

NDA withdrawn for fluoride and vitamin combinations

The FDA has addressed a “regulatory letter” to approximately 35 companies marketing combination drugs consisting of fluoride and vitamins. The letter states that these drugs are related to a product (Enziflur lozenges) for which FDA has withdrawn approval of a new drug application. The NDA for Enziflur was withdrawn because there is no substantial evidence of drug effectiveness as prescribed, recommended, or suggested in its labeling.

The FDA has therefore advised manufacturers of combination fluoride and vitamin preparations that their continued marketing is in violation of the new drug provisions of the *Federal Food, Drug, and Cosmetic Act*; they have, therefore, requested that marketing of these products be discontinued.

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