why Should You Use Nutrilite'; 'How to Get Well and Stay Well'—General Church Edition; or any written, printed, or graphic matter not expressly authorized in writing by defendant Mytinger & Casselberry, Inc.

"2. The use, in the sale of Nutrilite Food Supplement, of any written, printed, or graphic matter which states, represents or implies that Nutrilite Food Supplement will be effective as a preventive, adequate treatment, or cure of any disease, condition, or symptom covered by paragraph III, or which includes any of the representations prohibited by paragraph IV or any representation substantially to the same effect as those prohibited by paragraph IV, or any other representation that is not in conformity with the allowable claims of paragraph V including subparagraph 31.

"3. Representing that Nutrilite Food Supplement is useful in the prevention, treatment, or cure of any disease, condition, or symptom that is not stated and/or enumerated in the labeling thereof.

## VIII

and it is further

"ORDERED, ADJUDGED, AND DECREED that in applying or enforcing the provisions of the foregoing paragraphs of this decree any statement, representation, or implication contained in a testimonial, whether upon any written, printed, or graphic matter (including wire or tape recordings) or made orally, may be made if allowed under the claims authorized in paragraph V including subparagraph 31 and shall be regarded as if made directly by the person using the testimonial or causing it to be used.

## IX

and it is further

"ORDERED, ADJUDGED, AND DECREED that the defendant Mytinger & Casselberry, Inc., shall direct all distributors to forward to it all written, printed, and graphic matter in their possession obtained from Mytinger & Casselberry, Inc., the use of which is prohibited by this decree, and it shall not again be



used as labeling; and the defendant Mytinger & Casselberry, Inc., shall direct all distributors to discontinue the use in the sale of Nutrilite Food Supplement of any written, printed or graphic matter not expressly authorized in writing by it.

### X

and it is further

"ORDERED, ADJUDGED, AND DECREED that the defendants, and each of them, their officers, agents, distributors, representatives, servants, employees, attorneys, and all persons in active concert or participation with any of them who receive actual notice of this decree by personal service or otherwise be and hereby are perpetually enjoined from directly or indirectly employing the following practices in their sales program:

"1. Authorizing a beginning distributor to undertake sales prior to his completion of initial training and his approval by Mytinger & Casselberry, Inc.

"2. Authorizing persons to distribute Nutrilite, or to sponsor distributors of Nutrilite, before they have been instructed as to the allowable and prohibited claims of this decree.

"3. Making any representation as to the qualifications and professional background of any person associated with Nutrilite Products, Inc., or Mytinger & Casselberry, Inc., which is not expressly authorized in writing by Mytinger & Casselberry, Inc., and Nutrilite Products, Inc.

### XI

and it is further

"ORDERED, ADJUDGED, AND DECREED that the defendant Mytinger & Casselberry, Inc., shall call this decree to the attention of every present distributor who sells or offers for sale Nutrilite Food Supplement and require each such distributor to sign a written statement that he has read this decree.

### XII

and it is further

"ORDERED, ADJUDGED, AND DECREED that all written, printed, and graphic matter used in the future in the merchandising of Nutrilite Food Supplement may at defendants' option first be submitted to the United States Food and Drug Administration for inspection and comment which shall be made within a reasonable time, and in the event the defendants disagree with the opinion of the Food and Drug Administration or upon the failure of the Food and Drug Administration to inspect and comment within a reasonable time respecting such labeling, or without submitting such written, printed, or graphic matter to said Administration, they may seek modification of this decree to authorize its use before it is distributed to agents or distributors.

### XIII

and it is further

"ORDERED, ADJUDGED, AND DECREED that an indictment dated September 15, 1948, returned to this Court against Mytinger & Casselberry, a partnership, and Lee S. Mytinger, William S. Casselberry, and Carl F. Rehnborg, as individuals, No. 20289, be and the same is hereby dismissed; and that the consolidated libel proceedings against Nutrilite Food Supplement in the United States District Court for the Northern District of California, Southern Division, bearing numbers 24792-6, 25800, 25801, 25804, 25809, and 25817, shall be terminated pursuant to stipulation between the parties.

### XIV

and it is further

"ORDERED, ADJUDGED, AND DECREED that nothing in this decree shall be construed as to prevent defendants from doing anything which is authorized under or by the Federal Food, Drug and Cosmetic Act, as amended, or any other provision of law, nor shall this decree deprive said defendants of the immuni-

ties conferred by said Act as now in force or as hereafter amended, and in the event of conflict between this paragraph and any other provision of this decree, the provisions of this paragraph shall prevail.

## XV

and it is further

"ORDERED, ADJUDGED, AND DECREED that in applying or enforcing the provisions of this decree, any act done or any statement or representation made by any distributor of Nutrilite Food Supplement, which act, statement, or representation was neither done nor made, nor caused to be done or made, by the defendants Mytinger & Casselberry, Inc., or Nutrilite Products, Inc., their officers, employees, or persons acting under authority from them, shall be deemed and regarded as solely the act, statement, or representation of the distributor.

## XVI

and it is further

"ORDERED, ADJUDGED, AND DECREED that all claims for relief presented by the pleadings herein which are not specifically granted by this decree are hereby waived.

## XVII

and it is further

"ORDERED, ADJUDGED, AND DECREED that this action be, and it hereby is, dismissed as to the defendants Lee S. Mytinger, William S. Casselberry, and Carl F. Rehnborg.

## XVIII

and it is further

"ORDERED, ADJUDGED, AND DECREED that jurisdiction of this Court is retained for the purpose of enabling any of the parties to this judgment to apply at any time for such further orders and directions as may be necessary or appropriate for the construction or carrying out of this judgment or for modification of any of the provisions thereof and for the purpose of enforcing compliance therewith and the punishment of violations thereof. Nothing herein shall prejudice the right of any party to move the Court for modification of this judgment in the event of changed conditions of law, fact, or scientific opinion.

## STIPULATION

"It is stipulated between the parties that the libel proceedings against Nutrilite Food Supplement pending in the United States District Court for the Northern District of California, Southern Division, bearing numbers 24792-6, 25800, 25801, 25804, 25809 and 25817 present no questions for adjudication for the reasons that (1) the products may have become below label potency and therefore unmarketable by reason of lapse of time, and (2) the use of the labeling involved has been covered by a final consent decree entered in the District Court of the United States for the Southern District of California in *United State v. Mytinger & Casselberry, Inc. et al.*, No. 10344-BH.

"Now, therefore, upon consent and before any testimony has been taken and without any findings by the Court on any issue of fact or law, a final order may be made by the United States District Court for the Northern District of California, Southern Division, in each of said libel proceedings, directing the United States Marshals for the districts in which the shipments of said Nutrilite Food Supplement are under seizure, to deliver them to appropriate charitable institutions, for use by the inmates of the institutions, with an explanation that they may be below label potency and directing that the labeling be delivered to Mytinger & Casselberry, Inc., for disposition in accordance with paragraph IX of the final consent decree entered in the Southern District of California. The cost bonds filed in said libel proceedings may be discharged and the moneys deposited as cost bonds may be returned to Claimant Mytinger & Casselberry, Inc."


**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]

3384-3400

**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, and include, where indicated, the results of investigations of the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., August 20, 1951.

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\*For presence of a habit-forming narcotic without warning statement, see Nos. 3386, 3387; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3386, 3387.

## NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

3384. TB-1 tablets. U. S. v. 338 Bottles, etc. (F. D. C. No. 31055. Sample No. 17965-L.)

**LIBEL FILED:** April 11, 1951, Southern District of California.

**ALLEGED SHIPMENT:** On or about April 5, 1951, by Stanley Lindo and Co., for account of the Strand Pharmacal Corp., Los Angeles, Calif., consigned to Bangkok, Thailand.

**PRODUCT:** 338 bottles, each containing 100 tablets, and 54 bottles, each containing 1,000 tablets, of TB-1 at Long Beach, Calif.

**LABEL, IN PART:** "T-B RX Strand Brand of TB-1 Each tablet provides Para-Acetylamino Benzaldehyde Thiosemicarbazone 25 mg."

**NATURE OF CHARGE:** Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

**DISPOSITION:** May 2, 1951. Default decree of condemnation and destruction.

## DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

3385. Adulteration and misbranding of Dr. Merrick's Ear Canker Creme. U. S. v. 69 Cartons \* \* \*. (F. D. C. No. 30288. Sample No. 85882-K.)

**LIBEL FILED:** On or about December 6, 1950, Northern District of Texas.

**ALLEGED SHIPMENT:** On or about October 6, 1950, from Brookfield, Ill.

**PRODUCT:** 69 cartons, each containing 1 tube, of *Dr. Merrick's Ear Canker Creme* at Dallas, Tex.

**LABEL, IN PART:** (Carton) "Dr. Merrick's Ear Canker Creme Active Ingredients: Aureomycin, Tyrothricin, 2 Mercaptobenzothiazole, Bismuth Subnitrate, Bismuth Subgallate \* \* \* Net Contents ½ Ounce."

**NATURE OF CHARGE:** Adulteration, Section 501 (c), the strength of the article differed from, and its quality fell below, that which it purported and was represented to possess, namely (on display carton) "contains \* \* \* aureomycin," (on retail carton) "Active Ingredients: Aureomycin," and (on leaflet enclosed in retail carton) "Aureomycin and Tyrothricin \* \* \* By combining the two anti-biotics we obtain a very desirable synergistic action resulting in more effective curative action than when either Aureomycin or Tyrothricin is used separately," since the article contained an inconsequential trace, if any, of aureomycin.

Misbranding, Section 502 (a), the statements in the labeling of the article, which are quoted above in the adulteration charge, were false and misleading as applied to the article, which contained an inconsequential trace, if any, of aureomycin; and, Section 502 (1), the article purported to be and was represented as a drug composed in whole or in part of aureomycin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the law.

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

**DISPOSITION:** April 4, 1951. Default decree of condemnation and destruction.