

GAO

Report to the Chairman, Subcommittee
on Regulation, Business Opportunities,
and Energy, Committee on Small
Business, House of Representatives

March 1990

COSMETICS REGULATION

Information on Voluntary Actions Agreed to by FDA and the Industry



141081

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Human Resources Division

B-237810

March 13, 1990

The Honorable Ron Wyden
Chairman, Subcommittee on Regulation,
Business Opportunities, and Energy
Committee on Small Business
House of Representatives

Dear Mr. Chairman:

In July and September 1988, your Subcommittee held hearings on the potential health hazards of cosmetics to both cosmetologists and their clients. At these hearings, it was reported that cosmetic products used by cosmetologists have caused problems including asthma, upper respiratory infections, skin diseases, reproductive complications, and neurological damage. Further, your Subcommittee made public a list of chemicals available for use in cosmetics that have been identified as causing—or being suspected of causing—harmful side effects. When tested in animals, the side effects included biological mutation, reproductive complications, acute toxicity, tumors, and skin and eye irritation.

In view of all this, you expressed concern with the limited authority of the Food and Drug Administration (FDA) to assure the public that cosmetics are safe. For example, FDA cannot require cosmetics manufacturers to

- register their establishments with FDA,
- test their products for safety and effectiveness, or
- report to FDA ingredients used in products and included in consumer complaints or safety test data.

In place of federal legislation that would give FDA additional authority to regulate the cosmetics industry, FDA and Cosmetics, Toiletry and Fragrance Association (CTFA) officials agreed at your September hearing to initiate certain actions. These actions are intended to improve the voluntary program for regulating the industry. Subsequently, you requested that we obtain information on whether these actions had been started. To respond to your request, we obtained information from FDA and CTFA officials on their actions during the January-October 1989 period to increase (1) voluntary registration of cosmetics establishments and (2) safety data and injury reporting by cosmetics manufacturers, packers, or distributors. We also obtained information on how FDA and the industry would rank toxic chemicals for safety review. Because of the

limited scope of our work, we did not verify the information obtained. This information is summarized below and presented in more detail in appendixes I, II, and III.¹

Background

FDA's regulatory authority over the cosmetics industry is less comprehensive than its authority over food and drugs. Consequently, in its oversight of the cosmetics industry, FDA must rely, in part, on voluntary industry cooperation. Since 1972, the industry has encouraged companies to voluntarily (1) register manufacturing establishments, (2) file data on ingredients, and (3) report cosmetics-related injuries.

In our 1978 report on cosmetics safety we reported that, as of December 1977, about 40 percent of the manufacturers and packers had registered their plants; less than 20 percent of the manufacturers, packers, and distributors had filed ingredient listings; and less than 4 percent had filed injury reports. We concluded that the effectiveness of FDA's regulatory actions was limited by inadequacies in both FDA's legislative authority and the industry's participation.² With the exception of the ingredient listings, FDA's reported participation rates in 1989 show a slight decrease since 1977. (See apps. I and II for current participation data.)

FDA is authorized to inspect cosmetics manufacturers, collect sample cosmetics for examination and investigation, and take action through the Department of Justice to remove adulterated cosmetics from the market.³ But FDA cannot require that cosmetics be safety tested before marketing. Further, FDA is not authorized to require manufacturers to (1) register their plants or cosmetics, (2) file data on ingredients, or (3) report cosmetics-related injuries.

¹Appendixes IV and V include information on other issues that you requested concerning (1) the industry's study of cosmetology licensing and education laws, as well as education programs, and (2) the industry's voluntary program for ingredient labeling of cosmetics used by professionals.

²Lack of Authority Hampers Attempts to Increase Cosmetic Safety (GAO/HRD-78-139, Aug. 1978).

³FDA regulations require that the safety of cosmetic ingredients and products be substantiated before marketing or, in the absence of such substantiation, that cosmetics not adequately tested be labeled with a prominent warning. However, FDA does have authority to require that color additives, except for hair dye containing coal tar, used in cosmetics be safety tested before marketing. Products containing coal tar are not considered adulterated if their labels bear a conspicuously displayed warning of the dye's potential safety hazard.

FDA estimates there are 2,000 to 2,500 cosmetics manufacturers and 4,000 to 5,000 distributors. For fiscal year 1987, FDA reported it had conducted 288 inspections of cosmetics establishments and for 1988, 284. For the first 11 months of fiscal year 1989, FDA reported 221 inspections. Not all reported inspections are comprehensive; some may be abbreviated inspections or visits to nonmanufacturing facilities such as warehouses. Each district office develops its own inspection schedule based on knowledge of what establishments are located in its district and its allotted staffing. There is no requirement prescribing how often cosmetics establishments or any other facilities are to be inspected. Further, inspection reports are kept in the district offices and FDA does not centrally maintain information on the results of inspections.

CTFA is the cosmetics industry's main trade association. CTFA's declared mission is to ensure that safe cosmetics are marketed without "unnecessary" regulatory restrictions. CTFA's membership consists of more than 256 companies that manufacture or package approximately 80 percent of the cosmetics marketed in the United States.

CTFA established the Cosmetic Ingredient Review Program (CIR) in 1976. The program is carried out through (1) an organization that collects safety testing and other pertinent data on chemicals used as cosmetics ingredients and (2) a panel of internationally recognized scientific experts who review the compiled scientific literature to determine whether an ingredient is safe.

Disagreement Over the Number of Companies Failing to Register

Registration is important because it serves as the basis for determining where FDA will conduct its inspections. These inspections are FDA's primary enforcement tool for overseeing the cosmetics industry. As part of an inspection, FDA may collect samples that are tested at FDA laboratories for adulteration.

FDA and CTFA officials reported to us that, since September 1988, they have taken measures to encourage greater industry participation in the voluntary registration program. These measures include reducing the paperwork necessary to register and emphasizing the importance of registration at industry meetings. FDA reports that the number of companies registered increased by 94, to 778, between 1988 and 1989.

There is major disagreement, however, between the estimates by FDA and CTFA on the number of companies that are not registered. FDA believes that less than 40 percent of manufacturers are registered; it

estimates that 1,300 to 1,800 are not registered. CTFA believes that many of the companies that FDA identified as not registered either are no longer in business or not involved with cosmetics.

Gaps in Safety Testing Data and Injury Reports

FDA does not have authority to require the industry to do safety testing and injury reports. FDA officials have found that many manufacturers lack adequate data on safety tests and have generally refused to disclose the results of these tests. CTFA officials report that they are encouraging manufacturers to cooperate more in meeting FDA's requests for safety data on cosmetics; FDA has not yet assessed whether CTFA efforts have helped.

FDA also estimates that about 3 percent of an estimated 4,000 to 5,000 cosmetics distributors have filed injury reports. CTFA officials challenge the need for increased participation because they believe that the current reporting covers about 60 percent of the cosmetics marketed. However, an FDA official said, FDA needs experience data on the specific formulation for each cosmetic to identify those that may present safety problems.⁴

FDA Has No Plans to Do Safety Reviews of Toxic Chemicals

At the Subcommittee's request, in January 1989, FDA gave the Subcommittee its outline for ranking a list of 884 toxic chemicals the Subcommittee noted (1) were in the Registry of Toxic Effects of Chemical Substances and (2) might be used in cosmetics. At about the same time, CIR provided its priority ranking of the same chemicals for safety review. FDA is studying the CIR report, but has not committed any resources to rank the chemicals and has no plan to review their safety.

Summary

Since the hearings held by your Subcommittee on the potential health hazards of cosmetics, FDA and industry officials report that they have taken steps to improve the voluntary program for regulating the industry. In spite of these efforts, disagreement continues between FDA and the industry as to the extent of participation in the voluntary registration program. Because FDA cannot mandate participation, it cannot accurately assess how many companies may be avoiding registration.

In addition, FDA has not assessed whether industry efforts have resulted in increased reporting of data on safety testing. Because it is a voluntary

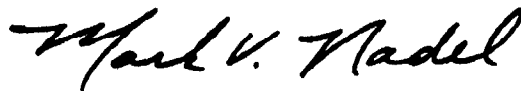
⁴A formulation is the chemical composition of a cosmetic presented in the statement on ingredients.

program, however, FDA will never be able to require reporting from all companies, particularly those that may be least likely to report because they have experienced problems with their cosmetics. Further, FDA officials continue to believe that they need injury reports on 100 percent of the cosmetics marketed.

Finally, FDA has been studying the industry report on toxic chemicals used in cosmetics, but has committed no resources to do its own safety reviews and ranking.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from its issue date. At that time, we will send copies to the Secretary of Health and Human Services as well as other interested parties and make copies available on request. If you have any questions concerning this report, please call me on (202) 275-5451. The other major contributors are listed in appendix VI.

Sincerely yours,



Mark V. Nadel
Associate Director, National
and Public Health Issues

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Abbreviations

CIR	Cosmetic Ingredient Review Program
CRS	Congressional Research Service
CTFA	Cosmetics, Toiletry and Fragrance Association
FDA	Food and Drug Administration

Efforts to Increase Voluntary Registration

FDA stated, at the September hearing, that it would attempt to get additional participation from the industry for voluntary registration and filing of formulations. Since then, FDA has responded to requests from manufacturers for registration forms and has continued its participation in the Independent Cosmetic Manufacturers and Distributors workshops; at these, all matters relating to cosmetics requirements are discussed, including product labeling and voluntary programs.

In addition, FDA and CTFA have identified ways to simplify the reporting process by reducing the information that must be reported. FDA has agreed that simplified reports may be implemented pending rulemaking. Changes in the voluntary reporting of cosmetics data will shortly be published in the Federal Register for public comment.

CTFA has, with FDA cooperation, developed a computer program to simplify the reporting process. In addition, the reports could be filed by electronic transfer to FDA, possibly reducing the clerical time needed to process them.

Although CTFA agreed to take steps to increase participation, it does not agree with FDA estimates that a large number of companies are not participating in the voluntary programs. FDA estimates a total of 2,000 to 2,500 companies are involved in manufacturing or packing cosmetics. This estimate is made up of the 684 companies that had voluntarily registered as of July 1988; another 741 companies that FDA had identified by name and believed should be registered; and about 600 to 1,100 additional companies FDA believes exist.

As part of CTFA's effort to increase participation, it conducted a survey of the 741 nonregistered companies FDA had identified. CTFA determined that only 190 of them were manufacturers or packers that were eligible to register. The other companies, according to CTFA, were no longer in business, not involved in cosmetics, or one of several companies listed under different brand names.

On identifying these 190 nonregistered establishments, CTFA provided each with information about the programs, including a packet of registration forms, and encouraged them to register. CTFA also gave the list of registered and nonregistered establishments to other industry associations, such as the Independent Cosmetic Manufacturers and Distributors; CTFA asked the associations to check the lists against their memberships and to encourage any of their nonregistered members to register.

In addition, CTFA has stressed the voluntary programs in newsletters, trade press, seminars, conferences, and correspondence with its members and other associations, including foreign associations. CTFA has provided packets of registration forms at seminars and conferences. As of March 31, 1989, CTFA had sent out at least 100 such packets in response to inquiries.

It will take about 1 year, FDA officials believe, before the results of CTFA's efforts to encourage participation in the voluntary programs are known. FDA data show that the number of registered manufacturers and packers increased by 94, to 778 (31 to 39 percent of those FDA estimates are eligible), as of July 1989, compared with 684 in July 1988. The number of filed formulations increased from 19,389 in July 1988 to 20,034 in July 1989 (40 to 50 percent of the total of 40,000 to 50,000 estimated by FDA). These were filed by 987 of the 4,000 to 5,000 companies FDA estimates distribute cosmetics, which may include manufacturers and packers.

Efforts to Increase Safety Data and Injury Reports

FDA does not have authority to require the industry to provide safety testing data and injury reports. FDA must rely on manufacturers to volunteer the data and reports.

The FDA Commissioner has stated that FDA investigators have found many manufacturers lack adequate data on safety tests of their cosmetics or, unless a significant safety issue has arisen, have refused to disclose the results of their tests. CTFA has encouraged manufacturers to cooperate more in meeting FDA's requests for safety data on cosmetics as part of its overall effort to encourage participation in the voluntary reporting programs. FDA is relying on CTFA's efforts to obtain more cooperation from industry in providing safety data.

Concerning injury reports, FDA estimates that about 3 percent of the estimated 4,000 to 5,000 distributors have filed such reports. In 1989, 141 companies (an estimated 2.8 to 3.5 percent) filed injury reports for calendar year 1988; 115 companies had filed reports for 1987. According to CTFA, the cosmetics handled by the companies that filed reports (1) included all categories of cosmetics—such as toothpaste, hairspray, or bubble bath—that are manufactured and (2) accounted for about 60 percent of the cosmetics marketed. CTFA therefore questions the need for increased participation in injury reports since “the companies that are filing injury reports are representative of the industry.” However, FDA needs experience data, an FDA official said, on each specific formulation to identify cosmetics that may present safety problems.

Ranking Toxic Chemicals for Safety Review

At the September 15 hearing, the Subcommittee made public a list of 884 toxic chemicals available for use in the manufacturing of cosmetics. These chemicals are listed in both the CTFA Cosmetic Ingredient Dictionary and in the National Institute of Occupational Safety and Health Registry of Toxic Effects of Chemical Substances. The Subcommittee expressed concern over the health implications of such chemicals in cosmetics and asked FDA to conduct safety reviews of them. FDA agreed to prepare an outline of how it would rank these chemicals for toxicological study, that is, safety review. CIR agreed to evaluate each chemical to determine its priority for safety review under CIR procedures.

FDA gave its outline to the Subcommittee in January 1989. Its ranking process included (1) deleting those chemicals not currently used in formulations, (2) deleting those already evaluated by FDA, CIR, or the International Fragrance Association's technical advisory committee, (3) identifying those already approved as food additives and food substances and reviewing the safety of their use (both on the body or within the body) in cosmetics, and (4) ranking the remaining chemicals on the basis of such factors as frequency of use in cosmetics, concentrations of use in formulations, known biological activity, and anticipated skin penetration.

CIR presented its evaluation report to the Subcommittee on January 30, 1989,¹ and scheduled 130 chemicals for safety review. The remaining chemicals were not scheduled because they (1) were already regulated by FDA, (2) had been determined by the industry to be safe, (3) were already under review by FDA, or (4) had little or no use in cosmetics. CIR believes that there were no major safety concerns in connection with any of the ingredients on the list.

Since completing its outline, FDA has taken no further action. Officials of FDA's Division of Colors and Cosmetics said (1) no resources have been committed to rank the chemicals and (2) no specific plan exists to do safety reviews. FDA is studying the CIR report to identify any differences in how FDA would rank the chemicals.

¹CIR, Report to Congressman Ron Wyden on Review of the 884 Chemicals Listed in the NIOSH Registry of Toxic Effects of Chemical Substances (RTECS) Which Are Also Listed in the CTFA Cosmetic Ingredient Dictionary (Washington, D.C., Jan. 1989).

CTFA Study of Cosmetology Licensing and Education Laws

State and local licensing agencies, through their licensing requirements, are responsible for (1) regulating the safe use of cosmetics in beauty salons and (2) training cosmetologists to handle cosmetics safely. The industry reviewed the adequacy of the licensing requirements and the education programs and is taking action to compensate for the shortcomings found.

To determine whether requirements are adequate to assure proper handling of cosmetics by cosmetologists in beauty salons, CTFA conducted a study of existing state and local licensing and education laws for cosmetology. Although states had general workplace safety laws, only a few had specific provisions covering beauty salons. Thus, CTFA drafted a model regulation, which can be adopted by state agencies, to provide for specific coverage of beauty salons. The regulation covers the safe use of cosmetics, workplace practices, and training of cosmetologists.

The model regulation was developed by CTFA in cooperation with four other industry associations—the American Beauty Association, National Cosmetology Association, Independent Cosmetic Manufacturers and Distributors, and American Health and Beauty Aids Institute. It was approved by CTFA's board of directors at its May 1989 meeting. CTFA will work with the National Cosmetology Association, which has 50 state organizations, to promote adoption of the model regulation.

CTFA also conducted a review of the existing education programs in cosmetology schools to determine whether they provide adequate instructions about the safe handling and use of cosmetics. Because CTFA found that safety information is available from a number of sources but may be in language too technical for cosmetology students, CTFA drafted a brochure to be used by cosmetology schools to educate cosmetologists. The brochure pulls together basic safety information in simplified, non-technical language and provides references to more detail for those who want it.

Voluntary Program for Ingredient Labeling

Cosmetics not customarily distributed for retail sale are exempt from FDA requirements for ingredient labeling. Therefore, cosmetologists and other professionals, as well as their clients, may not know what chemicals are in the cosmetics used in nonretail businesses, such as beauty salons. At the September hearing, CTFA made a commitment to (1) develop a new ingredient labeling program for cosmetics used in such places and (2) get agreement, within 6 months, with the other four cosmetics industry associations on how to implement the labeling program.

Since then, CTFA, in cooperation with the four associations, has developed and gotten association members' agreement to participate in a new voluntary labeling program. The program has been publicized in the industry through publications and meetings. CTFA has given information on the program to the Professional Hair Care and Beauty Trades Division of the United Food and Commercial Workers Union, which represents over 40,000 hair care professionals who use these cosmetics. The new program applies to cosmetics manufactured on or after December 31, 1989.

FDA has endorsed the industry's proposed voluntary labeling program. At the September 15 hearing, the FDA Commissioner said that he was pleased that the industry had agreed to work on providing information on cosmetics ingredients through several approaches, including a voluntary labeling program. Further, he agreed to oversee the labeling program, ensuring that it meets the needs of cosmetologists, their clients, and the physicians who see them. Since the program begins during fiscal year 1990, FDA investigators will not be checking on the extent of voluntary compliance under the program until fiscal year 1991.

Manufacturers have two options for presenting ingredient information—(1) alphabetically (with a statement explaining the order) to facilitate identification of professional cosmetics that have been diverted to the retail market or (2) in descending order by volume for cosmetics legally sold at retail. The information can be provided on the container, attached tag, or package insert.

Cosmetics sold at retail, that is, diverted, are misbranded under the Federal Food, Drug, and Cosmetic Act unless their ingredients are listed in descending order by volume. CTFA said diversion (1) places cosmetics for professional use in the hands of untrained consumers who may not have the skill necessary to apply them as required to safely achieve the

desired results and (2) does economic damage to salons and to manufacturers of cosmetics for professional use. Thus, CTEA believes that the option of alphabetical listing of ingredients is essential to the labeling program's success.

On learning of the industry's proposed voluntary program for ingredient labeling, the Subcommittee suggested that the label also include the phrase "For Professional Use Only." The industry took the position that "such a phrase would prohibit distributors from prosecuting someone who diverted the cosmetics from their intended use to the retail market." Therefore, the industry was not going to include this phrase in the new labeling program.

The Congressional Research Service (CRS), which reviewed the industry's position at the Subcommittee's request, concluded in a January 27, 1989, letter to the Subcommittee that (1) only FDA had the right to proceed against violators of labeling requirements and (2) such a phrase did not necessarily strengthen or weaken the prosecuting ability of FDA.

In its letter, CRS stated that manufacturers or distributors might have a private right to action for breach of contract; this is because, presumably, the sale and delivery of cosmetics to nonretail businesses are carried out under either a contract or franchise agreement that may include language that prohibits resale of cosmetics. If the contracts were so worded, CRS concluded that the inclusion of the "For Professional Use Only" phrase on cosmetics sold to nonretail businesses would probably strengthen such actions. We agree with the CRS conclusions.

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