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## Notices of Judgment—Cosmetics

### C. N. J.'s Nos. 1 to 205

This Study and the One Following It Continue the Fine Series Featured in This Journal in 1955, 1956 and 1958. These Two Deal with N. J.'s Under the 1938 Act Which Have Pharmacological Import. They Were Presented Before the American Pharmaceutical Association, at Los Angeles in April, 1958

THE PREVIOUS REPORTS on notices of judgment (N. J.'s) dealt with proceedings under the Federal Food and Drugs Act of June 30, 1906, published in accordance with Regulation 6. The N. J.'s were published from time to time, but information on foods, on drugs and on cosmetics was not segregated. Our studies, therefore, required classification of information under these various headings. The Federal Food, Drug, and Cosmetic Act of June 25, 1938, separated information and controls upon these three classes of products, after listing the general provisions of the Act which covered all products subject to it. Section 601 deals with adulterated cosmetics, Section 602 deals with misbranded cosmetics and Section 604 provides for regulations for harmless and suitable coal-tar colors. Section 705 authorizes publication of reports and information regarding cosmetics (as well as foods, drugs and devices). In accordance with this proviso, there have been a total of 205 notices of judgment, to date, dealing with cosmetics (C. N. J.'s).

Of this group of 205 N. J.'s, there were 112 which had some pharmacological significance and there were seven contests. A brow tint (C. N. J. 113) was seized, charging that it contained a poisonous or deleterious substance (paraphenylenediamine) which might render it injurious to users under conditions prescribed in the labeling, and that it was a coal-tar color which had not been listed for use in cos-

metics. The judge refused to dismiss the libel and gave judgment for the government. This decision was affirmed by the United States Court of Appeals for the Fifth Circuit.

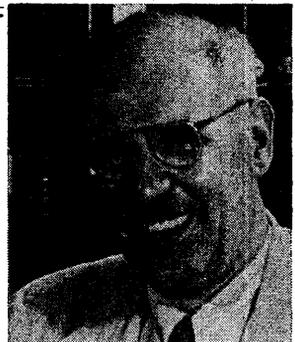
In a case brought against lacquer pads (C. N. J. 147), a plea of guilty was entered and the court directed a fine. On appeal, the decision of the district court was affirmed by the Seventh Circuit.

In another action against a different lacquer (C. N. J. 151), the defendant pleaded not guilty, the jury returned a verdict of guilty, and the court handed down a sentence of one year in jail and a fine of \$1,000 on each of four counts. Combined with an action against a drug product (D. D. N. J. 2121), the case was appealed to the Seventh Circuit, which reversed the lower court. After a petition for rehearing was denied, the defendant entered a plea of *nolo contendere* on both products, and a fine of \$2,000 and costs was imposed. In addition to a number of drug products, a cosmetic containing lead acetate and sulfur was the basis of C. N. J. 143. Entering a plea of not guilty, the case was tried, and the jury returned a verdict of guilty on the cosmetic and the drug counts, after which the court pronounced a sentence of 57 days in jail.

Action was brought against a lash and brow tint (C. N. J. 76) on the basis that it contained poisonous and deleterious substances—pyrogallol, ammoniacal silver sulfate and silver nitrate—which might render it injurious to users under the condition recommended in the labeling. A plea of not guilty was filed, and a lengthy trial was held before a jury, which was unable to agree on a verdict. The case was

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retried, particularly with reference to the possibility of injury from the use of the product as directed. The court pointed out in its charge to the jury that a poison has been defined as "any agent which introduced especially in small amounts into an organism may chemically produce an injurious and deadly effect."

A deleterious substance means a harmful or destructive article, usually understood to be capable of destroying life. "May" is an auxiliary verb expressing ability or liability, possibility or probability. It is necessary for the government to prove that substances are poisonous, deleterious, and likely to result in injury to users under conditions prescribed in the labeling. The expert witnesses who testified should be considered and their testimony weighed as the jury weighed the testimony of other witnesses, considering the reasonableness, the learning and the experience of such witnesses. The jury returned a verdict for the claimant, and the product was returned.

Misbranding was alleged, in C. N. J. 105, of a permanent wave solution and wave set which claimed tonic properties. The article contained ammonia and ammonium sulfite in water. Evidence was offered in the trial before the court and jury by the government and by the claimant, after which a verdict was returned for the claimant.

Misbranding was alleged against a hair lotion (C. N. J. 152) which had been manufactured for more than 90 years, in that its name was misleading since it contained only one part of quinine in 5,000 parts of the product. The government claimed that this was a very small or inconsequential amount of quinine. After hearing the evidence, the jury returned a verdict of not guilty.

Summarizing, it might be noted that the government won four of the seven contested cases brought against cosmetics.

A number of actions were brought against a permanent wave which contained ammonium sulfide; seizures were made. No claimant appeared, so the product was destroyed. Action was brought against lipsticks containing cadmium and selenium; against dental creams containing hard material with sharp edges; against a plastic mask containing clay and benzaldehyde; against a number of products containing uncertified dyes. A number of hair dyes contained lead acetate and cantharides; also, lash, eyebrow and hair colorings contained paraphenylenediamine. Shampoos contained a dangerous or deleterious quaternary compound. Other hair or lash tints contained ammoniacal silver nitrate and pyrogallol. Hair straighteners contained large amounts of sodium hydroxide. Bleaches contained mercuric chloride and urea peroxide. Other products were claimed to beautify the skin and remove wrinkles because of the presence of vitamins or lanolin.

There was some overlapping of claims between the cosmetic area and the drug area. [The End]

## Notices of Judgment—Foods

F. N. J.'s Nos. 1 to 23,400

NOTICES OF JUDGMENT published in accordance with Regulation 6 of the Federal Food and Drugs Act of June 30, 1906, were screened to permit study of those dealing with foods, in which there were some pharmacological implications. The Federal Food, Drug, and Cosmetic Act of June 25, 1938, separated information on foods into Sections 401-408, dealing with adulteration, misbranding, emergency permit control, exemptions, margarine, tolerances for poisonous ingredients and pesticide chemicals, and certification of