10888. Adulteration of orange coconut parfait. U. S. v. 53 Cartons * * *. (F. D. C. No. 18686. Sample No. 8131-H.)

LIBEL FILED: December 19, 1945, Eastern District of New York.

ALLEGED SHIPMENT: On or about August 6 and September 22, 1945, by the G. C. Murphy Co., from McKeesport, Pa.

PRODUCT: 53 cartons, each containing 30 pounds, of orange coconut parfait at Brooklyn, N. Y. Examination showed that the product was moldy and decomposed.

LABEL, IN PART: "Product of Cuba * * * Orange Coconut Parfait Ingredients: Fresh Coconut, Cane Sugar, Corn Syrup, Orange Peel, Edible Starch, Certified Color and Flavor U. S. P."

NATURE OF CHARGE: Adulteration, Section 402 (a) (3), the product consisted in whole or in part of a decomposed substance.

DISPOSITION: February 15, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

10889. Misbranding of Date Nut Spread. U. S. v. 62 Cases * * *. (F. D. C. No. 17999. Sample No. 36519-H.)

LIBEL FILED: October 19, 1945, Western District of Washington.

ALLEGED SHIPMENT: On or about August 14, 1945, by the Western Commerce Corporation, from Los Angeles, Calif.

PRODUCT: 62 cases, each containing 24 1-pound jars, of Date Nut Spread at Seattle, Wash. Examination showed that the product was short-weight and that there were not enough walnuts, the nut ingredient, present to characterize the flavor.

LABEL, IN PART: "Date Nut Spread Royal Palm Brand California Dates * * * Walnuts * * * Net Weight 1 Pound."

NATURE OF CHARGE: Misbranding, Section 403 (a), the designation "Date Nut Spread" was misleading as applied to an article which contained an inconsequential amount of walnuts; and, Section 403 (e) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents.

DISPOSITION: December 29, 1945, The National Grocery Co., Seattle, Wash., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Federal Security Agency.

VITAMIN PREPARATIONS AND FOODS FOR SPECIAL DIETARY USES

10890. Adulteration and misbranding of vitamin B complex tablets. U. S. v. S. O. Barnes and Son. Plea of nolo contendere on 2 counts; fine, $50. Plea of not guilty on 2 counts. Tried to the court. Judgment of guilty; fine, $400. Total fine, $450. (F. D. C. No. 15517. Sample Nos. 55525-F, 81779-F, 81994-F.)

INFORMATION FILED: July 30, 1945, Southern District of California, against S. O. Barnes and Son, a partnership, Gardena, Calif.

ALLEGED SHIPMENT: Between the approximate dates of February 22, 1943, and June 22, 1944, from the State of California into the States of Washington and New York.

LABEL, IN PART: "McCollum Vitamin B Complex Tablets * * * Distributed by McCollum Laboratories, Inc. Hollywood, California," or "JXL Vitamin B Complex * * * Prepared for and distributed by John X. Loughran Gardena, Calif."

NATURE OF CHARGE: Count 1, adulteration, Section 402 (b) (1), valuable constituents of the article had been in whole or in part omitted or abstracted therefrom, since the article was represented to contain in 2 tablets 350 International Units of vitamin B_1, 2,000 gamma of vitamin B_2 (G) riboflavin, and 10 milligrams of niacin, whereas it contained in 2 tablets not more than 175 International Units of vitamin B_1, not more than 0.44 milligram (440 gamma) of vitamin B_2, and it contained niacin in amounts ranging from 0.3 to 3.15 milligrams per 2 tablets.

Count 2, misbranding, Section 403 (a), (same lot as involved in count 1) dismissed.

Count 3, adulteration, Section 402 (b) (2), tablets of a laxative drug had been substituted in whole or in part for vitamin B complex tablets, which the article purported and was represented to be.

Count 4, adulteration, Section 402 (b) (1), a valuable constituent had been in whole or in part omitted or abstracted from the article since it was represented to contain in each tablet 1,670 gamma of niacin, whereas it contained not more than 1,222 gamma of niacin per tablet.

Count 5, misbranding, Section 403 (a), (same lot as covered by count 4) the label statement "Each tablet * * * contains the following * * * 1,670 Gammas Niacin" was false and misleading, and the label statements "Each tablet contains * * * 335 Gammas B_2, 45 Gammas B_6, 124 Gammas Pantothenic Acid, 1,670 Gammas Niacin" were misleading since they created the impression that the article contained large amounts of all of the vitamin substances named, whereas the article contained insignificant amounts of vitamin B_2, vitamin B_6, and pantothenic acid; Section 403 (j), the article purported to be and was represented for special dietary uses by reason of its vitamin properties in respect to vitamin B_6 and pantothenic acid, and its label failed to bear, as required by the regulations, a statement that the need for vitamin B_6 and pantothenic acid in human nutrition has not been established; and, Section 403 (f), the statements required by Section 403 (j) relating to the proportion of the minimum daily requirement for vitamin B_1, riboflavin, and the amounts of vitamin B_6, pantothenic acid, and niacin in a specified quantity of the article were printed vertically on the side panel of the label, and the quantities of certain vitamin substances were declared in gamma which would not be readily understood by the ordinary individual under customary conditions of purchase and use.

DISPOSITION: Count 2 having been dismissed on motion of the Government, a plea of nolo contendere was entered on behalf of the defendant to counts 1 and 3, and a plea of not guilty was entered on counts 4 and 5. On October 4, 1945, the issue raised by the plea of not guilty came on for trial before the court. The trial was concluded on October 13, and the defendant was found guilty on the said counts. The court imposed fines of $25 on each of counts 1 and 3, $390 on count 4, and $10 on count 5. In pronouncing sentence, the court delivered the following opinion:

HARRY A. HOLZER, *District Judge:* "I think, when all is said and done, this is the situation which confronts a court hearing the trial of a case of this nature. The evidence is essentially expert and particularly unusual in that it relates to a field in which the court is seldom called upon to take proof. It would be a very easy course to pursue to conclude that, because we have two sets of scientists who, let us assume, radically disagree, we should, to paraphrase a passage in Shakespeare's Romeo and Juliet, say, 'a plague on both your houses,' and find that the evidence is of such an intricate character that the lay mind can't follow it and, therefore, conclude that the government hasn't made out and in fact cannot make out a case. As we said a few moments ago, the evidence here isn't easily followed and understood but we think that certain passages of the testimony have been illuminating and provide what might be termed the guide posts and the lighthouses that should point the way.

"Admittedly, we are dealing with a product whose ingredients can only be determined through some one or more scientific procedures, commonly referred to as assay methods.

"As we understand the evidence, it establishes, beyond the peradventure of a doubt, that there are at least two scientific publications which are recognized as authoritative, and these two have been referred to during the trial. They consist of the United States Pharmacopeia and the publication of this Association of Official Agriculturalists. I may not have its exact title but I think we all understand the publication to which we are now referring. And all of the scientific literature that has been referred to here by any of the witnesses bears out the fact that for some years research has been conducted with a view of determining, among other matters, the most satisfactory assay method for determining the niacin content in various products and that, after years of research and exchange of reports and discussions among the scientists interested in the subject, one of these recognized scientific publications, namely, the U. S. P.,

officially published a certain assay method which, unquestionably, was the method applied by the government's employees. That method, through the publication thereof in the U. S. P., has been given sanction of a type which this court may and properly should respect. It has been criticized here by defendant's experts. The reasoning upon which those criticisms were advanced, as we construe the testimony, doesn't harmonize. One of the defendant's experts, Dr. Osman, advanced a theory which he admitted has never been called to the attention of the recognized authorities who are so vitally interested in improving the methods in this category and it strikes us as rather strange that, if an expert were convinced of the validity of his theory, he would, so to speak, keep it in hiding. In the absence of any recognition of his theory upon which he based his criticism of the method applied by the government experts, we feel compelled to discard the reasoning of Dr. Osman.

"More than that, it seems to us that, in the course of his testimony, he pointed to at least one of the weaknesses of the defendant's procedures. I do not have in mind the exact details but, under cross examination, he undertook to approve that particular procedural step applied in the defendant's laboratory which had to do with the measuring of the niacin content, and went on to explain that the measurement was made at that particular stage of the manufacturing process because later on the same quantity of niacin might not be found or shown to be present by the method which the defendant was employing and that there might be a loss through I think what he called oxidation or through oxidizing. Whether we have caught or grasped the full import of that statement I am not altogether certain but, when we recall that the defendant's own analysis of a portion of the accused product, the analysis made in September of this year, showed a marked difference in the niacin content as compared with the claimed quantity incorporated in the product, it strikes us that there is something wrong with the procedure that is applied in the defendant's laboratory because, when all is said and done, the law is not concerned with what niacin content is introduced into the defendant's product in defendant's laboratory if, when that product leaves the laboratory, it meets the requirements, but is concerned with the niacin content in the finished product as distinguished from the niacin content in the unfinished product. Whether Dr. Osman's explanation points to a vulnerable procedural step or not seems to us of only passing moment. What is of consequence here is that, when we come to assaying a finished product such as we have here, the reasoning which has been supplied by Dr. Kline impresses us as the logical and the sound analysis and explanation of the method which should be applied in determining whether or not the defendant's product meets the legal requirements.

"We could go on perhaps at considerable length but it would lead merely to the accumulation of circumstances which, to our mind, establish, beyond all reasonable doubt, that the government has found an assay method by which to measure the niacin content of such products as we are dealing with here. The application of that method demonstrates that not only was there a failure to meet the requirements of the law, as charged in count 4, but also as charged in that portion of count 5 which is to be found on page 7, lines 7 to 17, a count beginning at line 29, page 7, and ending at line 10 on page 8. Under these circumstances, we find the defendant guilty on counts 4 and 5. May I inquire whether there is something further to be brought to the court's attention with reference to what penalty should be imposed here?"

10891. Adulteration and misbranding of Super Multi-Caps 9 Vitamins and Multi-Caps 8 Vitamins. U. S. v. 102 Bottles, etc. (F. D. C. No. 18463. Sample Nos. 955-H, 956-H.

LIBEL FILED: On or about November 29, 1945, Southern District of Florida.

ALLEGED SHIPMENT: On or about October 1, 1945, by the Oxford Products Co., Inc., from Cleveland, Ohio.

PRODUCT: 102 bottles, each containing 100 tabsules, of Super Multi-Caps 9 Vitamins and 139 bottles, each containing 50, 100, or 500 tabsules, of Multi-Caps 8 Vitamins at Miami, Fla.

LABEL, IN PART: "Super Multi-Caps 9 Vitamins * * * [or "Multi-Caps 8 Vitamins * * * "] Each Tabsule Contains Vitamin A 5000 U. S. P. Units."