

III. Claims

III. Clarifying Comments on Claims for Antigingivitis/Antiplaque Ingredients

A. Use of the Three Verbs in Section 356.65(1)

The Subcommittee recommended the use of one of three verbs to express the antigingivitis claim in 356.56(1):

"...helps [select one of the following: 'control,' 'reduce,' or 'prevent'] [select one or more of the following: '[bullet] gingivitis,' '[bullet] gingivitis, an early form of gum disease,' or '[bullet] bleeding gums']."

Simply put, control, reduce and prevent have different meanings:

- Control: restrain, contain
- Reduce: diminish, decrease
- Prevent: block, hinder

Since the Subcommittee concluded that these verbs accurately defined the effects of the intended uses of antigingivitis products, companies should be able to use any one or more of these verbs depending on the intended use of their products, since these verbs have different meanings.

B. Use of the Disclaimer for the Antiplaque Claim in a Product Making an Antigingivitis Claim

In 356.65(b)(3), the Subcommittee recommends the following claims for all antigingivitis/antiplaque products:

"...helps [select one of the following: 'control,' 'reduce,' 'prevent,' or 'remove'] plaque that leads to [select one or more of the following: '[bullet] gingivitis,' '[bullet] gingivitis, an early form of gum disease,' or '[bullet] bleeding gums']."

While the same point in relation to the use of the selection of verbs is relevant here, and therefore is made by reference to the previous section, a second equally relevant point is important to consider in relation to this claim.

The plaque claim in proposed Section 356.65(b)(3) is only intended to be used on products that are classified as antigingivitis/antiplaque drug products. Such products would always bear the antigingivitis claim in proposed Section 356.65(b)(1):

"...helps [select one of the following: 'control,' 'reduce,' or 'prevent'] [select one or more of the following: '[bullet] gingivitis,' '[bullet] gingivitis, an early form of gum disease,' or '[bullet] bleeding gums']."

This means that an antigingivitis/antiplaque product might, for example, bear the claims:

- Helps prevent gingivitis, an early form of gum disease
- Helps remove plaque that leads to gingivitis an early form of gum disease.

Since the totality of the labeling for such a drug product would include by regulation a specific antigingivitis claim, there can be no question that any mention of plaque is in the context of a drug claim related to gingivitis.

Similarly, as pointed out in the joint task group's comments, a product making a cosmetic claim for plaque with no drug claims per se would be qualified as a cosmetic through the totality of its labeling.

Hence, we recommend that FDA permit the simple use of the phrase "controls plaque" (or "reduces plaque" or "prevents plaque", or any combination of verbs with "plaque") without the qualifier of gingivitis or bleeding gums on those drug products bearing the required labeling for an antigingivitis drug claim.

In conclusion, we submit these comments by way of sharing our perspective on selected aspects of the development of a Final Monograph on OTC antigingivitis/antiplaque products.