Revocation of Advisory Opinion Entitled “FD&C Act Trade Correspondence 61”

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; revocation.

SUMMARY: The Food and Drug Administration (FDA) is revoking an advisory opinion entitled “FD&C Act Trade Correspondence, TC–61,” (hereinafter called TC–61) dated February 15, 1940, because it is out of date with current scientific knowledge and is superseded by the final rule for over-the-counter (OTC) sunscreen drug products. As an advisory opinion, this correspondence was not published in the Federal Register.

EFFECTIVE DATE: (Insert date 30 days after date of publication in the Federal Register.)

FOR FURTHER INFORMATION CONTACT: John D. Lipnicki, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION: TC–61 is a 1940 advisory opinion regarding the drug and/or cosmetic status of sunburn and suntan preparations. TC–61 states that a product promoted for prevention of damage from the sun is a drug, and a product that is promoted solely for the purpose of acquiring an even tan can be considered a cosmetic. The agency updated this policy in 1976, by stating that a product containing a sunscreen ingredient, even when labeled solely as a tanning aid, is both intended and understood to be a sunburn preventive and, therefore, is a drug under the Federal Food, Drug, and Cosmetic Act (the act).
In the Federal Register of May 12, 1993 (58 FR 28194), FDA published a proposed rule for OTC sunscreen drug products. That document included a proposal to revoke TC–61 (58 FR 28204). One comment was received in response to the proposal to revoke TC–61. That comment
did not change the agency's position and is addressed elsewhere in the rule section of this issue of the Federal Register. Therefore, under the act and under authority delegated to the Commissioner of Food and Drugs, TC–61 is revoked.

Dated: 

May 10, 1999

William K. Hubbard
Associate Commissioner for Policy Coordination

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