NOTIFICATION

Addendum

The following communication, dated 15 April 2019, is being circulated at the request of the delegation of the United States of America.

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TITLE: Safety and Effectiveness of Consumer Antiseptic Rubs; Topical Antimicrobial Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS

ACTION: Final rule; finding of ineligibility for inclusion in final monograph

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing this final action establishing that certain active ingredients used in nonprescription (also known as over-the-counter (OTC)) consumer antiseptic products intended for use without water (referred to throughout as consumer antiseptic rubs or consumer rubs) are not eligible for evaluation under the OTC Drug Review for use in consumer antiseptic rubs. Drug products containing these ineligible active ingredients will require approval under a new drug application (NDA) or abbreviated new drug application (ANDA) prior to marketing. FDA is issuing this final action after considering the recommendations of the Nonprescription Drugs Advisory Committee (NDAC), public comments on the Agency's notices of proposed rulemaking, and all data and information on OTC consumer antiseptic rub products that have come to the Agency's attention. This final action finalizes the 1994 tentative final monograph (TFM) for OTC consumer antiseptic rub drug products that published in the Federal Register of 17 June 1994 (the 1994 TFM), as amended by the proposed rule published in the Federal Register (FR) of 30 June 2016 (2016 Consumer Antiseptic Rub proposed rule).

Effective 13 April 2020.

<https://members.wto.org/crnattachments/2019/TBT/USA/19_2197_00_e.pdf>

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