The articles were alleged to be misbranded in that statements in the labeling representing that the Flock Treatment for Poultry would be efficacious in the treatment of poultry afflicted with tapeworms; that the Nicotine for Poultry Round Worms would be efficacious for treatment and prevention of roundworms in poultry; and that the Herd Treatment for Hog Round Worms would be efficacious for treatment of hog roundworms and beneficial at any time to hogs of all ages, were false and misleading since they would not be efficacious for such purposes.

The Nicotine for Poultry Round Worms was alleged to be misbranded further in that the statement of active ingredients, which appeared in type of a very small size, was not placed on the label with such conspicuousness as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

On May 9, 1941, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

DRUGS FALSELY LABELED AS TO QUANTITY OF CONTENTS[4]

599. Alleged misbranding of rubbing alcohol compound. U. S. v. Adde, Inc. Plea of not guilty. Case tried to the court sitting as a jury of one; verdict of not guilty. (F. D. C. No. 2092. Sample Nos. 321–E, 322–E, 13026–E, 13027–E, 64236–E.)

This case was instituted on charges that the product was short of the declared volume.

On August 1, 1940, the United States attorney for the District of Maryland filed an information against Adde, Inc., a corporation, Baltimore, Md., alleging shipment on or about November 1 and 29 and December 26 and 27, 1939, from the State of Maryland into the States of North Carolina and Washington of quantities of rubbing alcohol compound that was misbranded.

The article was alleged to be misbranded in that the following statements on the carton and bottle labels, "Contents One Pint," "Contents 16 Fl. Ozs.," and "Contents 16 Fluid Ozs.," were false and misleading since each of the bottles did not contain 1 pint or 16 fluid ounces of rubbing alcohol, but did contain a smaller amount.

On October 20, 1941, a plea of not guilty was entered on behalf of the defendant and the case was tried before the court sitting as a jury of one. At the conclusion of testimony the court ordered the entry of a verdict of not guilty and delivered the following oral opinion:

COLEMAN, *District Judge.* "The court, sitting as a jury, concludes that the defendant company is entitled to a directed verdict in its favor, for the following reasons:

"The defendant company is charged with violating Section 502 (b) (2) of the Act of June 25, 1938, 21 U. S. C. A. Sec. 352 (b) (2), known as the Federal Food, Drug and Cosmetic Act, which provides that 'A drug or device shall be deemed to be misbranded—(b) if in package form unless it bears a label containing * * * (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by law.'

"Regulations have been prescribed under this section of the act and they have the force of law, provided they are consistent with the statute. In other words, rules promulgated by an administrative body in support of the legislation which it is charged with enforcing, are always subject to judicial review. In the present case the regulation here relied upon by the Government, namely, subdivision (j) of the regulations prescribed by the Secretary pursuant to section 502 of the act, is found by the court to be a reasonable and proper regulation. It reads as follows, insofar as its provisions relate to the present inquiry: 'Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure of a drug caused by ordinary and customary exposure, after such drug is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably

[4] See also Nos. 546, 551, 554–556, 571, 582, 583, 596.

result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large. * * *.'

"All of the bottles involved in the present suit contain as part of their label the words "Contents 16 fluid ounces," which this court believes must be construed as expressing a minimum quantity. So the above-quoted regulation applies.

"It is contended on the part of the Government that subsection (k) of this same section of the regulations also applies. That reads as follows: 'Where the statement does not express the minimum quantity—

"'(1) variations from the stated weight or measure of a drug shall be permitted when caused by ordinary and customary exposure, after such drug is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure;

"'(2) variations from the stated weight, measure, or numerical count of a drug or device shall be permitted when caused by unavoidable deviations in weighing, measuring, or counting the contents of individual packages which occur in good packing practices.

"'But under subdivision (2) of this paragraph variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the drug or device is below the quantity stated and no unreasonable shortage in any package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.'

"Even if we assume this last quoted regulation to be applicable to the present case, the testimony introduced clearly fails to establish that 'the average of the quantities in the packages comprising a shipment' is 'below the quantity stated.' The Government has not introduced any testimony sufficiently extensive to support that contention.

"The following regulation (1), prescribed under section 502, is also applicable to the present case: 'The extent of variations from the stated quantity of the contents permissible under paragraphs (j) and (k) of this regulation in the case of each shipment or other delivery shall be determined by the facts in such case.'

"When we apply the rule laid down in regulations (j) and (l) just referred to, the court is completely satisfied that the Government has failed to sustain the burden, imposed upon it in a case of this kind, of proving beyond a reasonable doubt that the defendant company is guilty of violating the act.

"It is true that proof of intent on the part of an alleged offender to do the forbidden act is not a condition precedent. The act prohibits doing certain things, and if the Government proves that they have been done then the person or firm shown to have been guilty of the violation, is liable under the act for the penalties imposed, regardless of intent. However, it seems to the court in the present case that the Government is taking what is, in substance, a contradictory position. First, it says that it believes the variation or deficiency in the weights of the samples taken is a clear violation of the law, as interpreted by the regulations which have just been referred to, and yet, at the same time, the Government admits that following these alleged violations, the loading facilities of the defendant company were never inspected, but that the Government accepted statements made by State of Maryland inspectors that such facilities were adequate and satisfactory. And what is more important, the record in the present case is totally devoid of any testimony tending to show what might be the shrinkage or evaporation in samples taken promptly after the bottles are loaded, and laid aside for a period of time approximating the time that elapsed between the shipment and the examination of the bottles that were actually sampled. This lack of testimony seems to the court to be very vital.

"It is clear that under some conditions, merely through evaporation greater shrinkages than those with respect to which Government witnesses have testified, occur in alcohol preparations of this character. This is proved by the analysis, made in the course of this trial at the court's request, of the contents of one of the bottles taken from one of the very shipments from which the Government took samples and made its measurements.

"The Government has not itself arrived at a standard by percentages which it is prepared to adopt. It simply says that the shrinkage here is on the average too great, after sampling some 70-odd samples out of many hundreds of bottles. There is no proof but what the deficiency complained of may just as well have been caused by the very sort of thing which the regulations allow to be taken into

account, namely, 'ordinary and customary exposure, after such drug is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure,' as by short loading.

"To repeat, it seems to the court that if the Government desires to prosecute defendants in a case of this kind, it should support its case with more accurate data. The court realizes that it is not possible to lay down a rule of thumb requirement. There is bound to be some tolerance. In the present case the Government asserts that a proven shrinkage in the samples taken in the neighborhood of 1 ounce for every 16 ounces, which is the minimum quantity each bottle is labeled to contain, is an excessive shrinkage. Yet, as has just been noted, the measurement in open court indicates that perhaps such a shrinkage is due 'to ordinary and customary exposure.' There is no testimony in the present case as to what the actual extent of the evaporation of alcohol, or water, or both, would be over a given period of time in a preparation of this kind, under stated temperature conditions. Perhaps any such tests would produce variations which would not enable one to adopt a percentage rule, in any event. But the sum and substance of this court's conclusion is that the Government can not properly rely solely upon samples taken long after the shipments had been made, under variable temperature conditions, which do not represent an average of anything like an entire shipment, or shipment, especially since the Government has given to this defendant a clean bill of health as to its present loading facilities, without having its own representatives inspect such facilities and determine, and be prepared to prove that there has been short loading.

"At first blush it would seem that if a man says to the public, by the label on his bottle, that he has put 16 ounces of his preparation in that bottle when as a matter of fact when the bottle reaches the consumer there are only 15 or 14½ ounces in it, there is something wrong. But in the present case the evidence shows that a considerable portion of the liquid is highly volatile, being alcohol. It also shows that the Government has failed to determine by direct evidence whether the shortage actually occurred in the loading or by evaporation. It merely draws the conclusion from a relatively small number of samples that this shortage could not have occurred except in the loading. If the Government had investigated defendant's loading methods, and had immediately laid aside a number of the loaded bottles under conditions similar to the conditions which existed with respect to the samples that were tested, it could then be determined with accuracy whether there was shrinkage after loading, and to what extent, if any, there was short loading.

"What the court has said is not to be taken as meaning that one who prepares and sells a volatile preparation is not himself required to take that characteristic into account in bottling his preparation. Of course he is. But he is given the benefit of the tolerance rule contained in the regulations just referred to. And since this is a criminal case, and the burden of proof is upon the Government to establish to the satisfaction of the court sitting as a jury beyond a reasonable doubt that the law has been violated, that rule must be given full force and effect also.

"The verdict is accordingly not guilty."

600. Misbranding of Essence of Caroid. U. S. v. 10 Bottles of Essence of Caroid. Default decree of condemnation. Product ordered delivered to Food and Drug Administration for technical use. (F. D. C. No. 6258. Sample No. 87104-E.)

On November 21, 1941, the United States attorney for the District of Columbia filed a libel against 10 1-gallon cartons of Essence of Caroid at Washington, D. C., alleging that the article had been shipped by the American Ferment Co., Inc., from Buffalo, N. Y., on or about October 21, 1941; and charging that it was misbranded.

The article was alleged to be misbranded (1) in that the statement on the label, "1 Gal.," was false and misleading since the quantity of contents of the package was materially less than 1 gallon; and (2) in that the label failed to bear an accurate statement of the quantity of contents.

On December 22, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to the Food and Drug Administration for technical use.