

Proactive Approaches to Communicating with FDA

Formal Advisory
Request Process

Request for
meeting

Submit a
complaint about
competitor

Voluntary
Compliance

Advisory Request Process

Why

- Area of uncertainty for company
- Mitigate risk for potential violation

When

- Prior to promotion in marketplace
- Promotion with great public exposure
- New product campaign
- Interpreting new FDA Guidance

How

- Cover letter, proposed promotion, references
- Note to reviewer, optional
- Separate submission path from 2253; eCTD or paper
- Launch vs Non-Launch

Strategic Considerations

Go-to-Launch
Promotion vs
Seek Advice

Aspect to
Mitigate

Best Tactic
Type

Length of
Time for
Response

Option to
withdrawal

Potential Consequences

Receive Written Correspondence from FDA

Potential Impact to Active Promotion for Requested Product
and Other Products

Receive Change of Opinion with 90 days to Update Active
Promotion *[21 CFR 202.1 (j)(4)]*

Advice Difficult to Interpret

Request a Meeting

Potential Purposes

- Input on Study Design for Future Use in Promotion
- Interpret new FDA Guidance
- Innovative Promotional Approach

Response

- Rarely Granted – Prior to Written Correspondence or Prior to Product Approval
- Typically Granted – After Enforcement Action
- If Granted – Teleconference Format with Pre-Reads and Specific Questions

Complaint about Competitor Activity

What? Alert OPDP by providing examples of potential violation

How? Identify areas of concern
Notify OPDP via call first
Submit letter via postal mail

FDA Response Acknowledge receipt and conduct assessment
May request update on status after complete or action taken

Voluntary Compliance Communication

Inform FDA when company identifies potential violation of its promotional material already introduced into marketplace

Content

- Description of promotion
- Concern
- Public exposure
- Company actions to rectify
- Actions taken to prevent reoccurrence

Strategic Consideration

- Demonstrates company active surveillance program to self-identify and correct
- Shows understanding of laws/regulations and intention to disseminate compliant communications

Potential Consequences

- Regardless of proactive notification, FDA could still enforce
- Company could be alerting FDA to issue that may have been otherwise missed