manufacturer, packer, or distributor, and a statement of the quantity of the contents; and, Section 502 (f) (1), the repackaged drugs bore no labeling containing directions for use.

Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and when repackaged, the tablets failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: October 23, 1950. A plea of nolo contendere having been entered, the court imposed a fine of $100.

3309. Action to enjoin and restrain the interstate shipment of a drug known as Nurse Dencker's ointment. U. S. v. Mimi E. Alcorn, William Vernon Alcorn, and Wilhelmina G. Stanley (Dencker Products). Consent decree granting injunction. (Injunction No. 135.)

COMPLAINT FILED: September 8, 1947, Southern District of California, against Mimi E. Alcorn, William Vernon Alcorn, and Wilhelmina G. Stanley, trading as Dencker Products, Long Beach, Calif.

NATURE OF CHARGE: That the defendants had been and were at the time of filing the complaint, introducing and delivering for introduction into interstate commerce quantities of the drug known as *Nurse Dencker's ointment*, consisting of zinc oxide, corn starch, salicylic acid, olive oil, vaseline, and 1 percent of carbolic acid.

The drug was alleged to be misbranded under Section 502 (a), in that certain statements in the accompanying labeling of the drug were false and misleading. The statements represented, suggested, and implied that the drug would be efficacious in the cure, mitigation, and treatment of surface skin irritations, such as leg sores, superficial sores, lesions, and irritations on the legs, arms, body, whereas the drug was not efficacious for such purposes.

The drug was alleged also be misbranded under Section 502 (f) (1), in that the directions for use, "Clean parts with pure olive oil, wipe dry, then apply ointment thickly, fresh every morning and night—bandage," appearing on the label, were inadequate for the use of the drug in the various disease conditions for which it was prescribed, recommended, and suggested in the labeling and advertising disseminated by the defendants.

The complaint alleged also that unless restrained, the defendants would continue to introduce and deliver for introduction into interstate commerce the misbranded drug.

DISPOSITION: October 30, 1950. The defendants having consented to the entry of a decree, the court issued an order permanently enjoining the defendants from directly or indirectly introducing or delivering for introduction into interstate commerce the drug in question, or any like drug, misbranded as alleged in the complaint.

3310. Misbranding of Ri-Co tablets. U. S. v. 33 Bottles * * *. Claimant's exceptions to the libel overruled. Government's motion for summary judgment granted. Decree of condemnation and destruction. Judgment affirmed upon appeal. (F. D. C. No. 22157. Sample No. 48752–H.)

LIBEL FILED: January 8, 1947, District of Colorado.

ALLEGED SHIPMENT: On or about November 25, 1946, by the Alberty Food Products Co., from Hollywood, Calif.

PRODUCT: 33 bottles each containing 275 *Ri-Co tablets* at Denver, Colo.

LABEL, IN PART: "Ri-Co Tablets. Homeopathic Combination."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the only direction appearing in the labeling, namely, "Three tablets with a cupful of hot water. Take four times daily. Before meals and on going to bed.," did not indicate the purpose or condition for which the article was intended and, therefore, was not adequate for intelligent and effective use.

DISPOSITION: On February 28, 1947, pursuant to agreement between the Alberty Food Products Co. and the Government, the libel proceedings were ordered transferred to the United States District Court for the Northern District of California. Thereafter, exceptions to the libel were taken by the claimant, Alberty Food Products Co., and on September 30, 1947, the court overruled the exceptions. On December 1, 1947, the claimant filed an answer denying that the product was misbranded as alleged in the libel. On October 15, 1948, the Government filed a motion for summary judgment, and after a hearing in the matter, the court, on November 16, 1949, rendered the following oral opinion:

BLACK, *District Judge:*

The CLERK. "United States v. 33 Bottles of Ri-Co Tablets. Motion for Summary Judgment, for decision."

Mr. HAUERKEN. "Ready."

Mr. DICKERMAN. "Your Honor, may I request I be heard briefly on a new development that came to my attention this morning. It involves another case, or another libel with the Food and Drug Law wherein the District Court of the Northern District of Illinois granted motion for summary judgment. I have a mimeographed copy of this opinion which I received this morning. I gave a copy to counsel."

The COURT. "You may hand it to me."

Mr. DICKERMAN. "I wish to call the attention of the Court, the question apparently was not raised as to whether the admiralty or civil rules applied."

The COURT. "In the matter of the United States of America v. 33 Bottles, More or Less, of an Article Labeled in Part 'Ri-Co Tablets Homeopathic Combination App. 275 Tablets,' Alberty Food Products Co., etc., Claimant, the Government is asking for summary judgment. The claimant suggested in the first instance that summary judgment is not applicable on the ground that under the statutes the proceeding is to be considered as one in admiralty, and that therefore the civil rules of Federal Procedure providing for summary judgment do not authorize action by the Court as requested by the Government.

"I say that the claimant has suggested that summary judgment is not applicable. Actually, counsel for claimant has further suggested to the Court that condemnation is appropriate and should be ordered, but that the Court should further provide that the claimant should be permitted to relabel the bottles in accordance with the practice counsel says the claimant is now following pursuant to a decision by the Federal Trade Commission. In effect, then, I take it the question of whether or not this is a proceeding in admiralty is, in so far as counsel is able to make it, somewhat academic. It might almost be said that it is the law of this particular case that condemnation on the record should enter, and that the issue is whether or not relabeling should be permitted.

"I have looked at the authorities: the decision of the Supreme Court in 226 U. S., beginning at page 172; 33 Supreme Court, beginning at page 50; and 57 Law Edition, page 175, has been cited to the Court by the Government as establishing that this proceeding is civil and is not one in admiralty. That Supreme Court decision in substance held that the law then before the Supreme Court likened the proceedings to one [in] admiralty in connection with the seizure of the property by process in rem, and that decision of the United

States Supreme Court in effect was that after the seizure the matter became a proceeding in law and was governed by the statutes and rules apart from admiralty.

"Counsel for the plaintiff has pointed out that that decision was before the enactment of the present statute. After reading the Supreme Court decision, it seems to me that the principal therein enunciated, properly applied to the present statute, strongly indicates that it is to be deemed a civil rather than an admiralty matter after the seizure. It would therefore appear that summary judgment would be applicable.

"My view of the force and effect of that Supreme Court decision, which I think was about 1912, is in harmony with the view of the Circuit Court of Appeals for the Sixth Circuit, after the enactment of the present statute, which decision was rendered June 22, 1943, and is found in 136 Fed. Rep., 2nd Series, beginning at page 523. The Court of Appeals of the Sixth Circuit, in substance, held that the proceeding was not intended to be likened to one in admiralty beyond the seizure of the property by process in rem under the statutes.

"Under the decisions cited to me, I am satisfied that the Federal Rules of Civil Procedure are effective and that a summary judgment, upon proper showing, can be entered.

"There has just been handed to me District Court decision from the Northern District of Illinois, United States v. 17 Cases, More or Less, of Nue-Ovo, Research Laboratories, Inc. In this decision, dated October 11, 1949, the judge assumed that entry of a summary judgment was within his authority. It does not appear, however, that anyone objected to his exercising the authority providing the showing was sufficient. But independently of this most recent decision, I am satisfied that the proceeding is, at this stage, not one in admiralty. The main contention of the claimant is that by virtue of the Federal Trade decision, the holding that its right to relabel these articles is established be on the doctrine of res adjudicata. Such is a most interesting contention. Counsel for claimant depends primarily upon the decision of the United States v. Willard Tablet Company, 141 Fed. (2d), beginning at page 141, being a decision by the Circuit Court of Appeals of the Seventh Circuit under date of March 7, 1944. That court undoubtedly does hold that a decision by the Federal Trade Commission is binding upon the court in an independent proceeding; and the court in that decision depended upon an earlier decision by the Circuit Court of Appeals for the Eighth Circuit in Lee v. Federal Trade Commission, 113 Fed. (2d) 583. However, the Circuit Court of Appeals for the Ninth Circuit, under date of February 24, 1942, in U. S. v. Research Laboratories, Inc., reversing a holding by myself at Tacoma, said the following:

> It is immaterial, if true, that the makers and advertisers of Nue-Ovo could have been proceeded against by the Federal Trade Commission under the Federal Trade Commission Act and could have been ordered to cease and desist from publishing and distributing the circular entitled "What is Arthritis?" The power of the District Court to condemn misbranded articles is not impaired, diminished, or in any wise affected by the possibility that such misbranding may also be the subject of a cease and desist order, or either by the fact, if it be a fact, that such an order has actually issued.

"I am bound and controlled by the decision of this circuit, regardless of whether I agree or disagree with its correctness. I am only to be persuaded by the decisions of the Seventh Circuit or the Eighth Circuit if they appeal to my reason and are not at variance with the decisions of the Court of Appeals for the Ninth Circuit.

"December 8, 1943, 139 Fed. Rep. (2d), page 197, in the Sekov Corporation v. United States, the Circuit Court of Appeals for the Fifth Circuit cited with approval the decision of 122 Fed. (2d) 42, U. S. v. Research Laboratories, of this Ninth Circuit, which I have just mentioned."

Mr. HAUERKEN. "Your Honor, may I say a word?"

The COURT. "It stated this:

> Appellant Sekov Corporation contends that the fact that it had been previously proceeded against by the Federal Trade Commission barred inquiry by the District Court into the questions presented by the Government's libel. There is no merit in this contention. The issues in that proceeding were not identical with those here presented. Moreover, the power and duty of the District Court to condemn the misbranded articles

was not impaired or diminished by the former proceeding. United States v. Research Laboratories, 9 CIR., 126 Fed. (2d) 42, 45.

"While the decision of the Eighth Circuit in 113 Fed. (2d) 583, which I previously mentioned, appealed to the Court of Appeals for the Seventh Circuit in the Willard Tablet Company case, such decision in 113 Fed. (2d) neither appealed to the Circuit Court of Appeals for the Fifth Circuit nor to the Circuit Court of Appeals for the Ninth Circuit.

"Unquestionably I must hold that what the Federal Trade Commission did in an independent and different proceeding is not res adjudicata here. Actually, such would appear not to be res adjudicata for further reasons. In the first place, what the Trade Commission did apparently was done pursuant to stipulation. Other courts, in independent proceedings where the showing is different, are very reluctant to consider themselves barred by a commission's holding on a stipulation. Further than that, I do not find that the Commission held anything. I am advised that the cease and desist order of the Federal Trade Commission required this claimant to cease and desist from disseminating advertisements in the United States mails or by any means in commerce which represent

that the preparation "Ri-Co Tablets" constitutes an adequate or competent treatment for arthritis, rheumatism, gout or rheumatic gout; or that said preparation will eliminate uric acid from the system; provided, however, that nothing herein shall be construed as prohibiting the representation that according to the principles of the homeopathic school of medicine the preparation is of value in ameliorating the symptoms of muscular or ligamentous pain and stiffness due to arthritis or rheumatism except when such symptoms are accompanied by a febrile condition.

"It is apparent that the Federal Trade Commission did not hold that Ri-Co Tablets were of value to ameliorate the symptoms of muscular or ligamentous pain and stiffness due to arthritis or rheumatism. The most that the Federal Trade Commission said was that it was not preventing the claimant from contending that such was of benefit. That is a far cry from any adjudication that should be considered as res adjudicata.

"But even if the Federal Trade Commission had done what counsel feels it did do, the Circuit Court of Appeals for the Ninth Circuit certainly told me that any holding of any Federal Trade Commission was of no avail in another and independent proceeding before the District Court. There is no showing in behalf of the claimant before me that the tablets have any efficiency or any value. All of the showing, so far as presented, is to the effect that they are worthless.

"The application for summary judgment based upon the pleadings, however, is upon the ground that the labels did not give adequate directions as required by the statute. The label did state that the tablets were to be taken at certain intervals, without even a hint that the tablets were helpful for anything. The Government's contention is that the directions, to be adequate, must not only tell how often the alleged remedy is to be taken, but for what it is to be used. The decisions of the Circuit Court of Appeals in this Circuit, both of the District Courts and of the Court of Appeals, are to the effect that as to remedies' directions, to be adequate they must not only say how often but for what.

"It seems to me that such holdings which are binding upon me are in accord with reason and in harmony with the purpose of the Pure Food and Drug Act.

"The condemnation asked will be ordered upon the ground that the directions printed did not comply with the statute, upon the ground that they were inadequate.

"I am not holding that Ri-Co Tablets are worthless. That issue actually was not presented to me. The Court has the authority, in its discretion, to permit the claimant to relabel these tablets; but certainly for the Court to allow claimant which has violated the law to relabel tablets, the claimant should make an affirmative showing that appeals to the judgment or conscience or both of the Court. No showing whatsoever has been made. It is conceded that the claimant has been held repeatedly to have violated the law, either as to these tablets or other preparations. The claimant has not attempted to persuade me that the tablets are good and that there would be any loss to humanity or posterity if I allow condemnation to be effected.

Claimant has relied solely upon the Willard Tablet case, which is a holding of the Northern Circuit and not binding on me, and which is contrary to a holding of this Circuit which does control.

"I know no good reason that I should require the Government to turn over these tablets for relabeling. Judgment and order will be presented in conformity with my announcement.

"Counsel, there was something you wished to say?"

Mr. HAUERKEN. "I presume it is too late inasmuch as your Honor has announced judgment. I do feel your Honor has erroneously construed the Research Laboratories Company case. I do not know whether your Honor wants me to be heard on this or not, but I would like to show my views on it."

The COURT. "Well, counsel, I told you I am quite familiar with that case. I am speaking now informally. It is not a part of my decision. I thought at the time I rendered decision in Tacoma that I was right. It might not be very hard for you to convince me that the Circuit Court was mistaken, but the Circuit Court reversed me and I am bound by what it said and certainly it said what I have quoted from it, because I read it verbatim. I have no quarrel with that portion of the Circuit Court's holding. I think, as I pointed out before to you, I have held the libel was so crudely and inexpertly drawn that it had no right to be considered by the Court and I dismissed it. The Circuit Court of Appeals in reversing me admitted the following:

> The libel is crudely and inexpertly drawn. It does not state directly and positively, as a competently drawn libel would have stated, that the 143 packages of Nue-Ovo were misbranded when introduced into or while in interstate commerce.

"But the Circuit Court of Appeals held that the crudeness and lack of expertness in the drawing of the libel, while not to be commended, was not as fatal as I thought it was. But I am satisfied now. Upon the problem you present I have disagreed directly with you and disagreed directly with the doctrine of the Willard case on which you relied."

Mr. HAUERKEN. "The point I make in that, that violation, if any, was a violation of the Federal Trade Commission Act and therefore there could be no prosecution under the Food and Drug Act, as I recall that case. The question was whether or not the pamphlets had accompanied the article in interstate commerce. Wasn't that the case where it was held common origin, common destination, and approximately a shipment at the same time constituted a libel? I think that is the case I have in mind."

The COURT. "Well, whatever was there at issue, the Circuit Court of Appeals announced the doctrine for this Circuit that answered your argument far better than any counsel could hope to answer it, and the Circuit Court of Appeals for the Fifth Circuit seemed to think that that doctrine was appropriate because, as I say, it disregarded the decision in 113 Fed. (2d) the court in the Willard case relied on."

Mr. HAUERKEN. "My concept of that case is that a person could violate both acts, and I think that is what those cases hold, that by the one action you would be in violation of both acts."

The COURT. "I have no question of that, counsel, but both courts say in an independent proceeding on different showings the court is not bound by what the Federal Trade Commission may do, and that is particularly true when what the Federal Trade Commission did, in so far as it did anything, was on stipulation; and most particularly true when the Federal Trade Commission didn't do anything, but just merely negatively said that its order was not to be construed as stopping you from doing something."

Mr. HAUERKEN. "I merely wanted to present that point, your Honor. I have no desire to draw the matter out."

The COURT. "The Court will say this: It has been very interested in the presentation by counsel on both sides. Counsel on each side have been very helpful to the Court and have ably presented their various matters. I am sure I understood the presentation of counsel for claimant. Under the law as I see it, and the facts as presented, I am holding against him. He may be right, but I do not think so. I thank counsel on both sides for your assistance to the Court.

"That is all."

In accordance with the above opinion, the court, on November 29, 1949, handed down its findings of facts and conclusions of law and on the same day entered a decree providing for condemnation and destruction of the product. Pursuant to the decree, the United States marshal destroyed the product on December 14, 1949. The notice of appeal was filed by the claimant on December 16, 1949. A motion to dismiss the appeal then was filed on behalf of the Government in the United States Court of Appeals for the Ninth Circuit on the ground that the product was no longer in existence and that the case therefore had become moot. On April 3, 1950, the appellate court denied the motion, without prejudice to its renewal by the Government if so advised on the hearing of the case on its merits. The case was argued before the court of appeals on October 18, 1950, and on November 20, 1950, the court handed down the following opinion affirming the judgment of the district court:

BONE, *Circuit Judge:* "Appellee filed a libel under which it seized appellant's drug here involved (33 bottles of Ri-Co Tablets) charging therein that the drug was 'misbranded' in violation of 21 U. S. C. A. Sec. 352 (f) (1) of the Federal Food, Drug, and Cosmetic Act (referred to hereafter as the Act). The specific ground of complaint was that the 'labeling' of the drug failed to bear adequate directions for use since it did not state the purpose or condition for which the drug was intended. The only directions for use on the label attached to the bottle read as follows: 'Three tablets with a cupful of hot water. Take four times daily. Before meals and on going to bed.'

"At the hearing below two newspaper advertisements from daily publications in large cities were introduced. These ads show that appellant's drug was there represented and recommended by appellant for use in the treatment, mitigation, and cure of arthritis and rheumatism. The two advertisements read as follows:

ROCKY MOUNTIAN NEWS Tuesday, Oct. 1, 1946—

ARTHRITIS
RHEUMATISM
RICO TABLETS
Another Alberty
Product

Do you suffer from ARTHRITIS or RHEUMATISM, two of the most painful ailments that afflict mankind?

These ailments arise from the same underlying cause—two [sic] much acidity that permits deposits of urates in joints or muscles that cause excruciating pain.

Science has spent many years searching for remedies for these ailments. If you have tried many remedies without relief TRY RICO, a formula discovered by a famous Homeopathic physician for relief of the pains of ARTHRITIS and RHEUMATISM. For over 15 years this formula has been used by many eminent Homeopathic Physicians.

RICO is harmless and does not upset the digestive tract or affect the heart.

275 TABLETS_____$2.00
In Colorado, include 2% state sales tax
SENT POSTPAID WHEN REMITTANCE ACCOMPANIES ORDER.
LEEDS HEALTH HOUSE
Under new ownership
Ethel Barnes and Helen Olson
725 15th St. KE. 9214
2 doors from Denver Dry Goods.

SAN FRANCISCO CHRONICLE Monday, June 7, 1948 Page 13—

TROUBLED with
Symptoms of
ARTHRITIS
RHEUMATISM?
ALBERTY'S
RICO TABLETS

WHY SUFFER FROM THE PAINS OF THE SYMPTOMS OF ARTHRITIS AND RHEUMATISM WHEN RICO MAY GIVE YOU AMAZING PALLIATIVE RELIEF LIKE IT HAS DONE FOR COUNTLESS OTHERS?

Some 25 years ago a famous Homeopathic Physician attacked this problem from the homeopathic point of view. He combined certain ingredients according to the theories of homeopathy for relieving certain symptoms of arthritis and rheumatism. This formula has stood the test of time and it has been widely used by many Homeopathic Physicians.

ALBERTY'S RICO TABLETS

Rico is made by the same formula originated by the famous Homeopathic Physician. And, according to the principles of Homeopathy, improves the symptoms of muscular or ligamentous pain and stiffness due to ARTHRITIS or RHEUMÁTISM except when accompanied by a febrile condition. They are not a SEDATIVE; do not upset the DIGESTIVE TRACT OR AFFECT THE HEART.

Try RICO today—
an ALBERTY PRODUCT
$1.00, TWO WEEKS' SUPPLY.
ECONOMY SIZE, $2.00
San Francisco
HEALTH FOODS
Store
415 Sutter St. Ex. 2-8477

"Appellant appeared as claimant of the drug and filed exceptions to the libel. In essence the exceptions were that the Act does not require the labeling of a drug to state the disease condition for which it is to be used. In this connection it contended that the misbranding here charged was merely a failure to include upon the label of the container information to consumers which was not required by the Act to be included thereon either as directions for its use or otherwise. As a consequence the libel failed to state a cause of action because the alleged misbranding was not a misbranding at all. Appellant's exceptions were overruled by the trial court. Appellant's subsequent answer to the libel admitted that the seized Ri-Co Tablets were a drug that had been shipped in interstate commerce.

"After the answer, appellee filed a motion for summary judgment which asserted (1) there were no facts in dispute and (2) the only legal issue had been decided in favor of appellee when the lower court overruled claimant's exceptions to the libel. It supported this motion by (1) an affidavit of a Food and Drug representative incorporating photostats of the complete labeling on the drug container and the two newspaper advertisements above noted, and (2) the affidavits of four physicians (licensed to practice in California) attesting to the complete worthlessness of Ri-Co Tablets in the treatment or cure of arthritis or rheumatism or their symptoms.[1]

"Appellant filed no counter-affidavits, and after hearing the court granted appellee's motion for summary judgment, made and entered Findings and Conclusions and a Decree pursuant thereto. The Decree condemned the drug, ordered it destroyed[2] and awarded certain costs to appellee. The appeal is from this Decree.[3]

"In urging reversal appellant presents five claims of error committed by the lower court and it simplifies the problem in this case by stating that these errors relate to only two basic issues. Claims 4 and 5 *both* relate to the pro-

[1] Despite the physicians' affidavits the lower court refused to consider the question of the therapeutic qualities of the drug. It held that the misbranding charge in the libel was sustained, and this ruling presents the controlling issue on this appeal.

[2] Pursuant to the decree the drug in question was destroyed by the United States Marshal. Because of the Ri-Co Tablets are no longer in existence, appellee's brief suggested absence of jurisdiction to entertain this appeal, but on argument appellee advised the court that it was not urging this point and we disregard it. In this connection we note that appellant did not seek a stay of the order of destruction.

[3] In its findings the court sets forth that appellant had proposed to consent to a decree of condemnation provided permission was given to relabel the drug so as to conform with certain language in a Federal Trade Commission Order. In the exercise of its discretion (under Sec. 334 (d) of the Act) the court denied this privilege. Appellant states that it does not question that ruling on this appeal and it is not in issue here.

cedural question of whether a summary judgment was proper in this case. Claims of error, 1, 2 and 3 *all* relate to the question of whether or not the Act requires that the directions (on the bottles) for the *use* of the tablets include a statement of the conditions for which the tablets are used.

"In appellant's argument on the issues as thus narrowed, it says:

> With the *exception* therefore of the procedural issues of whether a summary judgment can be granted in a condemnation proceeding and whether a summary judgment should have been granted in this proceeding, *the only issue* before this court is the issue of whether the Act requires that the directions for the use of the tablets include a statement of the conditions for which they are used.
>
> * * * * * * *
>
> *The directions printed on the label* of Ri-Co Tablets are adequate *for their use* in all conditions for which they are prescribed, recommended, suggested, or commonly and effectively used. The Act does not require a label to include a *statement of those conditions* and the decree should accordingly be reversed with instructions to dismiss the libel. In the alternative, the decree should be reversed, and the question of whether the directions are adequate for the intelligent and effective use of the tablets should be left to the determination of the jury. [Emphasis supplied.] [As later appears, this reference in the last sentence refers to the propriety of the summary judgment in this case.]

"As respects the legal sufficiency of the label appearing on its bottle, appellant clarifies its position by the further argument:

> The Government * * * contends that no information could be more essential to the consumer regarding a drug which he can purchase without prescription than a statement of the conditions for which the drug is used. We agree that no one is likely to purchase a drug without knowing the conditions for which the drug is used. That knowledge, however, *must* be imparted to the consumer by means other than the label. He must have it before he gets close enough to the label to be able to read its fine print. In other words, he will not buy the drug unless he learns of the conditions for which it is used *from sources outside the label,* as by prescription, recommendation, suggestion, or common and effective usage. By the time he sees the label, he needs only to be protected by being told how to use the drug for the condition for which he is purchasing it. If "4 times daily" is an adequate direction for the use of the drug in that condition, the label complies with the Act irrespective of whether it refers to that condition. [Emphasis supplied.]

"The foregoing argument conclusively shows that appellant relied exclusively upon these 'outside sources,' namely, the newspaper advertisements, to provide *all* of the information which could possibly enlighten prospective purchasers of its drug concerning 'the conditions' for which the drug was to be used by them.

"Appellant also offers some reasons for its failure to include on the bottle label nothing more than the dosage recommended. In substance it argues that: a statement of *all* conditions or symptoms for which the drug is used would be so long that it could not be included within the limits of the label. While it is true that Sec. 352 (f) (1) requires 'directions for use' on the labeling, and Sec. 321 (m) defines 'labeling' as including the 'label' on the immediate container and *all* other 'accompanying' literature, still this use of the more inclusive term 'labeling' is nullified by Sec. 352 (c) which deems a drug misbranded unless *all* information required to appear on the labeling be placed thereon in such manner as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

"The arguments in the preceding paragraph lack persuasiveness and merit.

THE BASIC ISSUE

"Two recent cases present a material bearing on the issue before us. Kordel v. United States, 335 U. S. 345 and United States v. Urbuteit, 335 U. S. 355. The Kordel case involved the shipment and sale of a drug—a charge of misbranding was made because of certain representations in 'accompanying' leaflets, circulars and pamphlets supplied by Kordel, and distributed by his vendors to consumers and users. These 'accompanying' documents contained statements relative to the use and efficacy of the drugs. As we understand

the doctrine announced in these cases it is that where *literature of the character above indicated* is shipped in interstate commerce *and distributed to consumers as part of an integrated distribution program,* the literature *which thus accompanies the drug and is distributed with it,* constitutes an essential supplement to the label attached to the package containing the drug although this literature may have been shipped separately and at a different time than the drug. This process made the product and the literature 'interdependent' so far as 'labeling' is concerned. In short, the supplemental literature was considered a part of the label on the drug container.

"In the case at bar we face a different set of facts. Appellant did not resort to the distribution of any sort of 'literature' to ultimate purchasers as a 'supplement' to its package label. Neither did it distribute such 'literature' to purchasers, actual or prospective, to promote sales and to describe and advertise the therapeutic qualities of its drug. Appellant used only the newspaper advertisements and we think that it cannot be said that these advertisements 'accompanied' appellant's drug into interstate commerce, and were 'distributed' by vendors, or otherwise, to ultimate purchasers of the drug as part of an 'integrated distribution program.' On the 'labeling' issue, this distinction should be borne in mind.

"What we have already said leads us to disagree with appellant's contention that by employing these 'remote' newspaper advertisements it fully supplied a legally adequate 'labeling' which described the *use* of the drug in the treatment or alleviation of arthritic or rheumatic conditions. It seems to us that supporting appellant's views would be a long and drastic step toward nullifying what we regard as salutary protective features of the act which Congress designed to control and regulate the sale of drugs to a helpless public—helpless because it is uninformed. (See comment on this phase of the law in United States v. Various Quantities—Instant Alberty Food, 83 F. Supp. 882.) The logic of the Kordel and Urbuteit cases would seem to repel the conclusion that the therapeutic claims made only in random newspaper advertisements, *must* be considered and deemed to be a part of, and to be 'accompanying' and 'supplementing,' the brief dosage statement appearing on the bottles containing appellant's drug. There is no hint in the record that these advertisements were reproduced in pamphlet or leaflet form and shipped with the drug on its interstate journey from appellant to its vendors to be distributed to ultimate consumers. No claim is made that the reading matter in the newspaper advertising appeared in any sort of literature (pamphlet, etc.) which was made available by vendors to purchasers of the drug.

"A wholly justifiable inference is that many of those who suffer from pains of arthritis and rheumatism—and they are legion—never heard of Ri-Co Tablets, and undoubtedly never saw, or had a chance to see, appellant's newspaper advertisements. It is certain that as to them, these advertisements gave absolutely no notice of the existence of the drug, its dosage, uses and *therapeutic qualities.* 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 to relieve the pains of arthritis and rheumatism are at least entitled to a chance to somewhere find and examine a 'label' which is complete enough to give them information which would lead them to purchase a drug for that purpose, or, in other words, 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 form of arthritis or rheumatic ailment. We are persuaded that the law requires this much.

"Since the kind of complete information we have indicated was not made available to the general run of victims of arthritis and rheumatism by a proper and adequate 'labeling' of appellant's drug, we must hold that it was 'misbranded' under Sec. 352 (f) (1) of the Act. This for the reason that what appellant insists is a proper and adequate 'labeling' falls far short of legal requirements. It failed to bear 'adequate directions for use' since it did not state the purpose or condition for which the drug was intended.

THE ISSUE OF SUMMARY JUDGMENT

"Appellant contends that a summary judgment was an 'improper' remedy and may not be obtained in this case because appellee is not 'a party seeking to

recover on a claim * * * or to obtain a declaratory judgment' (under Rule 56, F. R. C. P.) this being a condemnation proceeding and not an orthodox civil action. The contention rests on the language of the Act (Sec. 334 (b)) prescribing that procedure in condemnation cases 'shall conform, *as nearly as may be*, to the procedure in Admiralty.' [Emphasis supplied.] The argument is predicated upon the holding in two district court cases.[4]

"The heart of this part of appellant's argument is presented in the statement that 'this case presents a genuine issue of fact as to which Alberty is entitled [as it requested] to a jury trial' (as in ordinary civil cases)—this because the pleadings raised the question of whether directions given by Alberty for the use of the tablets are 'adequate for its intelligent and effective use.' Appellant supports this contention by reliance on two cases from this Circuit[5] but we think that they do not aid its case.

"Because of the nature of seizure cases, like the one at bar, a question has arisen in the past as to whether Admiralty rules apply in such seizure actions under the Act. After the enactment of the present statute the Sixth Circuit (United States v. 935 Cases, etc., 136 F. 2d 523) held that proceedings of the character here involved are not intended to be likened to those in admiralty *beyond the seizure of the property by process in rem under the statutes*. See also 443 Cans of Frozen Egg Product v. United States, 226 U. S. 172, 183. As appellee points out, an imposing group of authorities now support the proposition that despite a contrary holding in certain of the earlier cases dealing with enforcement of the 1938 Act, the better rule is that the Rules of Civil Procedure apply in these seizure actions as soon as the property proceeded against has been seized.[6] We prefer to accept and adopt the principle announced in these later cases and hold that the Admiralty rules do not apply in seizure actions like this beyond apprehension of the property. The lower court did not err in entering its Summary Judgment under Rule 56 (a) unless it can be said that the labeling here involved was not a misbranding of the drug, a view we have refused to accept.

"The record clearly discloses that a genuine issue of fact was not presented to the court. The basic question presented and properly considered by the lower court was whether the labeling on the drug failed to bear 'adequate directions for use' in violation of Sec. 352 (f) (1) of the Act. Having concluded, as a matter of law, that the labeling of the drug wholly and completely failed to conform to the requirement of this Section, the court properly held that the drug was misbranded. In this posture of the case it presented only a question of law and this clearly justified entry of the summary judgment as authorized in cases where the civil rules apply.

"The lower court correctly decided the case and its judgment is affirmed."

3311. Misbranding of diathermy device. U. S. v. 19 Devices * * *. (F. D. C. No. 25693. Sample No. 37847–K.)

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[4] United States v. 720 Bottles, etc., 3 F. R. D. 466 (1944); United States v. 149 Gift Packages, etc. 52 F. Supp. 993 (1943).

[5] Gifford v. Travelers Protective Ass'n., 153 F. 2d 209, and Koepke v. Fontecchio, 177 F. 2d 125.

[6] See further: Eureka Productions, Inc. v. Mulligan, 2 Cir., 108 F. 2d 760, 761; United States v. 88 Cases, etc., 5 F. R. D. 503 (1946); United States v. 300 Cans, etc., 7 F. R. D. 36 (1946); United States v. 935 Cases, etc., 6 Cir. (1943), 136 F. 2d 523, 525, cert. denied 320 U. S. 778; United States v. 20 Cases, etc., 77 F. Supp. 231 (1947); C. C. Co. v. United States, 5 Cir. (1945), 147 F. 2d 820, 824; United States v. 5 Cases, etc. 2 Cir. (1950) 179 F. 2d 519, 522, 524, notes 9 and 15. In this case the court said: "It now appears well established that the Rules of Civil Procedure do apply to condemnation proceedings." And see cases cited in Fed. Prac. and Procedure, Barron and Holtzoff, Vol. 1, page 219 (case cited as being in 8 F. R. D. 81 is at same page in Vol. 9, F. R. D.).