Industry News

FDA Update: Guidance on Presenting Quantitative Efficacy and Risk Information in Pharma Advertising

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On the heels of a proposed federal regulation that would require the inclusion of drug prices in television ads, it appears more change is underway for pharmaceutical advertising.

Last month, the FDA issued a draft of a 10-page document that provides industry guidance on how to appropriately present quantitative efficacy and risk information in direct-to-consumer (DTC) pharmaceutical labeling and advertising. The guidance covers all DTC channels: print, digital, and AV broadcast. The FDA is drafting these guidelines to "improve consumers' accuracy in estimating the drug's benefits and risks."

The draft guidance issues recommendations in 4 key areas:

Probability Presentations

- Quantitative efficacy or risk information should be presented in numerical terms of absolute frequencies (e.g., 57 out of 100) or percentages (e.g., 57%) rather than relative frequencies
- If relative frequencies must be used, include sufficient context and include corresponding absolute probabilities

Formatting Information

- Be consistent with formatting information within a single document, providing all probabilities in either absolute frequencies or percentages rather than in a mix of both formats, or use a mix of qualitative and quantitative descriptions
- Consider using denominators that are multiples of 10
- Express probabilities using whole numbers as long as these numbers accurately reflect the numerical value being described

Visual Aids

- Graphs, tables, and icons can improve consumer comprehension of quantitative efficacy or risk information
- Prioritize clarity and comprehension when choosing a visual aid
- Visual aids should include a description of their purpose and of the elements being displayed
- Graphic representations of numeric information should be proportionate to the quantities being described

Control Groups

- Include quantitative efficacy or risk information for both the treatment group and the corresponding control group
- The comparator used for the control group should be clearly communicated

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This FDA guidance leaves an element of subjectivity when choosing how to present quantitative data, but the goal is to make advertising more consumer-friendly and easier for the general public to comprehend. We encourage all brand teams to read the guidance in full.

The draft guidance is not finalized, but clients are advised to follow the FDA recommendation moving forward. Please reach out to your Evoke Client Services team for guidance on how this may impact your brand assets.