

Step Back and Think Through the Process

- Responses to inquiries from the agency, adverse event reports, other communications
- FDA inspections
- Response to FDA Form 483s
- Response to FDA Warning Letters and Untitled Letters

Responding to the Government Involves Legal Risk

Statements ...

- Must be truthful and accurate
- Are discoverable in litigation
- May become publicly available

*More than Just Individual Criminal and
Civil Exposure*

Risk to the Company: Product Liability Litigation

Responses to FDA can lead to ...

- Notice to plaintiff's lawyers
- Loss of preemption defenses
- Evidence of non-compliance
- Difficult admissions

Risk to the Company: Shareholder Derivative Actions

Does regulatory action pose a ...

- Threat of criminal investigation?
- Threat of disruptions in manufacturing?
- Threat of fines?
- Threat of product liability litigation?

Lesson: When FDA Comes Knocking, Legal Needs to Be Involved

- Legal's role is to:
 - Understand and evaluate risk
 - Protect the company from legal jeopardy
 - Facilitate open discussion about difficult compliance issues
- Legal cannot properly execute its function to protect the company if it is unaware of interactions with government regulators