

OMB-FDA Q&A
Focus Groups to assess the post-marketing safety of authorized generic drug products
June 2016

OMB Question:

Question for you about these focus groups. The supporting statement notes:

Information from these focus groups will be used to assess physicians' and pharmacists' knowledge of and beliefs about authorized generic drug products. Specifically, we aim to: (1) Assess physicians' and pharmacists' knowledge of and experience with authorized generics; (2) Elicit their opinions about whether, when, and why they would prefer that patients use authorized generics over brand-name or other generic products; and (3) Determine the price premium they would place on authorized generics relative to other products.

Why are pharmacists and physicians' views on the price (#3 above) helpful to know? Since they aren't the payers, we are trying to understand the relevance of their views on pricing.

FDA Response:

The pricing issue is less about participants' views on pricing and more about how they value authorized generics. Framing it around pricing gives us the opportunity to quantify the value that they place on authorized generics (if any) over independent generics.