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Food, Drug, and Cosmetic Law (1961)

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FOOD, DRUG AND COSMETIC LAW

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I

LEGISLATION

Color Additives.—Intended largely as a relief measure against the strict application of the “harmless per se” rule to coal-tar colors,¹ the Color Additives Amendments² this year joined the growing family of food, drug and cosmetic laws which provide for pretesting and prior clearance procedures. Forthcoming legislative provisions for the pretesting of cosmetics and therapeutic devices seem probable,³ if only to further a uniform administrative philosophy consistent with the amendments now governing new drugs, pesticide chemicals, food additives and color additives.

The Color Amendments of 1960 extend control to all colors, coal-tar or otherwise, whether added or applied to cosmetics, drugs, or foods. Thus, colors in foods are no longer subject to the Food Additives provisions and will be cleared for safety under the separate procedural rules of the Color Amendments. Both of these “additive” amendments adopt the general scheme of placing the burden of proving safety upon the manufacturers and relieving the Government of the necessity to prove the substances unsafe. However, the Color Law, while allowing for provisional listings of previously certified or used colors, does not, as does the Food Additives Law, broadly exempt from its definition of additives colors which are *generally recognized as safe* (“GRAS”).⁴

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1. See Grossman & Hart, Food, Drug, and Cosmetic Law, 35 N.Y.U.L. Rev. 727, in 1959 Ann. Survey Am. L. 221 (1960).

2. Pub. L. No. 618, 86th Cong., 2d Sess. (July 12, 1960).

3. Proposed bills for the pretesting of cosmetics were introduced in the 86th Congress, 1st Session: H.R. 1360, H.R. 5661. A bill to require pretesting of therapeutic devices has also been drafted by the Administration for submission to Congress. Speech by FDA Deputy Commissioner, Nov. 16-17, 1959, 2 CCH Food Drug Cosm. L. Rep. ¶ 7554 (1959). For reports of other proposed legislation, see 2 CCH Food Drug Cosm. L. Rep. ¶¶ 7554 (registration of barbiturates and amphetamines), 7571 (removal of contradiction in food additives between the “cancer clause” and the “grandfather clause”), 7599 (factory inspection and drug control) (1959).

4. Food Additives Amendment of 1958, § 2, 72 Stat. 1784, 21 U.S.C. § 321(s). Provisions are made, however, for the listing of colors which appear on FDA “white lists” of additives generally recognized as safe for use in foods. Pub. L. No. 618, 86th Cong., 2d Sess., §§ 203(b), (d)(1) (July 12, 1960).

Both amendments also contain similar statements of the "anti-cancer clause," but the Color Law in addition provides that where such clause is invoked against a proposed use, the affected parties may request, and the Secretary of Health, Education and Welfare must appoint, an advisory committee of experts to study and promptly report on the specific issue.⁵ The Secretary thereafter issues his order on the matter, but he is not bound by the committee recommendations.

Hazardous Substances.—The Federal Hazardous Substances Labeling Act,⁶ enacted on the same day as the Color Amendments, establishes standards for safe labeling of many substances in common household use. There are many substances, unregulated as to precautionary labeling, which are not foods, drugs and cosmetics nor "economic poisons" within the meaning of the Federal Insecticide, Fungicide and Rodenticide Act.⁷ This new law, to be administered by the Secretary of Health, Education and Welfare, will fill the gap in control. It repeals the Federal Caustic Poison Act⁸ (which had only covered 12 substances), except insofar as the latter applies to dangerous, caustic or corrosive articles subject to the Federal Food, Drug and Cosmetic Law.

II

CASES

Administrative Hearings.—In 1957, the FDA had proposed an order to delist four previously certified coal-tar colors. Timely objections were filed and a hearing requested on the question of safety in the amounts used. FDA had in new pharmacological studies discovered that the colors were toxic when fed to test animals at levels between 500 and 1,000 parts per million (far above the levels of actual use by industry). FDA's position was that it lacked the authority under the existing coal-tar provisions to set tolerances of safe use and could not otherwise certify the colors as absolutely harmless. The matter was postponed pending the resolution of the similar issue by the Supreme Court in the *Florida Citrus* case.⁹ Following that decision, FDA issued its final delisting order without granting the requested

5. Compare § 409(c)(3)(A), 72 Stat. 1786, 21 U.S.C. § 348(c)(3)(A) (1958), with Pub. L. No. 618, 86th Cong., 2d Sess., § 706(b)(5)(B)(i) (July 12, 1960).

6. Pub. L. No. 86-613, 86th Cong., 2d Sess. (July 12, 1960).

7. 61 Stat. 163 (1947), 7 U.S.C. § 135 (1958), as amended, 73 Stat. 286, 7 U.S.C. § 135 (Supp. I, 1959), which brings the entitled substances within the meaning of "economic poisons" and subjects their residues to the tolerance provisions of the pesticide chemical amendment.

8. 44 Stat. 1406 (1927), 15 U.S.C. §§ 401-11 (1958).

9. *Flemming v. Florida Citrus Exch.*, 358 U.S. 153, 2 CCH Food Drug Cosm. L. Rep. ¶ 7468 (1958).

hearing, and judicial review of such action was petitioned for in *Dyestuffs & Chemicals, Inc. v. Flemming*.¹⁰ The court of appeals affirmed the Government's contention that the hearing was not required, since the Supreme Court in *Florida Citrus* had ruled that the Government did not have the power to certify with safety tolerances. Therefore, a hearing on levels of safe use would have been unfruitful and useless.

While the authority to set tolerances for colors is now authorized under the Color Additives Amendments, the *Dyestuffs* case is noteworthy in its statement of the prerequisites for a hearing under Section 701(e) of the Federal Food, Drug and Cosmetic Act.¹¹ The holding of such hearings is not an unconditional statutory mandate, and it may be denied where the objections to an administrative order do not raise issues material to the legality of the order. The administration, in subsequent actions, has had occasion to grant hearings, but only where they have determined that reasonable grounds therefor have been presented.¹²

Cigarettes as "New Drugs."—In *United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*,¹³ a motion for summary judgment for seizure and condemnation of misbranded cigarettes was granted upon proof of misleading therapeutic claims. The cigarettes were also held to be "new drugs" for which no effective new drug application had been filed. In opposition to the Government's scientific affidavits of nonsafety, defendant produced an array of scientific opinion to the contrary. By doing so, the court held the defendant to have revealed a genuine difference of expert medical opinion which thereby demonstrated that the articles were not "generally recognized as safe," thus "new drugs" by definition. To escape the operation of the "new drug" (and "food additives") provisions, defendants should offer evidence not of safety, but of *general recognition* of safety, through the testimony of survey experts who have polled scientific opinion on the question of safety.

Seizure After Interstate Shipment.—The federal act provides that an adulterated or misbranded article which is held for sale after ship-

10. 271 F.2d 281, 2 CCH Food Drug Cosm. L. Rep. ¶ 7528 (8th Cir. 1959), cert. denied, 362 U.S. 911 (1960).

11. 52 Stat. 1055 (1938), 21 U.S.C. § 371(e) (1958).

12. Hearing was granted on objections to the order proposing to delist certain colors used in lipsticks. 25 Fed. Reg. 903 (1960). See also Health, Education and Welfare [hereinafter referred to as HEW] Releases of Jan. 28, 1960 (HEW-M37), and April 14, 1960 (HEW-M98), wherein the latter order established standards for orange juice products and was stayed upon objections, "several of which presented reasonable grounds in support of requests for a public hearing," thus making a public hearing mandatory. See 25 Fed. Reg. 1770, 3159 (1960).

13. 178 F. Supp. 847, 2 CCH Food Drug Cosm. L. Rep. ¶ 7565 (D.N.J. 1959).

ment in interstate commerce may be seized at any time thereafter. In *United States v. 31 Units . . . Gonsertron*,¹⁴ seizure was made against misbranded electrotherapy devices, although their component parts were purchased, assembled and the final product sold solely within the State of Michigan. The court refused to sustain the Government's contention that since the several components had traveled interstate, their interstate character followed into the final fabricated device. In *United States v. Allbrook Freezing & Cold Storage, Inc.*,¹⁵ raw strawberries had been shipped interstate and thereafter had become principal components of a new product. Though the new fabrication had not entered interstate commerce, a local seizure was sustained because the components, adulterated at the time, had gone interstate. The *Gonsertron* components, however, were not misbranded at the time of their interstate shipment and, being common industrial articles, could have been intended for many nontherapeutic uses. Perhaps charges of adulteration in foods bear more weight with the courts than misbranding of devices. Perhaps decisions rest upon the degree to which the components lose their identity in the final product. Soon to be tested in the same Michigan court is the question presented where unadulterated fresh fruits have traveled interstate, are then purchased and processed into a dietary food supplement (misbranded), and then held for sale locally:¹⁶ Can the interstate character of the fruit components be followed into the final local product?

Misleading Container.—In the few cases which have ruled upon misleading containers due to "slack-filling," the courts have demonstrated a wariness to interfere with modern packaging methods and the exigencies of machine filling. It has been established that "slack-filling" is in each case a question of fact, regardless of the percentage of fill. In *United States v. 174 Cases . . . Delson Thin Mints*,¹⁷ the New Jersey District Court found that where chocolate mints occupied only 45% of the interior of their package, the container was nevertheless not deceptive. This ruling is to be appealed on the grounds that the hollow ends and dividers in the package were not necessary to protect the contents, and further, that an honest declaration of net weight is immaterial to whether the container is misleading.¹⁸

Misbranded Surgical Nail.—Orthopedic Equipment Co. v. Euts-

14. 180 F. Supp. 52, 2 CCH Food Drug Cosm. L. Rep. ¶ 7580 (E.D. Mich. 1959).

15. 194 F.2d 937, 2 CCH Food Drug Cosm. L. Rep. ¶ 7227 (5th Cir. 1952).

16. *United States v. An Article of Drug Consisting of 39 Cases of Korleen Tablets*, Civil No. 20215, E.D. Mich., June 9, 1960.

17. 180 F. Supp. 863, 2 CCH Food Drug Cosm. L. Rep. ¶ 7581 (D.N.J. 1960).

18. See HEW Report on Enforcement and Compliance, June 1960, 2 CCH Food Drug Cosm. L. Rep. ¶ 7596 (1960).

ler¹⁹ was an action for common law negligence and negligence per se in the violation of the misbranding provisions of the Federal Food, Drug and Cosmetic Act. A surgical nail was held to be a "device" inasmuch as it was designed to affect the structure and function of the body. While administrative regulations exempted the device (intended for use by a skilled profession) from certain labeling requirements, once the manufacturer undertook to imprint measurements on the nail, he was obligated to avoid misbranding by incorrect or misleading designations.

Worthless Cancer Cure.—1960 marks the end of ten years of almost continuous litigation between the FDA and the now discredited Hoxsey Cancer Cure. Cancer patients had paid over \$50,000,000 for the Hoxsey treatment in their ill-fated search for a painless cancer cure. Under a decree of permanent injunction consented to by the last remaining cancer clinic and a supplemental consent decree against the original promoter, the sale of the treatment has been eliminated.²⁰

19. 276 F.2d 455, 2 CCH Food Drug Cosm. L. Rep. ¶ 7601 (4th Cir. 1960).

20. HEW Release, 2 CCH Food Drug Cosm. L. Rep. ¶ 7614 (1960).