FDA sends Procter & Gamble a warning

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The U. S. Food and Drug Administration has warned the Procter & Gamble Co. about claims it makes for its Vicks Early Defense Foaming Hand Sanitizer.

The agency said the product's claims and directions for use cause it to be an unapproved new drug under the Federal Food, Drug, and Cosmetic Act.

The FDA specifically citied P&G for promoting Early Defense for use by schoolchildren to prevent colds and to provide antimicrobial activity for up to three hours. Officials said the product has not been proven safe and effective for such claims.

Under its drug monograph system, the FDA allows OTC drugs to be marketed without first obtaining agency approval in certain circumstances. Such drugs must comply with applicable standards regarding monographs that specify conditions for the drugs' labeling and formulation.

In the Procter & Gamble case, the Cincinnati-headquartered company's claims the product prevents colds and provides up to three hours of antimicrobial activity are not allowed.