

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

3663. Action to enjoin and restrain the interstate shipment of various Alberty products. U. S. v. Alberty Food Products, et al. Tried to the court. Decree for injunction entered in district court. Judgment of district court affirmed on appeal to United States Court of Appeals. (Inj. No. 206.)

COMPLAINT FILED: September 16, 1949, Southern District of California, against Alberty Food Products, a partnership at Hollywood, Calif., also doing business under the name of Cheno Products, and against Ada J. Alberty and Kenneth Hackworth.

On October 7, 1949, an order was entered dismissing Kenneth Hackworth as a defendant; and, at the same time, an amended complaint was filed against Alberty Food Products, Ada J. Alberty, Harry Alberty, Florence Alberty, Margaret Quinn, and Helen Hackworth, as the individuals primarily responsible for the policies and activities of the partnership.

ALLEGED VIOLATION: The complaint alleged that the defendants were the manufacturers, packers, and distributors of certain drugs, namely, *Alberty's Vegetable Compound capsules*, *Alberty's Oxorin tablets*, *Alberty's Food Regular*, *Instant Alberty Food*, *Alberty Garlic perles (Alberty Garlic and Vegetable Oil perles)*, *Alberty's Sabinol*, *Alberty Phloxo B tablets*, *Alberty's Phosphate pellets*, *Alberty's Riol tablets*, *Alberty's Rico tablets*, *Alberty Special Formula tablets*, *Alberty's vitamin A (high potency) shark liver oil*, *Alberty's Vi-C*, *wheat germ oil*, *Alberty's vitamin B complex tablets with high-potency B₁*, *Alberty's vitamin B₁ with supplementary amounts of other B complex factors*, *Alberty's Lebara pellets, plain*, *Alberty's Lebara pellets No. 2*, *Cheno herb tea*, *Cheno Phytolacca Berry Juice Extract tablets*, *Cheno combination tablets*, *Pandora tablets*, *Recal tablets*, *Alberty's Vio-Min vitamin-mineral tablets*, *Alberty's R-Gon tablets*, *Alberty's Laxative Blend Tea*, *Alberty's Ca-Mo pellets*, *Alberty's vitamin A and G perles*, and *Alberty's Rego*.

The drugs consisted for the most part of dried vegetables, cereals, vitamins, and minerals, in various combinations.

The complaint alleged further that the defendants had been and were continuing to introduce into interstate commerce the above-named drugs which were misbranded under Sections 502 (a) and 502 (f) (1); that the defendants had caused and were continuing to cause certain printed matter to accompany the drugs while held for sale after shipment in interstate commerce, which acts resulted in the drugs being misbranded under Section 502 (a); and that the defendants had caused and were continuing to cause certain oral representations to be made by demonstrators regarding the therapeutic effect of the drugs while held for sale after interstate shipment, which acts resulted in the drugs being misbranded under Section 502 (f) (1).

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying printed matter relating to the drugs were false and misleading since the drugs were not effective for the prevention, treatment, or cure of the diseases or conditions represented; and, Section 502 (f) (1), the labeling of the drugs failed to bear adequate directions for use for the purposes and conditions for which they were intended and for the purposes for which they were recommended by oral representations sponsored by the defendant.

*See also No. 3661.

The complaint alleged further, upon information and belief, that the defendants would continue to introduce the misbranded drugs into interstate commerce and would continue to do those acts while holding the drugs for sale after shipment in interstate commerce, which result in misbranding of the drugs.

DISPOSITION: The Government and the defendants having stipulated and agreed to certain facts in the case and the Government having filed a motion for summary judgment, the court, on June 8, 1951, handed down the following decision:

MATHES, *District Judge*: "The Government invokes the jurisdiction of this Court under § 302 (a) of the Federal Food, Drug and Cosmetic Act [52 Stat. 1043, 21 U. S. C. § 332 (a)] to enjoin alleged violations by defendants of § 301 which prohibits 'introduction * * * into interstate commerce of any * * * drug * * * that is * * * misbranded' [21 U. S. C. § 331 (a)].

"The amended complaint for injunction alleges *inter alia*:

That defendants are "the manufacturers, packers and distributors of certain articles of drug * * *";

That "For some years, defendants have introduced said articles of * * * drug into interstate commerce, and have caused said articles to be accompanied by various leaflets and booklets when introduced into and while in interstate commerce and while held for sale after shipment in interstate commerce. Said leaflets and booklets are entitled 'Calcium, The Staff of Life' [Exhibit 30]; 'Dynamic Digests' [Exhibit 31]; 'Is There Hope That Graying Hair Can Be Restored? Read What Science Says - Pandora' [Exhibit 32]; 'Health Mysteries' [Exhibit 33]; 'Reduce! Streamline Your Figure—Follow the 5 Factor Cheno Plan' [Exhibit 34]; 'Happy Figures by the Cheno Plan' [Exhibit 35]. Each of these booklets and leaflets relates to one or more of the above-mentioned articles of drug * * *";

That "At all times, the aforesaid articles of drug, when introduced into interstate commerce, have been and are now misbranded within the meaning of section 502 (f) (1) of the Act [21 U. S. C. § 352 (f) (1)], in that their labelings fail to bear adequate directions for use for the purposes and conditions for which they are intended."

At pretrial hearing the parties stipulated:

(1) That "defendants' products referred to in the Amended Complaint for Injunction are drugs and are shipped interstate by the defendants."

(2) That "Defendants ship all of their products in interstate commerce to health food retail outlets and intend to continue so shipping these products. Defendants also ship these products interstate direct to ultimate consumers in response to mail orders from such persons."

(3) That "Defendants are currently distributing [the above mentioned literature] interstate in the following ways * * *:

"(a) Defendants obtain the names and addresses of prospective customers from the retail outlets to which they sell their products. Defendants mail said literature to said prospective customers, and on such literature defendants print the name and address of the retail outlet that furnished such names and addresses.

"(b) Defendants also obtain the names and addresses of prospective customers from demonstrators who are hired by the defendants to work in retail outlets and there promote the sale of defendants' products. Defendants mail the aforesaid literature to said prospective customers, and on such literature defendants print the name and address of a retail outlet located in the same area as the prospective customer.

"(c) Defendants also obtain the names and addresses of prospective customers when individuals write in to the defendants for literature or

to submit mail orders. Defendants mail the aforesaid literature to said prospective customers, and on such literature defendants print the name and address of a retail outlet located in the same area as the prospective customer."

"Section 201 of the Act provides in part that :

(a) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement * * * that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper * * *.

(1) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers, or wrappers, or (2) accompanying such article.

"The parties have stipulated to the identity and content of the label used 'upon the immediate container' of each article, and further that such 'label' [21 U. S. C. § 321 (k), (1)] constitutes the entire 'labeling' [21 U. S. C. § 321 (m)] as to each article, unless the above-mentioned 'literature' is to be considered as 'accompanying such article' in interstate commerce within the meaning of § 201 (m) (2) of the Act [21 U. S. C. § 321 (m) (2)].

"Based upon the facts established by the pleadings and the pretrial stipulations, the Government has moved for summary judgment upon the ground: 'That there are no facts in dispute with respect to that portion of the Amended Complaint which seeks an injunction under 21 U. S. C. § 332 (a) to restrain defendants from violating 21 U. S. C. § 331 (a) through the continued interstate shipment of drugs that are misbranded in violation of 21 U. S. C. § 352 (f) (1),' which provides that: 'A drug * * * shall be deemed to be misbranded * * * (f) unless its labeling bears (1) adequate directions for use * * *.'

"In order to determine whether the labeling as to any 'drug' [21 U. S. C. § 321 (g)] bears 'adequate directions for use' within the meaning of the Act it is necessary of course first to ascertain what comprises 'its labeling.' Section 201 (m) declares that: "The term "labeling" means all labels [see 21 U. S. C. § 321 (k), (1)] and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article' [21 U. S. C. § 321 (m)].

"In *Kordel v. United States*, 335 U. S. 345, 347, 348 (1948), where 'the literature involved * * * was shipped separately from the drugs and at different times' but 'had a common origin and a common destination,' the literature was held to accompany the drugs in interstate commerce within the meaning of the Act [21 U. S. C. § 321 (m)] and so to comprise a part of the 'labeling.' [See also *United States v. Urbuteit*, 335 U. S. 355 (1948); *United States v. Research Laboratories, Inc.*, 126 F. 2d 42, 45 (9th Cir. 1942).]

"As in the cases just cited, the literature involved at bar explains the claimed beneficial uses of each drug and was obviously 'designed for use in the distribution and sale'; while the 'label' itself is either totally or practically silent as to the purpose for which the drug is to be used; and usually, but not invariably, both the drug and the literature describing it have a common point of origin in interstate commerce. The point of difference in the case at bar is that generally speaking the article and the literature do not have a common destination, since defendants usually ship the drugs to a retail outlet, while the literature is shipped directly to prospective consumers.

"Thus the precise question on this phase of the case is whether the literature may properly be held to accompany the drug in interstate commerce within the meaning of 21 U. S. C. § 321 (m) (2), where the destination of the literature when shipped is not the distributor or consumer of the drug.

"The policy of the Act seems clearly to require that 'labeling' [21 U. S. C. § 321 (m)] which bears 'adequate directions for use' [21 U. S. C. § 352 (f) (1)] of the drug be placed 'upon the immediate container' [21 U. S. C. § 321 (k), (1)],

or accompany the container so closely that the ordinary consumer will be apprised of all directions, cautions and other information appearing thereon.

"Section 201 (k) provides that 'a requirement * * * that any word, statement or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper' [21 U. S. C. § 321 (k)].

"Section 201 (n) provides that: 'If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual' [21 U. S. C. § 321 (n)].

"And § 502 declares that: 'A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular. * * *

(c) If any word, statement, or other information required * * * to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. * * *

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users. * * *

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof. [21 U. S. C. § 352 (a), (c), (f), (j).]

"Nothing more than a reading together of these quoted provisions of the Act is required to demonstrate the emphasis placed by the Congress upon the contents of the labeling as a means of protecting the consumer, as well as the legislative intent that the labeling so closely accompany the drug into the hands of the consumer 'as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use' [21 U. S. C. § 352 (c); see *Alberty Food Products v. United States*, 185 F. 2d 321 (9th Cir. 1950)].

"Where, as here, the literature and drugs do not have a common destination and the literature is not shipped to either a distributor or a consumer of the drug, it would be in derogation of the policy and purposes of the Act to broaden further the content of the verb 'accompany' as employed in § 201 (m) (2), 21 U. S. C. § 321 (m) (2). [See *United States v. Dotterweich*, 320 U. S. 277, 280 (1943).] So it is my opinion that the scope of 'accompanying' should be limited under *Kordel v. United States*, *supra*, 335 U. S. 345 and *United States v. Urbuteit*, *supra*, 335 U. S. 355, to cases where the literature has the same destination as the drug and hence will likely reach the hands of the consumer to serve the purposes for which labeling is intended. [Cf. *Alberty v. United States*, 159 F. 2d 278 (9th Cir. 1947); also *Alberty Food Products v. United States*, *supra*, 185 F. 2d at 325.]

"It follows that in the case at bar the literature must be held as not 'accompanying' the drugs in interstate commerce and therefore as not constituting a part of the 'labeling.' [21 U. S. C. § 321 (m) (2).] The 'labels' alone then on each of the drugs in question [21 U. S. C. § 321 (k)] must be held to comprise the entire 'labeling' as to such drug.

"There remains the question whether the 'labeling' bears 'adequate directions for use' within the meaning of § 502 (f) (1) of the Act [21 U. S. C. § 352 (f) (1)].

"Labeling fails to bear 'adequate directions for use,' if it does not state 'the purpose or condition for which the drug was intended,' as well as the dosage

and frequency or duration of taking prescribed, recommended or suggested in connection with the diseases or conditions of the body for which such drug is held out to the public. [See 21 U. S. C. §§ 321 (n), 352 (f), 352 (j), 371 (a); 21 Code Fed. Regs. §1.106 (1949); *Colegrove v. United States*, 176 F. 2d 614, 616 (9th Cir. 1949); *United States v. Various Quantities * * * 'Instant Alberty Food.'* 83 F. Supp. 882, 885 (S. D. Cal. 1949).]

"As Judge Bone said in *Alberty Food Products v. United States*, *supra*, 185 F. 2d at 325:

We proceed upon the assumption that the "adequate directions for use" mandate of Sec. 352 (f) (1) requires that *all* who might want to use a drug * * * are at least entitled to a chance to somewhere find and examine a "label" which is complete enough to * * * provide sufficient information at the time of purchase upon which intelligent determination might be made as to whether the drug is one which is prescribed, recommended, or suggested for their particular * * * ailment. We are persuaded that the law requires this much.

"The following is typical of the 'labeling' of a majority of the drugs in the case at bar:

ALBERTY'S
SABINOL
Homeopathic
App. 525 Pellets
Each Pellet Contains
Berberis Vulgaris
Lycopodium
Manufactured for and Packed by
ALBERTY FOOD PRODUCTS
Hollywood, California
Directions:
Take 3 Pellets every 2 hours until
relieved. Then 4 times daily.

"Similar labels appear on defendants' products identified as:

Alberty's Vegetable Compound Capsules [Exhibit 1];
Alberty's Oxorin [Exhibit 2];
Alberty's Food Regular [Exhibit 3];
Instant Alberty Food [Exhibit 4];
Alberty Garlic Perles (Alberty Garlic and Vegetable Oil Perles) [Exhibit 5];
Alberty's Sabinol [Exhibit 6];
Alberty Phloxo B Tablets [Exhibit 7];
Alberty's Phosphate Pellets [Exhibit 8];
Alberty's Ri-Co Tablets [Exhibit 10];
Alberty Special Formula Tablets [Exhibit 11];
Wheat Germ Oil [Exhibit 14];
Alberty's Lebara Pellets, Plain [Exhibit 17];
Alberty's Lebara No. 2 Pellets [Exhibit 18];
Cheno Phytolacca Berry Juice Extract Tablets and Cheno Phytolacca Berry Juice [Exhibit 20];
Cheno Combination Tablets [Exhibit 21];
Pandora Tablets [Exhibit 22];
Recal Tablets [Exhibit 23]; and
Alberty's Ca-Mo Pellets [Exhibit 27].

"Such 'labeling' fails to state either 'the purpose or condition for which the drug was intended' or the duration of taking recommended for treatment of the diseases or conditions of the body for which the drug is held out to the public in defendants' literature.

"The remaining 'drugs' involved at bar, to wit:

Alberty Riol Tablets [Exhibit 9];
 Alberty's Vitamin A (High Potency) Shark Liver Oil [Exhibit 12];
 Alberty's Vi-C [Exhibit 13];
 Alberty Vitamin B Complex Tablets with High-Potency B₁ [Exhibit 15];
 Alberty's Vitamin B₁ Tablets with Supplementary Amounts of Other
 B-Complex Factors [Exhibit 16];
 Cheno Herb Tea [Exhibit 19];
 Alberty's Vio-Min Vitamin-Mineral Tablets [Exhibit 24];
 Alberty R-Gon Tablets [Exhibit 25];
 Alberty's Laxative Blend Tea [Exhibit 26];
 Alberty's Vitamin A & G Capsules [Exhibit 28]; and
 Alberty Rego [Exhibit 29].

may be classed as so-called dietary supplements and laxatives. As such 'the purpose or condition for which the drug was intended' is a matter of common knowledge.

"However defendants in their literature admittedly recommend these 'drugs' without exception for other than commonly known uses. For example, defendants recommend their Vitamin B₁ Tablets [Exhibit 16] in the pamphlet 'Calcium—The Staff of Life' [Exhibit 30] for 'preventing chronic ill health'; for 'certain cases of heart disease' and 'some cases of arthritis and neuritis'; for increasing 'the body's insulin output and sugar tolerance'; and for 'improving the intelligence of school children.'

"Yet the only directions for use appearing on the 'labeling' of Alberty's Vitamin B₁ Tablets are: '*Directions*—Two tablets, three times daily (six tablets a day) furnish 3½ times the minimum daily requirements of Vitamin B₁ for an adult, and ¼₁₀ such requirements of Vitamin B₂.'

"Comment on the manifest inadequacy of such labeling to give 'adequate directions for use' for the purpose recommended in defendants' literature would be surplusage indeed.

"The facts as to the 'labeling' of each 'drug' at bar being admitted, the Government is entitled to summary judgment for a writ of injunction permanently enjoining and restraining defendants from 'the introduction or delivery for introduction into interstate commerce' [21 U. S. C. § 331 (a)] of any of the 'drugs' involved in this action unless and until the labeling of each such 'drug' bears adequate directions for the use thereof in the treatment of the diseases and conditions of the body for which defendants in their literature and other advertising prescribe, recommend or suggest its use [*Colegrove v. United States, supra.* 176 F. 2d 614; *id.* 83 F. Supp. 880 (S. D. Cal. 1947)].

"Accordingly the Government's motion for summary judgment is granted, and the United States Attorney will submit proposed findings of fact, conclusions of law and judgment pursuant to local rule 7 within ten days."

In accordance with the foregoing opinion, the court handed down its findings of fact and conclusions of law on June 30, 1951. On the same day, the court entered an order permanently enjoining the defendant from introducing or delivering for introduction into interstate commerce, and from causing the introduction or delivery for introduction into interstate commerce, any of the above-named drugs or any other drug misbranded under Section 502 (f) (1), by reason of the failure of its labeling (1) to enumerate the disease conditions for which the drug was intended and offered to the public, (2) to specify the structures or functions of the body which it was intended to affect and for which it was offered to the public, and (3) to state the dosage, frequency, and duration of administration of such drug for the treatment or prevention of such conditions, or for affecting such structures or functions of the body.

On July 24, 1951, the defendants filed a notice of appeal to the United States Court of Appeals for the Ninth Circuit. On February 15, 1952, after consideration of the briefs and arguments of counsel, the following opinion was handed down by that court, affirming the judgment of the district court:

ORR, *Circuit Judge*: "The facts of this case have been stipulated. They appear in detail in the opinion of the District Court (98 F. Supp. 23, D. C. S. D. Cal. 1951). For our purposes it is sufficient to state that appellants manufacture, pack and distribute certain drugs in interstate commerce. The District Court found the drugs in question to be 'misbranded' within the meaning of the Federal Food, Drug and Cosmetic Act in that their labeling failed to bear

'adequate directions for use.' 21 U. S. C. A. § 352 (f) (1). An injunction was issued permanently restraining appellants from introducing into interstate commerce said drugs or any other drug * * * which is misbranded within the meaning of 21 U. S. C. § 352 (f) (1) by reason of the failure of its labeling (1) to enumerate the disease conditions for which said drug is intended and offered to the public, (2) to specify the structures or functions of the body which it is intended to affect and for which it is offered to the public, and (3) to state the dosage and frequency and duration of administration of such drug for the treatment or prevention of such conditions, or for affecting such structures or functions of the body.'

"The principal contention made on this appeal is that the trial court erred in taking into consideration, in making its finding that the drugs in question were misbranded, certain collateral literature (leaflets and booklets, etc.)¹ sent by appellant to prospective customers. Appellants obtained customer names in various ways: (a) from retail outlets selling the drugs; (b) from demonstrators hired by appellants to work in retail outlets, and, (c) from customer inquiries and mail orders. Newspaper and magazine advertising was also used to promote sales of the drugs. These promotional materials contained claims, representations and suggestions relating to use of the drugs not present on the labels.² It is asserted by appellants that a consideration by the trial court of the literature and advertisements is an invasion of a field exclusively under the jurisdiction of the Federal Trade Commission, which has control of false advertising. This contention fails to grasp the scope and purpose of the inquiry with which the Court was concerned. It is not the truth or falsity of the literature and advertising which is challenged; it is merely consideration, as evidence, of claims promulgated by the manufacturer in measuring whether the information communicated by means of the label adequately describes the diseases or conditions for which the drug was intended as well as relevant facts containing dosage.

"In order for the labeling of a drug to bear 'adequate directions for use' within the meaning of 21 U. S. C. A. § 352 (f) (1) it must, among other things, state the purposes and conditions for which the drug was intended and sufficient information to enable a layman to intelligently and safely attempt self medication. *Alberty Food Products v. United States*, 185 F. 2d 321, 325 (9 Cir. 1950); Cf. H. Rep. No. 2139, 75th Cong., 3d Session 8.

"While appellants agree with this construction they argue that such fact must be determined from the labeling alone. This contention is without merit. It is not sufficient that the labeling contain a minimum of information and the use of the drug be induced by elaborate collateral representations. To permit the operation of such an escape valve would render the aims and purposes of labeling requirements nugatory. Adequate labeling is best suited to obtain the beneficial purposes contemplated by the Act, viz: broad protection of the consumer from adulterated or misbranded drugs, etc., and as a practical matter places no burden on those motivated by an honest belief that the claims made for their drug will be accomplished by its use.

"In the instant case appellants argue that the drugs involved in this case can properly be classified as 'dietary supplements and laxatives,' and labeling to that effect is sufficient, because such uses and purposes are of common knowledge. Such an argument has no validity because it is admitted that the drugs have been held out to the public as having beneficial and curative qualities other than their commonly known uses.

"The finding of the trial Court that the labels in question do not bear adequate directions for use finds ample support in the law and evidence. See *United States v. Various Quantities of Articles of Drugs*, 83 F. Supp. 882 (D. C. D. C. 1949); *Colegrove v. United States*, 176 F. 2d 614 (9 Cir. 1949),

¹ The leaflets and booklets were entitled, "Calcium, The Staff of Life," "Dynamic Digests," "Is There Hope That Graying Hair Can Be Restored? Read What Science Says—Pandora," "Health Mysteries," "Happy Figures by the Cheno Plan," "Reduce! Streamline Your Figure—Follow the 5 Factor Cheno Plan."

² For example, one of the drugs involved is *Alberty's Garlic & Vegetable Oil Perles*. The label simply states, "Fresh Garlic Concentrated Eight to One and Combined in Vegetable Oil," "One or 2 Perles Before Meals, a Convenient Way of Including Garlic in the Diet." In the collateral literature "Perles" are mentioned in connection with high blood pressure, various gastro-intestinal disorders, heart failure, hardening of the arteries, gastritis, some forms of dyspepsia, peptic ulcer, exerting an anti-diarrheal effect in gastro-intestinal disease, etc.

Cert. den. 338 U. S. 911 (1950); *Alberty Food Products v. United States*, 185 F. 2d 321 (9 Cir. 1950); *United States v. El-O-Pathic Pharmacy*, 192 F. 2d 62, 77 (9 Cir. 1951).

"*Judgment affirmed.*"

3664. Alleged misbranding of Kordel-E capsules, Aminex tablets, Fero-B-Plex tablets, and Garlic Plus tablets. U. S. v. 1 Case, etc. (F. D. C. No. 27269. Sample Nos. 57736-K, 57737-K, 57741-K, 57743-K.)

LIBEL FILED: May 26, 1949, Southern District of California; amended libel filed June 2, 1949.

ALLEGED SHIPMENT: On or about July 30, 1948, to April 7, 1949, from Chicago, Ill.

PRODUCT: 1 case of 36 30-capsule boxes of *Kordel-E capsules*, 1 case of 20 100-tablet boxes of *Aminex tablets*, 1 case of 29 90-tablet boxes of *Fero-B-Plex tablets*, and 96 50-tablet boxes of *Garlic Plus tablets*; at Los Angeles, Calif.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use since it did not state the diseases or conditions of the body for which the articles when used as directed would be effective. The products were alleged to be misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: Lelord Kordel appeared as claimant and filed an answer to the libel. Thereafter, on February 29, 1952, upon stipulation by the parties that the case presented no question for adjudication for the reason that the products under seizure had deteriorated and become unmarketable, and without any finding by the court on any issue of fact or law and with the consent of the parties, judgment was entered ordering that the products be destroyed.

3665. Misbranding of amphetamine sulfate tablets and Seconal Sodium capsules. U. S. v. Enos A. Hilterbrand (Live Oak Pharmacy). Plea of guilty. Sentence of 2 years in prison. (F. D. C. No. 31258. Sample Nos. 20962-L, 20963-L.)

INFORMATION FILED: September 17, 1951, Northern District of Texas, against Enos A. Hilterbrand, trading as Live Oak Pharmacy, Dallas, Tex.

INTERSTATE SHIPMENT: From the States of New Jersey and Indiana into the State of Texas, of quantities of *amphetamine sulfate tablets* and *Seconal Sodium capsules*.

ALLEGED VIOLATION: On or about May 30, 1951, while the drugs were being held for sale at the Live Oak Pharmacy after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *amphetamine sulfate tablets* and the *Seconal Sodium capsules* failed to bear labels contain-