regulatory policy decisions and actions. As demonstrated in the Appendix to Legal Analysis, FDA has used both general knowledge and recognition of products' nature and effects, as well as their actual uses and effects, to determine whether products fall within the statutory definitions of drug or device.

FDA has used the known or inherent pharmacological effects of particular ingredients to determine that products are "intended to affect the structure or any function of the body," even where there are no public expressions by the seller that the product is to be used for those effects. See Appendix to Legal Analysis. For example, in the context of a proposed rule on vaginal products for over-the-counter use, the Agency stated:

If an active ingredient is present in a therapeutic concentration, the product is a drug, even if that product does not claim to produce the effect which will result from the action of the therapeutically effective ingredient.

48 Fed. Reg. 46694, 46701 (October 13, 1983). In its tentative conclusion to comments on this issue, the Agency reiterated:

[t]he type and amount of ingredient(s) present in a product, even if that product does not make explicit drug claims, must be considered in determining its regulatory status. For example, the mere presence of a pharmacologically active ingredient could make a product a drug even in the absence of explicit drug claims. In these cases, the intended use would be implied because of the known or recognized drug effects of the ingredient (e.g., fluoride in a dentifrice).

59 Fed. Reg. 5226, 5227 (February 3, 1994) (emphasis added).

Thus, products containing ingredients or components with known pharmacological effects, including fluoride and hormones, have -- on that basis alone and in the absence of express claims -- been determined to be "intended to affect the structure or function of the body" because they contained a pharmacologically active ingredient. See Appendix to Legal