Updates on Compliance Action Approach to Promotion, Advertising, and Labeling for Medical Devices

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Office of Compliance (OC)

- OC's mission:
  - To protect and promote public health by evaluating, enhancing, and ensuring compliance with medical device laws
- OC's vision:
  - To take actions that enable maximum device safety and effectiveness

CDRH Compliance Action Approach

- OC takes **targeted, risk-based** compliance actions that address **significant violations** of device-related laws.
  - We also promote public health by facilitating innovation and **fostering a culture of quality** within an ever-expanding global medical device market.

CDRH Compliance Action Approach

Focused on the following:

- Impact on patients
- Resolution of violations or issues
- Proactive collaboration and timely communication
- Use of non-enforcement actions (outreach)
  - To resolve less significant issues
- Risk-based on significant violations
  - Premarket clearance and approval
    - No PMA or 510(k)
    - Modification of a 510(k) cleared device or a 510(k) exempt device (when applicable)
  - Labeling, advertising and promotion
    - Restricted medical devices
    - False or misleading statements

OC Benefit-Risk Guidance

Benefits

Type of benefits(s), magnitude of benefit(s), likelihood of patients experiencing one or more benefits, duration of effects, patient perspective on benefit, benefit factors for HCPs or caregivers, medical necessity

Risks

Severity of harm, likelihood of risk, distribution of nonconforming devices, duration of exposure to population, false-positive or false-negative results, patient tolerance of risk, risk for healthcare professionals or caregivers

Additional Factors

Uncertainty, mitigation, detectability, failure mode, scope of the device issue, patient impact, preference for availability, nature of violations or nonconforming product, firm compliance history

Final Guidance: Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions

Finalized December 2016

Allegations of Regulatory Misconduct

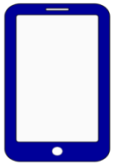
- A claim that a medical device manufacturer or individuals marketing medical devices may be doing so in a manner that violates the law

- Can help FDA identify potential risks to patients

- Anyone can report an allegation

Reporting Allegations

Ways to Report Allegations of Regulatory Misconduct

Regular Mail	Email	Phone	Online Form
			
	OCMedicalDeviceCo@fda.hhs.gov	240-402-7675	Allegations of Regulatory Misconduct Form

Attention: Office of Compliance
Center for Devices and
Radiological Health
Food and Drug Administration
WO Bldg. 66 RM 3523
10903 New Hampshire Ave
Silver Spring, MD 20993

Division Contact Information

- **Telephone Number**

  301-796-5770

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  301-847-3138

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