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The Food and Drug Administration's Regulation of Cosmetics.
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Testimony before the House Committee on Interstate and Foreign
Commerce: Oversight and Investigations Subcommittee; by Gregory
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Organization Concerned: Food and Drug Administration; Cosmetic,
Toiletry, and Fragrance Association.

Authority: Federal Food, Drug, and Cosmetic Act, as amended.
Fair Packaging and Labeling Act. Food Color Additive
Amendments of 1960.

About 33 million women use hair dyes to temporarily or permanently change their hair color. There is increasing evidence that some colors used in coal tar hair dyes, the dyes most commonly used, carry a significant risk of cancer to users. Several studies have demonstrated that coal tar hair dye ingredients are absorbed through the skin and scalp. Coal tar hair dyes whose labeling contains a prescribed statutory warning concerning possible skin irritation and blindness are exempt from adulteration provisions of the Federal Food, Drug, and Cosmetic Act. Congress should repeal the exemptions for coal tar hair dyes. Other cosmetic products may pose significant hazards to consumers. About 100 ingredients listed in the Cosmetic, Toiletry, and Fragrance Association's Cosmetic Ingredient Dictionary are suspected carcinogens. Products such as bubble baths, shampoos, and feminine sprays have been associated with consumer complaints. Hairsprays have been shown to cause a lung disease which may lead toward lung malignancy, and there have been reports of vision loss resulting from the use of microbially-contaminated eye makeup. Although the Food and Drug Administration has established regulations designed to improve its control over cosmetics, the effectiveness of many of its regulatory efforts has been limited. (RRS)

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STATEMENT OF
GREGORY J. AHART, DIRECTOR, HUMAN RESOURCES DIVISION
BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE
ON
THE FOOD AND DRUG ADMINISTRATION'S
REGULATION OF COSMETICS

Mr. Chairman and Members of the Subcommittee, we are pleased to appear here today to discuss our report to the Subcommittee entitled "Cancer and Coal Tar Hair Dyes: An Unregulated Hazard to Consumers" (HRD-78-22, December 6, 1977) and the results of our broader review of the Food and Drug Administration's (FDA's) regulation of cosmetics.

Our work has been directed to determining whether (1) coal tar hair dyes and other cosmetics pose an unnecessary hazard to consumers, (2) FDA has sufficient legislative authority to effectively regulate cosmetics, and (3) FDA has effectively used its existing authority.

FDA's authority to regulate cosmetics in interstate commerce is derived from the Federal Food, Drug, and Cosmetic (FD&C) Act and the Fair Packaging and Labeling Act. The FD&C Act requires that a cosmetic be

- free of substances that may make it injurious;
- packaged in a safe and non-deceptive container;
- produced under sanitary conditions; and
- labeled with information about the product's manufacturer, packer, or distributor, and the quantity of its contents.

FDA has authority under the Fair Packaging and Labeling Act to require that a cosmetic label list the product's ingredients.

Before highlighting the results of our review of cosmetics regulation, I would like to briefly discuss our report to the Subcommittee on coal tar hair dyes and subsequent developments.

COAL TAR HAIR DYES

About 33 million women use hair dyes to temporarily or permanently change their hair color. There is increasing evidence that some colors used in coal tar hair dyes--the dyes most widely used--may carry a significant risk of cancer to users. However, exemptions in the FD&C Act do not permit FDA to regulate coal tar hair dye products effectively; they bar FDA from banning or restricting the use of cancer-causing coal tar hair dyes.

Coal tar hair dyes are divided into three groups--temporary, semipermanent, and permanent--depending on the type of coal tar color used, the method used to apply the dye, and the permanence of the color.

Colors known or suspected of causing cancer reportedly are being used in all three types of coal tar hair dyes. Specifically:

- Temporary hair dyes may contain coal tar colors shown to cause cancer in laboratory animals and banned by FDA for use in other cosmetic products.
- Temporary and semipermanent hair dyes may contain azo colors derived from benzidine, a known human

carcinogen. Such colors contain benzidine as a contaminant, and some of the colors may break down in the body and release benzidine.

--Other coal tar colors available for use in temporary or semipermanent hair dyes have reportedly caused cancer in laboratory animals.

--Evidence from screening tests or animal studies indicate that several coal tar colors used in permanent hair dyes, including toluene-2,4-diamine and 2,4-diaminoanisole, may cause cancer.

Several studies have demonstrated that coal tar hair dye ingredients are absorbed through the skin and scalp.

Subsequent to release of our report to the Sub ommittee, newspaper articles quoted the Cosmetic, Toiletry, and Fragrance Association (CTFA) as stating that no major hair dye manufacturer has used benzidine-derived azo colors in their products since 1973. However, we purchased eight temporary rinses at Rockville, Maryland, drug stores containing one or more benzidine-derived azo colors. The manufacturer of these rinses is a CTFA member.

Generally, a cosmetic is considered adulterated if it contains any poisonous or deleterious substance. However, coal tar hair dyes whose labeling contains a prescribed statutory warning concerning possible skin irritation and blindness are exempt from these provisions.

In addition, a cosmetic is considered adulterated if it contains a color additive not approved for safety by FDA under the color additive provisions of the FD&C Act. Again, however, coal tar hair dyes are exempted.

We recommended that Congress repeal the exemptions for coal tar hair dyes.

A cosmetic is considered misbranded if its labeling is false or misleading. Although coal tar hair dyes are subject to FDA labeling requirements, the agency has not used this authority to require a cancer warning on labels of coal tar hair dyes containing known human or animal carcinogens.

We recommended that FDA evaluate safety data on coal tar hair dye ingredients and require, where applicable, a cancer or other appropriate warning statement on product labels.

On January 6, 1978, FDA published in the Federal Register a proposal to require that labels of hair dyes containing 2,4-diaminoanisole carry a cancer warning statement. A determination has not yet been made on the need for a similar statement on labels of hair dyes containing other ingredients suspected of causing cancer.

OTHER COSMETIC HAZARDS

Results of our broader cosmetics review indicate that some cosmetic products may pose significant hazards to consumers. Specifically:

- Ingredients listed in the CTFA Cosmetic Ingredient Dictionary as available for use in cosmetic products include about 100 ingredients that the National Institute of Occupational Safety and Health's Registry of Toxic Effects of Chemical Substances lists as suspected carcinogens. In addition, 24 ingredients listed in the dictionary are suspected of causing birth defects and 20 may cause adverse effects on the nervous system including headaches, drowsiness, and convulsions. Many different routes of exposure and species of animals were used in the studies referenced by the NIOSH Registry. The applicability of the test methods and results to cosmetics exposure has not been evaluated.
- Certain cosmetic products including bubble baths, shampoos, and feminine sprays have been associated with many consumer complaints.
- Hairsprays have been shown to cause a lung disease which may lead toward lung malignancy.
- FDA has received several reports of vision loss resulting from the use of microbially-contaminated eye makeup. Results of an FDA-sponsored study published in 1974 showed that about half of the eye makeup tested after it was partially used by consumers contained bacterial contamination.

--Serious burns, including at least one death, have been reported from the use of flammable cosmetics.

NEED FOR ADDITIONAL
LEGISLATIVE AUTHORITY

Before 1972 FDA did not have a formal program to control cosmetic products. Since then FDA has established several regulations designed to improve its control over cosmetics. However, because FDA lacks adequate legislative authority, the effectiveness of many of its regulatory efforts has been limited.

For example, FDA established regulations providing for the registration of cosmetic manufacturers and packers and the filing of cosmetic product ingredient and product experience reports by manufacturers, packers, and distributors. But FDA does not have authority to require compliance with the regulations. As a result, voluntary compliance has been limited. As of December 31, 1977,

--896 (40 percent) of the approximately 2,200 cosmetic manufacturers and packers FDA had indentified had registered,

--768 of the estimated 4 to 5 thousand cosmetic manufacturers, packers, and distributors had filed ingredient statements, and

--130 of the 4 to 5 thousand cosmetic manufacturers, packers, and distributors had filed product experience reports.

An FDA regulation also requires that labeling of cosmetics that have not been adequately tested for safety bear a warning to that effect. However, this regulation cannot be effectively enforced because FDA does not have authority to require cosmetic manufacturers to test their products for safety or make their test results available to FDA.

In addition, many manufacturers have refused FDA inspectors access to manufacturing records such as qualitative and quantitative formulas, sales or shipping records, and consumer complaint files because FDA lacks authority to require manufacturers to permit FDA inspectors access to such records.

Legislation (S.2365) has been introduced in the 95th Congress to amend the FD&C Act to provide FDA with additional authority to regulate cosmetics.

BETTER USE OF EXISTING AUTHORITY

Although FDA's efforts to regulate cosmetic products have been hampered by the lack of adequate legislative authority, many improvements in FDA's regulation of cosmetics could be made under its existing authority. FDA has authority to (1) inspect cosmetic plants and

collect and test cosmetic samples, (2) establish manufacturing standards, (3) take regulatory action against violative manufacturers, (4) restrict the use of hazardous cosmetic ingredients and require appropriate precautionary labeling on cosmetic products, (5) require manufacturers to prove the safety of color additives used in cosmetics, and (6) establish by regulation, tests to be used in evaluating cosmetic safety. Our review indicates that FDA has not effectively used its authority to regulate cosmetics. For example:

1. FDA has not inspected most cosmetic manufacturers' plants or sampled most of their products for compliance with the FD&C Act. Only about half of the known cosmetic establishments were inspected between 1968 and 1975. Since 1975 FDA identified about 1,000 additional manufacturers, which it had never inspected because they had been unknown to the agency.

2. FDA has not established manufacturing criteria to determine whether adequate methods, facilities, and controls are used in all phases of manufacturing and distribution of cosmetics. According to a summary in its 1975 Compliance Program Guidance Manual, FDA inspectors found during establishment inspections that:

--Less than 33 percent of the firms had established raw material specifications.

- Less than 50 percent maintained adequate batch control records.
- Less than 15 percent tested equipment for microbial contamination.
- Only 20 percent tested the effectiveness of the preservative system used in their cosmetics.
- Only 25 percent maintained an inventory system adequate to facilitate a recall.

According to an FDA official about 75 percent of a sample of over 300 firms inspected since 1976 had deficiencies in their manufacturing practices.

3. When violations of the FD&C Act are identified, FDA can seize the violative product, enjoin a manufacturer from shipping the product in interstate commerce, or prosecute the firm violating the act. Manufacturers are notified of violations through issuance of citations, regulatory letters, and information letters depending on the nature and severity of the violation. Between 1974 and 1976 FDA identified over 400 violations of the cosmetic provisions of the FD&C Act which the agency found warranted some form of regulatory action, yet only about 140 regulatory actions--including seizures, prosecutions, injunctions, citations, and issuance of regulatory and information letters--were taken. Fifty-four of those actions involved one violative product.

4. Establishing regulations to prohibit or limit the use of an individual ingredient, or require the use of a specific warning statement on the label is an effective way to increase consumer safety with regard to a specific product or category of products. As of January 1, 1978, FDA had established ingredient standards governing the use of only eleven ingredients in cosmetics, and had required precautionary labeling only on feminine sprays, aerosols containing chlorofluorocarbon propellants, and aerosol cosmetics in selfpressurized containers.

Some ingredients banned or restricted for use in cosmetics in other countries are available for use without restriction in the United States. For example, 9 ingredients banned for use in cosmetics by a European Economic Community directive adopted by several countries were reported to FDA by cosmetic manufacturers as being used in cosmetics in the United States. An FDA official told us that FDA has not ascertained the basis for restricting the use of these ingredients in other countries.

Similarly, the Consumer Product Safety Commission has established regulations requiring that specific warning statements be placed on the labels of household products containing certain toxic ingredients, but FDA has not established similar regulations governing the

use of these ingredients in cosmetics.

5. The 1960 Color Additive Amendments to the FD&C Act require FDA to establish regulations listing color additives that are safe for use in cosmetics. However, as of December 1977, the safety of about 25 color additives available for use in cosmetics had not been established. In one case--caramel--FDA permitted the continued use of the color additive for 15 years before a color additive petition was filed. That petition did not contain all of the required safety studies and FDA has given the petitioner until 1980 to complete additional studies.

6. FDA has not established by regulation, specific tests to be used in evaluating the safety of cosmetic products. Without such regulations, FDA may not be able to use the tests for enforcement purposes. For example, FDA attempted to prosecute a shampoo manufacturer for marketing an adulterated shampoo, but the evidence it used to show that the shampoo was hazardous was not acceptable because it had not established by regulation the appropriateness of the test used by the agency to evaluate the safety of the shampoo.

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Mr. Chairman, that completes my prepared statement. We will be happy to answer any questions that you or other members of the Subcommittee may have.