FDA in Brief: FDA seeks input on making sure the drug risk information in statements included in direct-to-consumer broadcast advertisements accurately informs consumers

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> "In addition to providing consumers with the benefits of the potential treatment, today's direct-to-consumer prescription drug advertisements must also present the risks. But if the risks aren't provided in a way that consumers understand, they may not be able to appropriately weigh the benefits and risks," said FDA Commissioner Scott Gottlieb, M.D. "The FDA's own research on broadcast TV drug advertisements suggests that a more targeted method for delivering risk information may lead to better retention of those risks. To inform our policies on how risks should be disclosed, we're asking consumers, providers and other members of the public to help us better understand what risk information is most useful in TV and other broadcast ads. Our goal is to make sure consumers who view broadcast ads walk away properly informed of the key potential tradeoffs of using a prescription medicine."

Americans should be confident that the information in the advertisements they see on prescription drug products is truthful, non-misleading and balanced – and appropriately represents both the risks and benefits of the

drug. The FDA plays an important role in helping to ensure that when firms choose to advertise prescription drugs directly to consumers and patients, such advertisements provide this balanced information in a way the public can fully understand.

When considering a change to the FDA's policy on direct-to-consumer drug advertisements, the agency often examines and conducts research to ensure that any changes are grounded in science and will have the greatest benefit to public health. For this reason, the FDA conducts research about the content and delivery of drug advertisements to ensure it is delivered in a way that will optimize healthcare professional and patient understanding of the benefits and risks of prescription drugs. Our research on presentations of risk information in broadcast TV ads suggest that a more targeted presentation of risks may lead to better retention of the most relevant potential side effects that consumers should weigh as they inform their decisions. Based on that research, the agency is exploring the usefulness of limiting the risks in the major statement for most drug advertisements to those that are severe (life-threatening), serious or actionable, coupled with a disclosure to alert consumers that there are other product risks not included in the advertisement.

The FDA is interested in hearing from stakeholders, including consumers and medical professionals, about the information that should be included in the disclosure of risk information in direct-to-consumer broadcast advertisements for prescription drugs. To facilitate this feedback, the FDA issued a Federal Register notice requesting comments to a public docket. More information on how to submit feedback on the content of risk information in direct-to-consumer broadcast advertisements for prescription drugs and the questions posed can be found in the Federal Register notice.