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Food, Drug, and Cosmetic Law (1959)

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FOOD, DRUG, AND COSMETIC LAW

FREDERICK M. HART

THE Food Additive Amendment of 1958 clearly stands out as the principal legislative achievement during the *Survey* period, while the Supreme Court's decision in the *Florida Citrus* case offers the most important judicial development.

I

FEDERAL LEGISLATION¹

Food Additives Amendment of 1958.—Characterized as “the most important advance of our national pure food law, in its entire history,”² the Food Additive Amendment of 1958³ is the result of over seven years of legislative investigation, hearings, and debate.⁴ Essentially, the amendment requires pretesting by industry of potentially unsafe food additives before their use.

When the Federal Food, Drug and Cosmetic Act of 1938⁵ was passed, no specific provisions were included regulating food additives other than coal-tar colors.⁶ Most additives used at that time had been long recognized as safe and suitable for use in food, and scientific experimentation had not as yet demonstrated the harmful effects possible from some of these apparently innocuous added substances. During and subsequent to World War II, however, amazing progress was made by the food and chemical industries in developing anti-oxidants, emulsifiers, stabilizers, preservatives, flavors, and other additives designed to better foods. Concurrent to this development, improved scientific testing methods and greater scientific knowledge cast doubt upon the safety of certain food additives.⁷

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¹ For other recent enactments not discussed in the text see Livestock Marketing and Meat-Packing Industry Act, 72 Stat. 1749, 7 U.S.C.A. § 227 (Supp. 1958) (jurisdiction of Federal Trade Commission extended to stockyard activities); Humane Methods of Slaughter Act, 72 Stat. 862, 7 U.S.C.A. §§ 1903-06 (Supp. 1958) (providing for humane method of livestock slaughter).

² Dunn, *Fundamental Progress of the Pure-Food Law*, 13 *Food Drug Cosm. L.J.* 615, 616 (1958).

³ 72 Stat. 1784, 21 U.S.C.A. § 348 (Supp. 1958).

⁴ See Kleinfeld, *Congress Investigates Chemicals in Foods*, 6 *Food Drug Cosm. L.J.* 120 (1951).

⁵ 52 Stat. 1040 (1938), as amended, 21 U.S.C. §§ 301-92 (1952).

⁶ 52 Stat. 1046 (1938), 21 U.S.C. § 342(c) (1952); 52 Stat. 1049 (1938), as amended, 21 U.S.C. § 346(b) (1952).

⁷ See H.R. Rep. No. 2356, 82d Cong., 2d Sess. (1953); H.R. Rep. No. 3254, 81st Cong., 2d Sess. (1951).

Under the 1938 act, regulation of additives was possible only through the enforcement of provisions which prohibited the addition to food of any poisonous or deleterious substance except where it was unavoidable in good manufacturing practices. Where good manufacturing practices required the use of a toxic substance, the Food and Drug Administration was empowered to establish tolerances, setting the maximum amount of the additives which could be used.⁸

This method of control was unsatisfactory for three reasons: (1) it required the Government to prove affirmatively that the added substance was poisonous or deleterious, proof of which might require two years of scientific testing; (2) during this period of testing the manufacturer was permitted to continue using the product, and allowed to offer it to consumers; and (3) the act, as interpreted, absolutely prohibited any unnecessary poisonous or deleterious substance to be added, thus keeping from the market some additives which, although toxic if taken in large quantities, might be used at safe levels to the advantage of the consumer.

In general, the Food Additive Amendment follows the traditional administrative procedure. All additives which are not generally recognized among qualified experts to be safe under the conditions of intended use, or which are not within certain exempt classes, render a food adulterated⁹ unless there is in effect a regulation issued by the Secretary of Health, Education, and Welfare prescribing the conditions under which the additive may be safely used.¹⁰ Any person may file a petition proposing the issuance of such a regulation.¹¹ In support of his application, adequate scientific evidence must be presented proving the additive safe under the intended conditions of use.¹²

Within ninety days (which time limit may be extended by the Secretary to a maximum of one hundred and eighty days), the Secretary must promulgate an order ruling upon the petition.¹³ Up to

⁸ 52 Stat. 1046 (1938), 21 U.S.C. § 342(a)(2) (1952); 52 Stat. 1049 (1938), as amended, 21 U.S.C. § 346(a) (1952). Some degree of regulation was also afforded by sections of the act providing for the standardization of foods. 52 Stat. 1046, 21 U.S.C. § 341 (1952). See *Atlas Powder Co. v. Ewing*, 201 F.2d 347, 2 CCH Food Drug Cosm. L. Rep. ¶ 7247 (3d Cir. 1952), cert. denied, 345 U.S. 923 (1953); Lovell, *Administrative Procedure in the Regulation of Food Additives: A Comparative Study*, 11 Food Drug Cosm. L.J. 413 (1956).

⁹ 52 Stat. 1046 (1938), as amended, 21 U.S.C. § 342(c) (1952).

¹⁰ 21 U.S.C.A. § 348(a) (Supp. 1958).

¹¹ 21 U.S.C.A. § 348(b) (Supp. 1958).

¹² Although the Food and Drug Administration apparently will not foreclose the use of new tests to prove safety, the present method of testing requires extensive experimentation usually taking in excess of two years. See Lehman, *Procedures for the Appraisal of the Toxicity of Chemicals in Foods, Drugs and Cosmetics*, 10 Food Drug Cosm. L.J. 679 (1955).

¹³ 21 U.S.C.A. § 348(c) (Supp. 1958).

this point there is no hearing procedure available, but anyone who is adversely affected by the order may, within thirty days of its promulgation, file objections and request a hearing.¹⁴ His request must be accompanied by a specification of the parts of the order to which he objects, and reasonable grounds for his objection. The Secretary is then required to hold a public hearing, after notice, for the purpose of receiving evidence relevant and material to the issues raised by the objections. At the completion of the hearing an order ruling upon the objections must be made, including detailed findings of fact and conclusions.¹⁵

This order is then subject to judicial review in the United States courts of appeal upon the petition of any adversely affected person. The scope of review to be applied by the court is indicated by the provision in the act that, "the findings of the Secretary with respect to questions of fact shall be sustained if based upon a fair evaluation of the entire record at such hearing."¹⁶ That Congress intentionally refrained from using the phrase "substantial evidence" in formulating the scope of judicial review is apparent from the legislative history of the amendment, wherein it is indicated that an attempt was made to establish other guideposts for the reviewing courts.¹⁷ Considering, however, the lack of success which judges have had in reducing the well-known "substantial evidence" test to a working formula,¹⁸ it is unlikely that food additive regulations will receive any different review from that given cases arising under statutes requiring an agency to base its determination upon substantial evidence. No matter how legislatures may phrase the "test" for sustaining agency action, judges will still be left with wide discretion, and will be greatly influenced by the character of the agency, the nature, consequences, and fairness of the initial ruling, and by their own competence to decide the issues raised.

The legislative history of this amendment shows many instances of sharp disagreement among those most interested in its adoption. The Food and Drug Administration, consumer organizations, and industry representatives each sponsored and backed different schemes for governmental control in this field. The bill which was finally enacted into law is, in a sense, a compromise designed to satisfy, at least partially, each of these parties. However, in a more real sense,

¹⁴ 21 U.S.C.A. § 348(f) (Supp. 1958).

¹⁵ 21 U.S.C.A. § 348(f) (Supp. 1958).

¹⁶ 21 U.S.C.A. § 348(g) (Supp. 1958).

¹⁷ S. Rep. No. 2422, 85th Cong., 2d Sess. 8 (1958); Legislative History of 1958 Food Additives Amendment to Federal Food, Drug, and Cosmetic Act 66 (Dunn ed. 1958).

¹⁸ See Cooper, Administrative Law: The "Substantial Evidence" Rule, 44 A.B.A.J. 945 (1958).

it is an amalgamation of the best of the many suggestions offered. The result is a strong bill for consumer protection which gives broad powers to the Food and Drug Administration while still being consistent with a philosophy of government which favors industry initiative and responsibility over governmental licensing.

II

MUNICIPAL LEGISLATION

During the year New York City rewrote those provisions of its Health Code which regulate foods, drugs, and cosmetics.¹⁹ A part of a general revision of the code, these regulations are of special importance due to the probability that they will become model provisions influencing other municipalities restudying the problem. A major objective of the revision was to conform the language of the local regulations to the applicable federal and state law in order to allow greater cooperation among enforcement officers, and to relieve industry of the burden of having to comply with conflicting regulations. As a result, the New York City regulations now closely follow the Federal Food, Drug and Cosmetic Act, with the exception that the city has deleted all provisions aimed at economic fraud, on the rationale that this situation is more adequately handled by the state and federal government, and does not constitute a health problem.²⁰

III

CASES²¹

Coal-Tar Colors.—In 1955 FD & C Red No. 32 was removed from the approved list of coal-tar colors by the Secretary of Health,

¹⁹ New York City Health Code, tit. IV, arts. 70, 71, 111, 113.

²⁰ Introduction to 3d Draft of Articles 70, 71, 111 and 113 presented by Legislative Drafting Research Fund of Columbia University to The Board of Health of the City of New York (mimeo.). This draft was approved in principle by the board on October 20, 1958.

²¹ Other cases decided since the 1957 Survey, but not discussed in the text, include: *Marshall v. United States*, 258 F.2d 94, 2 CCH Food Drug Cosm. L. Rep. ¶ 7446 (10th Cir.), cert. granted, 358 U.S. 892 (1958) (actions by government agents held not to constitute entrapment); *United States v. Miller*, 256 F.2d 89, 2 CCH Food Drug Cosm. L. Rep. ¶ 7442 (8th Cir. 1958) (writ of mandamus to compel district court to omit part of judgment denied); *United States v. 1500 Cases, More or Less*, 249 F.2d 382 (7th Cir. 1957) (pre-seizure storage charges not recoverable from federal government); *United States v. Rutstein*, 163 F. Supp. 71, 2 CCH Food Drug Cosm. L. Rep. ¶ 7443 (S.D.N.Y. 1958) (labelling requirement of § 407(b) held not to apply to wholesale packages); *United States v. 42 Jars . . . "Bee Royale Capsules ***"*, 160 F. Supp. 818, 2 CCH Food Drug Cosm. L. Rep. ¶ 7438 (D.N.J. 1958) (prior adjudication under postal fraud statute held not res judicata in seizure action); *United States v. 3963 Bottles, More or Less*, 2 CCH Food Drug Cosm. L. Rep. ¶ 7460 (N.D. Ill. 1958) (agreement between claimant and Post Office Department in fraud action held not applicable to seizure action); *United States v. Delmar Pharmacal Corp.*, 2 CCH Food Drug Cosm. L. Rep. ¶ 7456 (N.D.N.Y. 1958) (consent decree in injunction action);

Education, and Welfare.²² The validity of this delisting order was sustained against a general attack by the Court of Appeals for the Second Circuit,²³ but was set aside by the Court of Appeals for the Fifth Circuit insofar as it removed certification of the color as harmless and safe for external use on oranges.²⁴ The Fifth Circuit, in a confusing opinion, held that the term "harmless" in the statute²⁵ was to be construed in a relative sense, and that the Secretary was required to certify a color whenever it was harmless under the conditions of its intended use. The court also held that it was incumbent upon the Secretary to determine whether the color was necessary in good production practices, and if it were, he was required to promulgate tolerances within which the color could be safely used.

Certiorari was granted in the Fifth Circuit case, *Folsom v. Florida Citrus Exchange*,²⁶ and the Supreme Court reversed.²⁷ Considering the legislative history of the Federal Food, Drug, and Cosmetic Act of 1938,²⁸ the Court concluded that Congress, intending to treat coal-tar colors (which add only to the appearance of a food) with greater caution than other toxic ingredients, had dictated that "the test of certification . . . concentrates on the color substance itself [which] is to be listed only if it is harmless."²⁹ In interpreting the key word "harmless," the Court said that "Congress may have intended 'harmless' in a relative sense, but we think it was in relation to such laboratory tests [toxicological tests] as the ones the Secretary performed."³⁰ From a literal reading of the statute, the Court found no grounds for the contention that the Secretary is empowered to set tolerances for the use of coal-tar colors.

It is likely that the opinion will result in legislation extending the stay of the Secretary's order, effected by a congressional amend-

United States v. W. F. Morgan & Sons, 155 F. Supp. 40, 2 CCH Food Drug Cosm. L. Rep. ¶ 7421 (E.D. Va. 1957) (proof insufficient to establish violation of oyster standards).

²² 20 Fed. Reg. 8492 (1955). For the present approved list see 21 C.F.R. ¶ 9.3 (1955).

²³ Certified Color Indus. Comm. v. Folsom, 236 F.2d 866, 2 CCH Food Drug Cosm. L. Rep. ¶ 7367 (2d Cir. 1956).

²⁴ Florida Citrus Exchange v. Folsom, 246 F.2d 850, 2 CCH Food Drug Cosm. L. Rep. ¶ 7404 (5th Cir. 1957).

²⁵ 52 Stat. 1049 (1938), as amended, 21 U.S.C. § 346(b) (1952).

²⁶ 356 U.S. 911 (1958).

²⁷ Fleming v. Florida Citrus Exchange, 358 U.S. 153, 2 CCH Food Drug Cosm. L. Rep. ¶ 7468 (1958).

²⁸ 52 Stat. 1040 (1938), as amended, 21 U.S.C. §§ 301-92 (1952).

²⁹ 358 U.S. at 162, 2 CCH Food Drug Cosm. L. Rep. at p. 8603. For a fuller discussion of the circuit court opinions see 33 N.Y.U.L. Rev. 302, in 1957 Ann. Survey Am. L. 263 (1958), wherein it was stated, "the clear language of the statute contradicts the fifth circuit's interpretation. The section directs that the color must be safe, not the use to which it might be put."

³⁰ 358 U.S. at 164, 2 CCH Food Drug Cosm. L. Rep. at p. 8604.

ment to the Act in 1956, specifically allowing the use of the color on oranges until April of 1959.³¹

Physician's Dispensing Drugs Without A Prescription.—In *Brown v. United States*,³² the Court of Appeals for the Fifth Circuit held that the Durham-Humphrey Amendment³³ to the Federal Food, Drug, and Cosmetic Act³⁴ applied to the sale of prescription drugs by a registered physician. Doctor Brown dispensed barbiturates in one thousand pill lots to federal agents posing as truck drivers, without giving them a prescription, or examining them to ascertain whether the use of these drugs was therapeutically indicated.

The court refused to refer to the legislative history of the amendment on the grounds that the law had been interpreted to be for the benefit of the public on several occasions by the Supreme Court.³⁵ Literally construing the language of the statute to require a prescription prior to the dispensing of drugs, even by a physician, the court found the trial judge's charge to the jury unobjectionable. The trial judge had charged that:

. . . in determining whether he [defendant] dispensed the drugs . . . on prescription, you may properly consider whether a doctor-patient relationship existed . . . whether he considered the individual needs of the person to whom he dispensed the drug, the quantity of the drug dispensed and the manner in which he supervised the use of the drug.³⁶

This charge, the court felt, placed the doctor in a better position than he would be in if the statute were taken on its face.

Although the court specifically held the charge correct, a close reading of the case gives the impression that the court actually held that whenever a physician dispenses drugs covered by section 503(b)³⁷ of the act, he is technically violating the law. It is as difficult to conceive that Congress intended such a result as it is to believe that a physician, by virtue of his being a physician, is to be allowed to engage in the uncontrolled retail sale of restricted drugs. The more realistic approach was taken by the trial court in instructing the jury that a physician is exempt from the act only so long as he acts as a medical doctor.

Relabeling of Condemned Drugs.—The United States filed a

³¹ 70 Stat. 512 (1956), as amended, 21 U.S.C. § 342(c) (Supp. V, 1958).

³² 250 F.2d 745, 2 CCH Food Drug Cosm. L. Rep. ¶ 7425 (5th Cir.), cert. denied, 356 U.S. 938 (1958).

³³ 65 Stat. 648 (1951), 21 U.S.C. § 353(b) (1952).

³⁴ 52 Stat. 1040 (1938), as amended, 21 U.S.C. §§ 301-92 (1952).

³⁵ The court cited *United States v. Sullivan*, 332 U.S. 689 (1948); *United States v. Dotterweich*, 320 U.S. 277 (1943).

³⁶ 250 F.2d at 747, 2 CCH Food Drug Cosm. L. Rep. at p. 8509.

³⁷ 65 Stat. 648 (1951), 21 U.S.C. § 353(b) (1952).

libel asking condemnation of a "skin conditioner" on the ground, *inter alia*, that the name of the preparation, "buticaps," caused it to be misbranded because it represented to the public that the product had a therapeutic effect, when in fact it did not. The claimant admitted that the articles were misbranded on other grounds charged in the complaint, but denied the allegations as to the name. Judgment was given to the Government on the pleadings, but the court released the goods to the claimant for relabeling under the supervision of the Food and Drug Administration. Thereafter, the claimant moved for an order that since there had been no judicial determination that the name did not comply with the statute, they had the right to continue the use of this name. This motion was denied by the district court. The court of appeals, in *Buticaps, Inc. v. United States*,³⁸ reversed, holding that the terms and conditions of salvage are to be set by the court, not by the Food and Drug Administration, and that the failure of the court to give claimant a hearing on the issue would be a deprivation of due process.

*Multiple Seizures of New Drugs.—Merritt Corp. v. Folsom*³⁹ is interesting on two grounds. First, it held that multiple seizures may be instituted without the making of any probable cause determination under section 304.⁴⁰ Secondly, the case furnishes the first judicial recognition that, "where there is a genuine difference of medical opinion among the experts on the question of whether a drug is generally recognized as safe for the treatment of a particular disease, it must be concluded that the drug is not *generally* recognized as safe for use in the treatment of that disease,"⁴¹ and that, hence, it is a new drug under section 201(p).⁴²

³⁸ 252 F.2d 634, 2 CCH Food Drug Cosm. L. Rep. ¶ 7432 (D.C. Cir. 1958). *Contra*, *United States v. 1322 Cans, More or Less, of Black Raspberry Puree*, 68 F. Supp. 881 (N.D. Ohio 1946).

³⁹ 165 F. Supp. 418, 2 CCH Food Drug Cosm. L. Rep. ¶ 7462 (D.D.C. 1958).

⁴⁰ 52 Stat. 1044 (1938), as amended, 21 U.S.C. § 334 (1952).

⁴¹ 165 F. Supp. at 421, 2 CCH Food Drug Cosm. L. Rep. at p. 8583.

⁴² 52 Stat. 1041 (1938), 21 U.S.C. § 321(p) (1952).