

and carton label contained false and misleading representations that the article was effective in the treatment of sties, granulation, inflammation and congestion of the eyes and eyelids, and conjunctivitis.

DISPOSITION: 9-20-54. Default—destruction.

## DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

### DRUGS FOR HUMAN USE\*

4595. C-Tone. (F. D. C. No. 36608. S. Nos. 26-473 L, 26-489 L.)

INFORMATION FILED: 10-29-54, S. Dist. N. Y., against Balanced Foods, Inc., New York, N. Y., and Samuel H. Reiser, secretary and treasurer of the corporation.

SHIPPED: Between 9-30-53 and 11-4-53, from New York to Pennsylvania.

LABEL IN PART: (Btl.) "Rich in Activated Enzymes C-Tone The *Natural* Vitamin C Tonic \* \* \* 8 Fl. Oz Net Sole and Exclusive Distributors Byrne Products, Inc. New York 7, N. Y."

ACCOMPANYING LABELING: Leaflets entitled "Which of These Dread Killers Threaten Your Advancing Years?"

CHARGE: 502 (a)—the labeling of the article when shipped contained false and misleading representations that the article would be of nutritional and therapeutic value because of its enzyme content; that it would be effective as a tonic; that it would be an adequate and effective treatment for high blood pressure, hardening of the arteries, ulcerative colitis, fading strength, nervous exhaustion, failing memory, cerebral rupture, valvular disease of the heart, pulmonary tuberculosis, general weakness, fatigue, headaches, and dizzy spells; and that it would be effective to provide energy.

PLEA: Not guilty.

DISPOSITION: The case was tried before the court without a jury on 5-27-55, and at the conclusion of the trial, the case was taken under advisement for consideration of the briefs of counsel with respect to the defendants' motion for dismissal of the information. On 6-23-55, the court sustained the defendants' motion in accordance with the following opinion:

REEVES, *District Judge*: "The defendants are charged in two counts with having shipped a misbranded food product in interstate commerce in different periods during the year 1953. The product complained against was entitled 'C-Tone.' This product was represented to contain valuable and important nutrients. It is admitted that the product thus shipped in interstate commerce was misbranded and that it fell within the prohibitions of section 321, Title 21 U. S. C. A., relating to the general subject of Food and Drugs.

"While acknowledging that the product was misbranded within the purview of the law, yet defendants urged as a defense a reliance upon that portion of section 331, Title 21 U. S. C. A. and the exception set out therein by paragraph (h) and by paragraph (c) of section 333, of said title. It is provided by pertinent provisions of section 331, Title 21 U. S. C. A. as follows:

The following acts and the causing thereof are hereby prohibited:

\* \* \*

(h) The giving of a guaranty or undertaking referred to in section 333 (c) (2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith, the food, drug, device, or cosmetic; \* \* \*. [Emphasis mine.]

\*See also Nos. 4581-4584, 4589-4591, 4593, 4594.

It will be noted from the foregoing that the giving of a false guaranty is prohibited, but there is no prohibition against one who in good faith receives a product backed by a full guaranty.

"Section 333 provides penalties for the violation of section 331, and it is to be noted that one found guilty of shipping in interstate commerce misbranded food or food products may be imprisoned not exceeding one year or be subject to both such imprisonment and fine.

"By paragraph (c) of said section 333, it is provided :

No person shall be subject to the penalties of subsection (a) of this section \* \* \* (2) for having violated section 331 (a) or (d) of this title, if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received *in good faith* [emphasis mine] the article, \* \* \*.

At the trial of the case the defendants submitted a guaranty from a responsible producer, as contemplated by the several sections of the statutes, and the defendants strongly asserted their good faith in receiving said product because of said guaranty. Before the shipments in question were made, the defendants were advised of the contention made by government agents and agents of the City of New York, that the product was misbranded and in fact some of the merchandise held by the defendants was seized by said agents. The defendants communicated these facts to the guarantor and were given assurances that the charge was a mistake and that, if necessary, a slight change would be made in the labels as well as in the company's literature, so as to satisfy the government through its agents. With these assurances the defendants continued to deal in the product and to make shipments.

"It is now the contention of counsel for the government that the seizures made by local and national authorities were sufficient to advise the defendants of the misbranding, and to justify or warrant this prosecution.

"1. It is to be noted that the gravamen of the offense is the alleged bad faith on the part of defendants at the time they received the merchandise or product. While it is the government's contention that such bad faith would follow the complaints or seizures by the authorities, and that, after such complaints, and after such seizure, any product received by the defendants must be received in bad faith or, rather, not received in good faith.

"2. The testimony of the defendant Samuel H. Reiser, who spoke for himself as well as for the corporate defendant, indicated that he was reassured by the guarantor and that he believed sincerely that he had a right to continue the shipment of the product in interstate commerce. Moreover, it is the law that the acts and words of the agents of the government were not such notice to him as would warrant him and the corporate defendant in desisting from further shipment of the product.

"3. There are many cases which, by analogy, would not make an individual subject to punishment merely because of the acts of municipal agents, whether arbitrary or otherwise. The defendants, in the transaction of their business handling, as the testimony indicated, from 1500 to 2000 different products would undoubtedly have a right, with such assurances as were given in this case, to proceed in the transaction of their business until there was such an adjudication or authoritative determination that the merchandise was misbranded as to bring home to them definite knowledge of the fact that by such shipments they were in fact violating the law. It should be noted and emphasized that the statute provides an exemption if and when the merchandise or product is received in good faith.

"4. In good faith has several meanings, each of which is well defined. It means, among other things, honesty and in an attitude of trust and confidence.

"The evidence justifies the court in believing that the personal defendant, who acted for the corporate defendant at all times in receiving the product, was actually in an attitude of trust and confidence, and in such trust and confidence the shipments complained against were made.

"It would follow that the motion for an order directing acquittal should be sustained, and IT IS SO ORDERED."