Extended Dosing Regimens

Question 23a. If the modified or extended dosing regimen does not expose a women to a greater daily or monthly quantity of either hormonal component of an approved and marketed otherwise identical product, does a Sponsor need to meet any criteria other than the criteria for efficacy and safety required for a traditional 21/7 product?

Question 23b. If so, what should these criteria be?

Question 24. If the modified or extended dosing regimen exposes a woman to a greater daily or monthly quantity of either hormonal component of an approved and marketed otherwise identical product, what are the additional criteria that a Sponsor needs to meet to support approval for marketing?

Question 25. In reviewing extended regimens, how should the Division balance a decrease in scheduled bleeding against an increase in unscheduled bleeding?

Question 26. What cycle length should be used when analyzing cycle control in extended cycle products?