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UNITED STATES GOVERNMENT

Memorandum

U.S. CONSUMER PRODUC
SAFETY COMMISSIO
WASHINGTON, D.C. 2020

TO : Don Early, SCAL

DATE: APR 17 1975

THRU : Stan Parent, Executive Director

THRU : Margaret A. Freeston, Acting Assistant General Counsel

FROM : Alan H. Schoem, Office of the General Counsel

SUBJECT: Jurisdiction Over Wigs

We advised your Office, in a memorandum dated January 16, 1975, that our Office was soliciting FDA's views on whether "wigs" were considered "cosmetics" under the Food Drug and Cosmetic Act and, therefore, exempt from the Commission's jurisdiction under the CPSA.

Our Office was advised by letter dated March 24, 1975 (attached) that wigs are considered by HEW to be "cosmetics" within the meaning of the Food Drug and Cosmetic Act. We concur with that opinion and, therefore, request that any investigations concerning wigs as cosmetics be terminated and any relevant information collected by the Commission submitted to FDA for their consideration. The Commission does, however, have authority under the Flammable Fabrics Act (15 U.S.C. 1191, et seq.) to regulate flammability problems involving wigs and investigations along those lines are not affected by this memorandum.

Attachment

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CONSUMER PRODUCT SAFETY COMMISSION

ADVISORY OPINION

U.S. GOVERNMENT PRINTING OFFICE: 1974 733-533/3604 1-3

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
ROCKVILLE, MD. 20857

March 24, 1975

Michael A. Brown, Esq.
General Counsel
Consumer Product Safety Commission
Washington, D.C. 20207

Dear Mr. Brown:

This replies to your letter of January 16, 1975 to Peter Barton Hutt inquiring whether FDA considers wigs to be cosmetics. We have carefully reviewed our policy on this matter, since our conclusion effectively determines the status of a number of products besides wigs.

Section 201(i) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(i), defines "cosmetic" as meaning "articles intended to be ... applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance...." Literally, this language is broad enough to include wigs, toilet articles that contact the body when used, and numerous other articles not commonly thought of as cosmetics.

The legislative history is not too revealing on what the scope of the term "cosmetic" was intended to be. In early bills the definitions of "food" and "cosmetic" were limited to "substances and preparations," while "drug" was defined as including "substances, preparations, and devices." See S. 5, 74th Cong., 1st Sess. (1935). Subsequently, the Wheeler-Lea Act was enacted to regulate advertising of foods, drugs, and cosmetics, and the definitions in that act refer to "articles" without distinguishing between "substances and preparations" on the one hand and "devices" on the other. The Federal Food, Drug, and Cosmetic Act adopted the Wheeler-Lea Act definitions without further discussion in committee reports or floor debate.

During Senate debate at a time the bill under discussion defined cosmetics as "substances and preparations," one of its opponents

thought it even then applied to wigs. He stated that "the term 'cosmetic' could well include a 'transformation,' which is what the ladies call the article they add to their own natural hair. The term could cover such an article and might include many things which ladies wear in order to make their appearance more attractive." See Dunn, Federal Food, Drug, and Cosmetic Act: A Statement of its Legislative Record, at 730. Despite this concern for the definition's coverage, as eventually enacted the even broader term "articles" was used.

Some idea of the intended scope of the Act's coverage as to cosmetics is suggested by the intended breadth as to therapeutic devices. Items such as shoulder braces, radium belts, electrical devices, bathroom weight scales, hospital air conditioning apparatus, and crutches were identified by Congressmen as potentially subject to regulation under the act as devices. See United States v. An Article of Drug ... Bacto Unidisk, 394 U.S. 784 (1969). The Bacto-Unidisk Court indicated its agreement that the term "device" extends to "basic aids used in the routine operation of a hospital," thus giving it the broadest possible scope.

As indicated in the legislative history of the 1938 Act, the motivation for expanding the Food and Drugs Act of 1906 to cover cosmetics was incidents involving injurious cosmetics in the years preceding 1938. In extending the Act to include cosmetics, Congress seems to have had no particular characteristic of cosmetics in mind other than the fact that these products were causing physical injury through contact with the body. Consequently, we conclude that a literal reading of the definition of the term "cosmetic" is appropriate. Numerous cosmetic "devices," such as false eyelashes, are potentially injurious through contact with the body in the same way as are cosmetic substances and preparations. Since there seems to be no way to distinguish between such products and products less obviously cosmetics, such as wigs, a broad reading of the statute's coverage is necessary to carry out the intent of Congress.

Such a broad reading is supported by the Court's holding in Bacto-Unidisk that the scope of the term "drug" was as broad as the literal language of its definition and "broader than any strict medical definition might otherwise allow."

On a number of occasions FDA has initiated seizure actions against hair brushes as adulterated cosmetics because they contained nits. See Cosmetics Notice of Judgment (C.N.J.) 207, 208, (February 1959); FDA Papers, February 1971, at 39; FDA Papers, March 1971, at 36;

FDA Consumer, February 1973, at 40; FDA Consumer, March 1973, at 40; FDA Consumer, April 1973, at 39; FDA Consumer, May 1973, at 40. Action has similarly been taken against cinnamon hot tooth picks containing an injurious substance. See C.N.J. 247-251 (August 1964); FDA Papers, February 1967, at 36; FDA Papers, July/August 1967, at 44; FDA Papers, November 1968, at 36. In addition, a seizure was instituted against stockings containing lotions under the misbranded cosmetics provisions of the act. See C.N.J. 229 (September 1962).

We therefore conclude that wigs are cosmetics within the meaning of the Act. The Federal Trade Commission has similarly classified wigs as cosmetics. See 35 Fed. Reg. 12718 (Aug. 11, 1970).

Sincerely yours,

Terry Coleman

Terry Coleman
Attorney