

Role and Impact of Labeling

Question 30a. Can labeling information be made more useful for counseling patients to better inform patients about the likely effectiveness, safety, and other “acceptability considerations” (e.g., that a reduction in scheduled bleeding may be offset by an increase in unscheduled bleeding)?

Question 30b. Would such information likely reduce discontinuation rates and improved actual product effectiveness?

Question 31. Should product labeling be modified to include pregnancy rates or safety data for specific subgroups when available?

Question 32. How do we communicate the risk of an unplanned pregnancy in the days or weeks immediately following discontinuation of a product?

Question 33. How can labeling best communicate how to manage a situation where a patient misses pills?

Question 34. Should potential secondary, non-contraceptive, benefits of hormonal contraceptives be discussed in labeling?