

FDA Fact Sheets: Direct-to-Consumer Advertising

Medical device manufacturers risk violating the *Federal Food, Drug, and Cosmetic Act* (FDCA) if their advertising in support of a product are not consistent with product's FDA cleared or approved use. The regulation of promotional materials and activities also fall within the jurisdiction of the Federal Trade Commission. Industry takes its responsibilities seriously to ensure compliance, foster responsible and informative DTC communications, and encourage discussion with health care professionals to learn about healthcare treatment options.

Under FDCA, manufacturers, packers, and distributors who advertise “restricted devices” must include, in every advertisement, particular information regarding the device's uses and risks. In order to be designated as a restricted device, FDA imposes the restriction by regulation as a condition of a PMA approval. As required by FDCA, advertisements for restricted devices must contain a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications. Device advertising must also be consistent with a device's labeling and may not discuss unapproved uses of a product.

FDA regulations require that consumer-directed advertisements:

- Are not false or misleading;
- Offer information about effectiveness and risk in a balanced manner;
- Convey through a major statement the device's most significant warnings, precautions, side effects, and contraindications in consumer-friendly language; and
- Relay information relating to device indication and include a statement on intended use(s) and any limitations of use in consumer-friendly language.

Apart from DTC advertising, “help-seeking” and other disease awareness broadcast communications that help consumers recognize symptoms, but do not specifically mention the name of a drug or device are not subject to FDA's risk disclosure requirements. However, in cases where the disease is only associated with one company's commercially available product or if communications can closely be tied to existing drug or device advertisements (through graphic visual, thematic and other presentation elements), FDA may treat the communication as an advertisement and apply appropriate risk disclosure regulation.