"Larkspur Lotion"] * * * Distributed by Powers-Taylor Drug Company, Richmond, Virginia."

The product purporting to be spirits of ammonia was alleged to be adulterated in that its strength differed from and its quality and purity fell below that which it purported or was represented to possess in that each of the bottles was represented to contain spirits of ammonia aromatic U. S. P.; whereas each of said bottles did not contain spirits of ammonia aromatic U. S. P. but a number of them did contain larkspur lotion. It was alleged to be adulterated further in that another substance, namely, larkspur lotion, had been substituted in part for spirits of ammonia aromatic U. S. P.

The product purporting to be spirits of ammonia was alleged to be misbranded in that the statements, "Spirit of Ammonia Aromatic U. S. P. Alcohol 65% By Vol. * * * An Agreeable stimulant and carminative preparation," borne on the label, were false and misleading in that they represented that the article consisted of aromatic spirits of ammonia which conformed to the requirements of the United States Pharmacopoeia, that it contained 65 percent of alcohol by volume and was an agreeable stimulant and carminative preparation; whereas it was not as represented in that the article in a number of bottles consisted of larkspur lotion, the larkspur lotion in the said bottles contained not more than 22.1 percent of alcohol by volume, and larkspur lotion is not an agreeable stimulant and carminative preparation. It was alleged to be misbranded further in that it consisted in part of larkspur lotion and was offered for sale under the name of another article, namely, "Spirits of Ammonia Aromatic U. S. P."

The product purporting to be larkspur lotion was alleged to be adulterated in that its strength differed from and its quality and purity fell below that which it purported and was represented to possess in that each bottle was represented to contain larkspur lotion; whereas a number of said bottles contained spirits of ammonia aromatic. It was alleged to be adulterated further in that another substance, namely, spirits of ammonia aromatic U. S. P. had been substituted in part for larkspur lotion.

The product purporting to be larkspur lotion was alleged to be misbranded in that the statement "Larkspur Lotion * * * Alcohol 20% by Vol.," borne on the bottle label, was false and misleading since it represented that the article consisted of larkspur lotion and contained 20 percent of alcohol by volume; whereas the article in a number of the bottles consisted of aromatic spirits of ammonia and the aromatic spirits of ammonia in the said bottles contained not less than 68.1 percent of alcohol. It was alleged to be misbranded further in that it consisted in part of aromatic spirits of ammonia and was offered for sale under the name of another article, namely, larkspur lotion.

On October 24, 1940, pleas of nolo contendere having been entered on behalf of each of the defendants, they were found guilty by the court. The corporation and each of the individual defendants were fined $100 and one-fourth of the costs on count I, and the individual defendants were placed on probation for 3 years on the remaining three counts.

350. Adulteration of tincture of digitalis. U. S. v. Yates Drug & Chemical Co. Tried to the court. Judgment for the Government. Fine, $500. (F. D. C. No. 940. Sample No. 68344–D.)

This product differed from the strength, quality, and purity set forth in the United States Pharmacopoeia for tincture of digitalis.

On July 30, 1940, the United States attorney for the Southern District of New York filed an information against the Yates Drug & Chemical Co., a corporation, New York, N. Y., alleging delivery for introduction in interstate commerce, namely, a delivery on or about September 18, 1939, for shipment from the State of New York into the State of New Jersey, of a quantity of tincture of digitalis that was adulterated.

The article was alleged to be adulterated in that its label bore the words "Tincture Digitalis U. S. P. XI," which purported and represented that it was a drug the name of which is recognized in an official compendium, namely, the United States Pharmacopoeia, eleventh edition, and that it was of the strength, quality, and purity of tincture of digitalis as set forth in said compendium; whereas its strength fell below the standard for strength of tincture of digitalis so set forth in this, that whereas the eleventh edition of the United States Pharmacopoeia states that the potency of tincture of digitalis shall be such that 1 cubic centimeter thereof shall possess an activity equivalent to not less than 1 and not more than 1.1 U. S. P. digitalis units, the potency of the article was such that 1 cubic centimeter possessed an activity equivalent to not more than 0.58 U. S. P.

digitalis units, and its label did not plainly state that the drug differed in strength from the standard of strength prescribed for such drug in such compendium.

On November 19, 1940, a jury having been waived, the case came on for trial before the court. Evidence was introduced on behalf of the defendant and by the Government, and on December 2, 1940, the court entered judgment for the Government, handing down the following opinion:

LEIBELL, *District Judge.* "Of course, a jury does not render any opinion, and I am sitting as a jury in this case, both sides having waived a trial by jury and consented to a trial by the court without a jury; the defendant on its part through a stipulation signed by one of its officers and by its counsel, and also the Government having signed the stipulation waiving the jury trial and consenting to this arrangement.

"I have given close attention to the evidence that was offered, and sitting as a court I have also asked a number of questions as the case went along. I realize, of course, that the burden is on the Government to establish the guilt of the defendant beyond a reasonable doubt. The court having charged what a reasonable doubt means in so many cases, I do not need to remind myself of it. I have reached the conclusion that the proof of the Government was most detailed both as to the preparation and use of the standard powder of digitalis and also the sale, delivery in interstate commerce, and the subsequent tests of the defendant's tincture of digitalis contained in this Exhibit 9.

"I have not any doubt that the tincture of digitalis sold by the defendant, as charged in the information, was substandard and that it did not exceed 60 percent of the standard required by the United States Pharmacopoeia, eleventh edition. A variance of some 20 percent from standard was allowed, but this is a variance of 40 percent. I believe that the test set forth in the United States Pharmacopoeia is definite, understandable, and readily followed by those whose business it is, with expert knowledge, to make those tests. I think the testimony of the experts here all shows that they knew how to go about making the tests required by the United States Pharmacopoeia for the preparation of the tincture of digitalis.

"The test prescribed in the pharmacopoeia is the one that under the law must be followed. It may be that at some future date more accurate tests will be developed. However, in this case it has been shown that the 1-hour frog method does produce a very accurate result when applied by different experts to the same sample of tincture of digitalis.

"It may be that the defendant when it sold the bottle of tincture of digitalis, which is the subject of this information filed against the defendant, believed that it complied with the standard required by law, but that is not the test that the law lays down. I do not question and have no reason to question the good faith of the defendant, and I have no reason to believe that a concern that has been in business 40 years would deliberately and wilfully sell this bottle of tincture of digitalis knowing that it was substandard, as the proof has shown here. But it is not necessary that the Government show under the statute that the sale was wilful and deliberate and with full knowledge of the substandard condition of the tincture of digitalis. I do not see what this defendant had to gain from selling the substandard tincture of digitalis, in a monetary way, considering the reputation of the defendant in its field as a manufacturing chemist, so that in finding the defendant guilty as charged in the information and, of course, subject to the imposition of a penalty under the provisions of the act, subject to the punishment provided in the act, I think it is only fair that I should state that there is not anything to show that the defendant deliberately set out to sell a substandard digitalis. In fact, the only proof as to the potency of the tincture of digitalis at the time that this particular batch was made up. namely, the testimony of Dr. Pearson, is to the effect that it was then standard tincture of digitalis. I think his percentage was around 94 percent, was it?"

Mr. KELLY. "Ninety-six percent."

THE COURT. "Ninety-six percent. But I have not any doubt at all but that the Government has shown that this particular tincture of digitalis sold by the defendant in interstate commerce was substandard in that it had a potency of less than 60 percent of the unit of potency required by the U. S. Pharmacopeia, which in turn is referred to in the statute itself, Section 351 (b), Title 21, U. S. code annotated, which is part of the Food and Drug Act.

"There is not any doubt either that the label on Exhibit 9 represented that this was tincture of digitalis of standard strength. When I say 'standard

strength' I mean the strength prescribed for the drug tincture of digitalis in the U. S. Pharmacopeia, eleventh edition. Now, just how this happened to be in a substandard condition, while that is immaterial on the question of the violation of the statute, it may have occurred through deterioration; it may have occurred in the packaging of it; it may have been the fault of some employee, or it may have been through an oversight or negligence. But I think all of that is outside the case, or the realm of proof in determining the guilt or innocence of this defendant, and the question involved is whether or not it was actually substandard and was sold by the defendant represented as standard and sold in interstate commerce.

"It is unfortunate, of course, that a concern which has been in business as long as the defendant, the Yates Drug & Chemical Co., should be found guilty of a violation of the Food and Drug Act, but, as I stated before, there is nothing to indicate that the violation was deliberate or undertaken for the sake of gain or profit for the defendant.

"So, sitting as both the court and jury in this case, I find the defendant, Yates Drug & Chemical Co., guilty as charged in the information.

"I will hear you on the question of the penalty, section 333. * * *

THE COURT. "Of course, the particular statute involved here is section 331 (a) the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."

Mr. KELLY. "Yes, sir."

THE COURT. "The label represented that this tincture of digitalis was the U. S. P. XI and had been biologically tested so that it was supposed to comply with the U. S. P. XI as to potency, and the representation was that it did comply. Of course, then, there is this section 351 (b) relating to the strength or purity different from the official compendium which, of course, must be read together with section 331 as constituting the offense. Then we come to section 333 (a) which is just a straight violation, and the penalty may be imprisonment of not more than a year or a fine of not more than $1,000 or both. Of course, this defendant is a corporation. So, we have to consider the question of a fine. The penalty does not fall under section 333 (b) where intent to defraud or mislead is an essential element and the penalty accordingly higher. Well, of course, the Government has been put to a lot of proof. I think that you might have stipulated to some of it."

Mr. KELLY. "Well, I was not asked to do that, if your honor please."

THE COURT. "I know, but there was then this proof about the shipment in interstate commerce and also the actual use of a part of Exhibit 9 in making these tests by the Government."

Mr. BURLING. "If your honor please, I did not take it up with Mr. Kelly. I requested another attorney of Milbank, Tweed & Hope, who specifically declined to stipulate as to the interstate commerce shipment."

Mr. KELLY. "I think counsel is referring to the shipment in interstate commerce, is that it?"

THE COURT. "Yes."

Mr. BURLING. "Your honor, after that I made no request for stipulation, because Mr. O'Connell, who I believe was the party, told me that counsel for the defendant would stipulate as to nothing and, of course, I did not make further requests."

THE COURT. "Well, then, there was the question of the ampuls and they had to go through a lot of detailed proof as to the fact that what was used as the official test powder came from the proper source and all that, and I think a lot of that proof might have been saved. I suppose, of course, that a lot of the cross-examination of the Government witnesses as to the methods of the test and the proper testimony of experts for the defendant was to be expected.

"Under all the circumstances, I am of the opinion that the sentence of the court in this case should be that the defendant, Yates Drug & Chemical Co., shall pay a fine of $500.

"Well now, the case is completed and, of course, it is a case that has been one of great interest to follow, and the attorneys on both sides have presented their respective proofs and arguments showing great care in preparation, and conducted themselves throughout the trial as attorneys who knew how to go about the work of trying their case and had a proper respect not merely for the court but for each other, which is a delightful thing to see in any case, lawyers having respect for each other. It has been a pleasure to have you both here."

The defendant was sentenced to pay a fine of $500.