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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

147-160

COSMETICS

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

OSCAR R. EWING, *Administrator, Federal Security Agency.*

WASHINGTON, D. C., *July 23, 1948.*

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COSMETIC ACTIONABLE BECAUSE OF ADULTERATION WITH A POISONOUS AND DELETERIOUS SUBSTANCE

147. Adulteration of Locks-Up Hair Lacquer Pads. U. S. v. Parfait Powder Puff Co., Inc. Tried to the court. Fine, \$100 and costs. Judgment affirmed on appeal. Petition for writ of certiorari denied. (F. D. C. No. 14228. Sample Nos. 12571-F, 12580-F, 21933-F, 35459-F, 35817-F, 35825-F, 35831-F, 46805-F.)

INFORMATION FILED: January 14, 1945, against the Parfait Powder Puff Co., Inc., Chicago, Ill.

ALLEGED SHIPMENT: On or about August 3, 5, 6, and 9, 1943, from the State of Illinois into the States of Washington, Georgia, South Carolina, North Carolina, Pennsylvania, and Wisconsin.

LABEL, IN PART: "[Design of bow] Prevents Stray Locks No more loose ends. Fixes hair firmly and invisibly. Keeps that fresh look all day. **DIRECTIONS** Stroke coiffure lightly with Locks-Up pad. Hair dries quickly, leaving a clear bright lustre. By Parfait **LOCKS-UP**"; "[Design of back and side view of woman's head, one hand applying a pad to back hair] 100 Pads **HAIR LACQUER PADS** Parfait Powder Puff Company, Chicago."

NATURE OF CHARGE: Adulteration, Section 601 (a), the product contained a poisonous and deleterious substance which may have rendered it injurious to users under the conditions of use prescribed on the jar labels, i. e. "Stroke coiffure lightly with Locks-Up pad."

DISPOSITION: On November 15, 1946, a plea of guilty having been entered by the defendant, the case was tried before the court and the defendant was

*For failure to bear a label containing an accurate statement of the quantity of the contents, see No. 153.

fining \$100 and costs. On November 20, 1946, a motion for a new trial or to vacate judgment was filed, and on December 17, 1946, the motion was denied. The defendant appealed to the Circuit Court of Appeals for the Seventh Circuit, and on November 4, 1947, the following memorandum opinion was handed down affirming the decision of the district court:

LINDLEY, *Judge*: "Defendant appeals from a judgment of conviction of a charge of violation of Section 301 (a) of the Federal Food, Drug and Cosmetic Act (21 U. S. C. 301, *et sequi*), entered after trial without a jury, largely upon stipulated facts.

"Section 301 (a) prohibits introduction into interstate commerce of any food, drug, device, or cosmetic which is 'adulterated or misbranded.' Anyone violating this enactment is subject to prosecution under Section 303 (a), reading: 'Any person who violates any of the provisions of Section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than \$1,000, or both such imprisonment and fine; * * *' There is no dispute that the cosmetics involved, hair lacquer pads, were adulterated in that they contained a substance which rendered them deleterious in use under the conditions prescribed on their labels, or that they were introduced into interstate commerce.

"The only issue here, whether the defendant was rightfully held responsible for the violation, must be determined upon the facts. Defendant, engaged in the manufacture and sale of cosmetic products, in 1943, entered into a contract with Helfrich Laboratories whereby the latter agreed to manufacture, place in packages and distribute to defendant's customers hair lacquer pads. Defendant supplied Helfrich with jars, caps, labels, display cards, flannel pads and shipping containers. Helfrich impregnated the pads with a shellac lacquer, placed them in labeled jars bearing defendant's name, shipped the packages, in accord with shipping directions furnished by defendant, consigned by defendant to its purchasers as consignees, and rendered bills to defendant for the commodity.

"The sample submitted by Helfrich, when the arrangement was first made, was tested by defendant and found satisfactory. Later, without defendant's knowledge, so far as this record discloses, Helfrich substituted for shellac in the lacquer, a gum, for the reason, as it claimed, that it was impossible to obtain shellac. This element proved to be deleterious in use. As soon as defendant learned of the substitution it forbade use of the gum.

"In this situation, it is defendant's position that the violation was not that of itself but that of Helfrich. It argues that Helfrich was not its agent, but an independent contractor, for whose acts it is not responsible. But we are not concerned with any distinction between independent contractors and agents in the ordinary sense of those words. It is clear that defendant was engaged in procuring the manufacture and distribution of the article in interstate commerce. It saw fit to create out of Helfrich's activities in its behalf an instrumentality and to avail itself of the acts of that instrumentality, which effected an introduction into commerce of an adulterated article violative of the standards fixed by the Act. This we think it could not do without incurring the criminal penalty imposed by the statute. The liability was not incurred because defendant consciously participated in the wrongful act, but because the instrumentality which it employed, acting within the powers which the parties had mutually agreed should be lodged in it, violated the law. The act of the instrumentality is controlled in the interest of public policy by imputing the act to its creator and imposing penalties upon the latter. *New York Central and Hudson River Railroad Company v. United States*, 212 U. S. 481.

"In *United States v. Balint, et al.*, 258 U. S. 250, 254, the court directed attention to authorities approving legislation in aid of maintenance of a public policy, prohibiting and punishing particular acts, commenting that 'he who shall do them shall do them at his peril and will not be heard to plead in defense, good faith or ignorance' and proceeding as follows: 'Congress weighed the possible injustice of subjecting an innocent seller to a penalty against the evil of exposing innocent purchasers to danger from the drug, and concluded that the latter was the result preferably to be avoided.' And in the comparatively recent case, *United States v. Dotterweich*, 320 U. S. 277, the court said: 'The offense is committed * * * by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws, namely,

to put into the stream of interstate commerce adulterated or misbranded drugs. Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrong-doing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.

"In other words, when defendant engaged in manufacture and distribution of cosmetics in commerce, there was in force this statute, enacted as a matter of public policy for the protection of the purchasing public. Defendant knew that the goods would pass into commerce. It knew that if those goods violated the provisions of the Act, liability would be incurred. This liability it could not shift to the instrumentality which it had created for the purpose of accomplishment of the completed transaction of manufacture, distribution and sale. Rather defendant was bound to see that its product, when introduced into commerce, was not antagonistic to and violative of the sovereign will, which, expressed in the act of Congress, enters into and becomes a part of all contracts relating to the production and distribution of articles in commerce. The person who brings goods into commerce, by whatever means or implements, is bound to see that the commodity thus put in commerce is not beyond the pale of the legislative act. In other words, one who owes a certain duty to the public and entrusts its performance to another, whether it be an independent contractor or agent, becomes responsible criminally for the failure of the person to whom he has delegated the obligation to comply with the law, if the non-performance of such duty is a crime. Defendant may not put into operation forces effectuating a placement in commerce of a prohibited commodity in its behalf and then claim immunity because the instrumentality it has voluntarily selected has failed to live up to the standards of the law. *Cummer-Graham Co. v. Straight Side Basket Corp.*, 142 F. 2d 646 (CCA 5); Anno. 152 A. L. R. 761; *John Griffiths & Son Company v. National Fireproofing Co.*, 310 Ill. 331, 38 A. L. R. 559; *U. S. v. Wilson*, 59 F. 2d 97; *U. S. v. Buchanan*, 9 F. 689; *Weeks v. U. S.* 224 F. 64 (CCA 2); 1 Burdick Law of Crime, p. 232, *et seq.*

"Defendant makes the further contention that it is exempt from prosecution by virtue of Section 303 (c) of the Act. Section 303 (a) provides that any person who violates any of the provisions of Section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to a fine. Section 303 (c) provides that 'no person shall be subject to the penalties of subsection (a) of this Section. (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith,' unless certain conditions precedent are complied with. Defendant insists that it is a person who has 'received in interstate commerce' the deleterious article within the meaning of this provision. But the weakness of the contention is that defendant is not within the class mentioned in Section 303 (c). It has not received in interstate commerce the article complained of. On the contrary, it is the moving force in the procurement of introduction of the article into commerce. The facts will not justify the strained construction that when Helfrich delivered the goods to carriers in behalf of defendant as consignor, addressed to its purchasers as consignees, defendant thereupon received the goods in interstate commerce within the meaning of the Act. Rather than having received the goods in commerce, defendant in fact caused them to be placed in commerce. This is apparent when we consider the purpose of this provision. It is clear that it was designed to protect innocent dealers who receive goods shipped in interstate commerce. Thus, in Senate Report No. 493, 73d Cong. 2d Sess., accompanying S. 2800, the Senate Committee reported as follows: 'The existing law provides for a guaranty whereby a dealer who buys on faith may be protected from liability under the law. This provision has safe-guarded innocent dealers and has been extremely useful in fixing responsibility on guilty shippers. It would be continued in effect by paragraph (e). The bill affords in this paragraph further protection to the innocent dealer who distributes goods he has received from interstate sources. If he has failed to secure a guaranty he can escape penalties by furnishing the records of interstate shipment, thus allowing the prosecution to lie solely against the guilty shipper.' It is clear, we think, that the Act was intended to furnish protection to innocent receivers of goods shipped to them in interstate com-

merce in violation of the Act and not to consignors of such goods, such as defendant.

"The judgment is affirmed."

The defendant filed before the Supreme Court of the United States a petition for a writ of certiorari, which was denied on January 12, 1948.

COSMETIC ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

148. Adulteration of Elmo Special Nite Cream. U. S. v. 250 Cartons * * *
(F. D. C. No. 23976. Sample No. 33313-K.)

LIBEL FILED: November 21, 1947, Northern District of California.

ALLEGED SHIPMENT: On or about July 3, 1947, by the Elmo Sales Corp., from Philadelphia, Pa.

PRODUCT: 250 cartons, each containing 12 6¼-ounce jars, of Elmo Special Nite Cream at San Francisco, Calif. Examination showed that the cartons were moldy and had a putrescent odor and that the same odor permeated the contents of the jars.

NATURE OF CHARGE: Adulteration, Section 601 (b), the article consisted in whole or in part of a filthy substance; and, Section 601 (c), it had been held under insanitary conditions whereby it may have become contaminated with filth.

DISPOSITION: January 5, 1948. Default decree of condemnation and destruction.

USE OR DISTRIBUTION OF UNCERTIFIED COAL-TAR COLORS

149. Adulteration of Tropical Sun Tan Oil. U. S. v. Park Drug Co., Inc., and Louis Klatzkie. Plea of guilty. Fines, \$750. (F. D. C. No. 20187. Sample Nos. 7835-H, 41801-H.)

INFORMATION FILED: December 26, 1946, Southern District of New York, against the Park Drug Co., Inc., and Louis Klatzkie.

ALLEGED SHIPMENT: July 30 and August 22, 1945, from the State of New York into the States of New Jersey and Virginia.

LABEL, IN PART: "Tropical Sun Tan Oil * * * Distributed by Park Laboratories, New York, N. Y."

NATURE OF CHARGE: Adulteration, Section 601 (e), the article was not a hair dye and contained coal-tar colors, Butter Yellow (Colour Index No. 19) and Sudan IV (Colour Index No. 258), which have not been listed for use in cosmetics in accordance with the regulations and were other than colors from batches that had been certified.

DISPOSITION: January 24, 1947. Pleas of guilty having been entered, fines of \$500 and \$250 were imposed against the corporation and Louis Klatzkie, respectively.

150. Adulteration of coal-tar color. U. S. v. Evergreen Chemical Co., Inc., and Arthur M. Strang. Pleas of guilty. Fine of \$300 against corporation. Imposition of sentence against individual was suspended, and he was placed on probation for 10 days. (F. D. C. No. 20205. Sample No. 10293-H.)

INFORMATION FILED: November 25, 1946, Southern District of New York, against the Evergreen Chemical Co., Inc., New York, N. Y., and Arthur M. Strang, secretary.

Between the dates of June 19, 1942, and March 15, 1945, the defendant mixed a quantity of Tartrazine (FD&C Yellow No. 5) and Guinea Green B (FD&C Green No. 1), coal-tar colors, and shipped in interstate commerce the colors so mixed, on or about March 15, 1945.

LABEL, IN PART: "Liquid Evergreen 'C' Certified Color For Foods, Drugs and Cosmetics * * * Lot #B-992."

NATURE OF CHARGE: Section 301 (i), the defendant, by designating the coal-tar color as hereinbefore indicated, falsely represented and without proper authority, used an identification device authorized and required by regulations; and, Section 601 (e), the article was not a hair dye, and it contained a coal-tar color other than one from a batch that had been certified in accordance with the regulations.

DISPOSITION: December 10, 1946. Pleas of guilty having been entered on behalf of both defendants, the court imposed a fine of \$150 on each count against the corporation, a total fine of \$300; imposition of sentence against the individual