Knowing these top ten code infractions may help you submit APS which are closer to approval. The infractions are ranked in order of frequency (#1 being the issue most frequently encountered by reviewers in 2008).

10.0 Ensure that the content is fair and not overly selective. For example, if discussing endpoints for which the promoted brand was better than a competitor, also disclose the endpoints for which the competitor was better or the endpoints for which no statistically significant difference could be detected. PAAB code s3.5 & 5.12.

9.0 Ensure that study result are conveyed in a manner emphasizing the actual treatment effect for evaluated groups (rather than relative treatment effects such as relative risk reduction). When the data presentation includes data expressed in relative or proportional terms, the actual treatment effects (eg: absolute risk reduction and number needed to treat) should have, at least, equal prominence. PAAB code s4.2.3.

8.0 Ensure that non-clinically significant claims are kept separate and distinct from clinically significant claims. Otherwise, the presentation may accord clinical significance to the non-clinically significant claims. PAAB code s3.1.4/ 2.6.2/ 5.10.2.iii.

7.0 Ensure that quantifiable claims are quantified (eg: for claims like "long duration" and "low incidence" quantify how long and how low within the body of the piece). PAAB code s4.2.

6.0 Ensure that utilized studies are well designed (eg: randomized, blinded and controlled). Also ensure that they have been published in peer-reviewed journals. PAAB code s3.1.1 & 3.1.2 & 5.7 & 5.8.

5.0 Ensure that the advertisement reflects an attitude of caution. For example, the fair balance should appear within the body of the ad (above references and footnotes and product logos and in a font size which is similar to the claim copy). Also ensure that all relevant safety copy is present. PAAB code s2.4.

4.0 Ensure that submitted claims are not absolute. Keep in mind that a claim does not necessarily need to state words like "100%", "completely" or "everyone" in order to be considered absolute. Ask yourself whether the word "help", "generally", or "profile" are required. PAAB code s2.6.

3.0 Ensure that all comparative claims identify the comparator (ie: avoid hanging comparisons such as "ARBace demonstrated more blood pressure reduction"). PAAB s5.6.i.

2.0 Ensure that study related claims are worded in a study context (ie: utilize the past tense). PAAB s2.3.

1.0 Drum role please… Ensuring that all product statements are consistent with the product monograph (PM) may save you from receiving a response with our most frequently quoted code infraction. The PM takes precedence over the guidelines, and newly published landmark studies. PAAB code s3.1