COMPTROLLER GENERAL OF THE UNITED STATES
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The Honorable Harrison A. Williams, Jr.
Chairman, Committee on Human Resources
United States Senate

Dear Mr. Chairman:

We have reviewed S. 2365, a bill to amend the Federal Food, Drug, and Cosmetic Act (FD&C Act) with respect to cosmetic safety, as requested by your letter of January 11, 1978. We believe the bill could be strengthened by providing the Food and Drug Administration (FDA) additional authority to regulate coal tar hair dyes and cosmetic preservatives.

Many of the colors used in coal tar hair dyes are known to cause or suspected of causing cancer and there are indications that these colors may be absorbed through the scalp, thereby posing a potential hazard to consumers. Exemptions granted to coal tar hair dyes under sections 601(a) and 601(e) of the FD&C Act currently prevent FDA from effectively regulating these dyes. Although S. 2365 would repeal the 601(a) exemption, the 601(e) exemption would remain in effect.

Since July 12, 1960, the color additives amendments to the FD&C Act have required the establishment of regulations listing color additives that are safe for use in food, drugs, and cosmetics. Under these amendments, FDA must approve a color additive for safety before its use in cosmetics is permitted. However, section 601(e) of the Act exempts coal tar hair dyes from these requirements.

We believe that coal tar hair dyes should be subject to the same regulation and safety appraisal as other cosmetics. Our report of December 6, 1977, to the Chairman of the Subcommittee on Oversight and Investigations, Committee on Interstate and Foreign Commerce, United States House of Representatives, entitled "Cancer and Coal Tar Dyes: An Unregulated Hazard to Consumers," recommended that the Congress repeal the exemptions in both sections 601(a) and 601(e) of the FD&C Act to enable FDA to better regulate coal tar hair dyes. We therefore recommend that S. 2365 be amended to repeal the exemption in section 601(a).

We also believe that it is necessary to prove the effectiveness of preservatives used in cosmetics. S. 2365 does not provide FDA

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authority to require manufacturers to prove the effectiveness of preservatives used in cosmetics to prevent the growth of potentially harmful microorganisms. Eye cosmetics that are free of microorganisms when the product is marketed can become contaminated with pathogenic organisms during use because they do not contain an effective preservative. FDA could better insure the safety of eye makeup and other cosmetics providing a good medium for microbial contamination if it had authority to require manufacturers to prove the effectiveness of the preservatives used in their products. We recommend that the committee amend the bill to provide FDA such authority.

Sincerely yours,

[redacted] KELLER

[redacted] Comptroller General
of the United States

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