HCCA Research Compliance Conference

What Every Compliance Professional Should Know About Dealing With The FDA

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June 13, 2011

Key Take-Aways

- Insights into what’s going on at FDA today
- Examples of new areas of focus for FDA
- Tools to deal with the FDA
The Old FDA

- Slow
- Entangled in its own bureaucracy
- Alleged by some to be too friendly with the industry it was supposed to regulate

What is the Current Climate Inside FDA?

- New Administration
  - “Old Guard” out
  - New management
- Significant increase in new field inspectors
- Increased enforcement
- Use of a more flexible regulatory approach
What is the Current Climate Inside FDA?

- Use of a public health approach to the law
- What is the right policy approach to address the new challenge?
- How can the law help the agency get as close as possible to the best solution?

FDA cannot inspect its way to safety and must apply the basic principle of prevention to imports.
- Better controls at the point of production
- Hold importing companies responsible for their supply chain
What’s Going on at FDA Today?

- Enforcement actions (including BIMO)
  - Prompt
  - More (which shows FDA is, “…on the job.”)
  - Less involvement of FDA’s Chief Counsel
- Imports
  - Foreign and domestic registration and listing
  - Lower threshold for entry refusal

What’s Going on at FDA Today?

- Recalls
  - More “Class I” recalls
  - Very early FDA press releases
  - Risk management by FDA for industry sectors
- Aggressive plans to regulate software
New Areas of Focus for FDA

- Revamping the 510(k) process
- Establishment of international offices
- Off-label promotion
- Individual responsibility (Park Doctrine)
- Transparency
- Laboratory-developed tests

FDA Discretion

- Case law shows that FDA has a great deal of discretion in its interpretation of the FDCA.
  - “[The] Food, Drug, and Cosmetic Act (FDC Act) provides [the] Food and Drug Administration (FDA) with broad authority to regulate food, drug and dietary supplement products in order to ensure public health and safety.”
  - Nutritional Health Alliance v. Food and Drug Administration, 318 F. 3d 92 (2003)
FDA Limitations

- However, some limitations have been imposed on FDA’s level of discretion
  - Regulatory authority exercised by the agency must be rooted in statute
    Nutritional Health Alliance v. Food and Drug Administration, 318 F. 3d 92 (2003)
  - FDA must treat all similar products in a similar manner
  - Interpretation of the FDCA is subject to the intent of Congress and subsequent congressional actions

FDA Limitations

- 5 U.S.C.A. § 706 requires that government agencies’ actions must not be unlawfully withheld or unreasonably delayed and that agency action, findings, and conclusions must not be
  - Arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law
FDA Limitations

- Contrary to a constitutional right, power, privilege, or immunity
- In excess of statutory jurisdiction, authority, or limitations, or short of statutory right without observance of procedure required by law
- Unsupported by substantial evidence
- Unwarranted by the facts to the extent that the facts are subject to trial de novo by a reviewing court

FDA Information

- Sources of Information for FDA Requirements
  - Federal Food, Drug, and Cosmetic Act
  - Code of Federal Regulations
  - Federal Register
  - FDA Guidance Documents
  - FDA Regulatory Procedures Manual
  - FDA Compliance Program Manual
  - FDA Compliance Policy Guides
  - Case law
FDA Information

- Sources of Information for FDA Requirements
  - FDA Website
  - Informal meetings with FDA personnel
  - Formal FDA meetings
  - FDA public presentations
  - Trade press

FDA and the Outside World

- FDA Oversight
  - Congressional
    - Congressional inquiries
      - Industry initiated
      - Senator/Representative initiated
      - FDA initiated
    - Congressional Committees
    - Reports requested by Congress
      - GAO, etc.
FDA and the Outside World

- FDA Oversight
  - Public/Media
    - Press coverage (newspaper, television, internet, etc.)
    - Trade associations (AdvaMed, AMDA, FDLI, etc.)
    - Patient or consumer advocacy groups (American Cancer Society, American Heart Association, etc.)
    - Professional medical associations (American Academy of Neurosurgeons, American Medical Association, etc.)
    - The courts/judicial – See prior slides

How to Deal with FDA

- Understand issue
- Research applicable history
- Outline key facts
- Identify goal(s)
- Identify audience/decisionmaker
- Develop outline of key points
- Develop support for key points
- Organize presentation of key points
- Prepare to present in less time
How to Deal with FDA

- Anticipate FDA responses
- Identify types of speakers
- Draft agenda for FDA
- Provide real evidence, not just promises
- Practice presentation
- Practice presentation
- Practice presentation

Who Do I Talk To?

- CDRH Office of Device Evaluation
  - IDE
  - 510(k)
  - 510(k) modification
  - PMA
Who Do I Talk To?

- CDRH Compliance
  - PMA Inspections
  - Form FDA-483
    - QSR
    - MDR
    - Part 806/recall

- Warning Letter/Untitled Letter
  - QSR
  - MDR
  - Labeling/advertising/promotion
  - Part 806/recall
  - Seizure
  - Injunction
  - Civil Penalties

- Trade Complaint
Who Do I Talk To?

- Field Offices
  - Form FDA-483
  - Warning Letter/Untitled Letter
  - Trade Complaint

How High Do I Go In FDA?

- Types of FDA personnel to communicate with (CDRH/Field Offices)
  - Responsible/authority
  - Not responsible
  - Hierarchy
    - Low
    - Medium
    - High
Methods of Communication

- E-mail
- Letter
- Individual telephone call
- Conference call
- In-person meeting

Communication Strategy

- Who should contact FDA?
- Who should be company’s primary spokesperson?
- Do lawyers help or hurt?
- How visible should outside consultants and lawyers be?
- What role should the CEO/President play?
- What role should the RA/QA person play?
Communication Strategy

- Is it appropriate to bring up non-substantive matters?
- Can you have more than one meeting?
- Is there a cost to having a meeting?
- How do you decide if you want a meeting?
- When should you involve... 
  - Office of Chief Counsel?
  - Ombudsman?
  - Commissioner’s Office?

Communication Strategy

- Is it appropriate to go around or above a particular FDA person/position?
- What works better – honey or vinegar?
- Do threats really work?
- What about political pressure?
Human Factors

- Different approaches for different people

“Listening Too Little (or Too Much)”

- Too many device firms forge ahead with FDA-related projects or steps without all the relevant facts, i.e., without doing their “homework” on the applicable FDA laws or policies
- This can lead to uninformed decisionmaking, suboptimal strategies or simply wrong conclusions
- Device firms need to research the relevant laws and policies, and even discuss issues with FDA officials (e.g., CDRH Office of Compliance or Office of Device Evaluation) so that they can make the best informed decisions
“Listening Too Little (or Too Much)”

- On the flip side though, some firms can at times too blindly follow FDA pronouncements, policies or interpretative dictates without challenging them where they are questionable and do not have the force and effect of law.
- Other legitimate legal positions may exist.
- Firms need to challenge where appropriate so that again they can make the most informed and educated decisions.

“Listening Too Little (or Too Much)”

- Finally, challenging does not necessarily mean not following FDA’s recommendation, but it allows a firm to better assess how aggressive or conservative it wants to be on a particular matter based on the follow-up dialogue with the Agency.
Bottom Line. . .

- It’s a new day at FDA
- What worked before may not work now
- Be prepared
- Have real evidence, not just promises
- Be honest

QUESTIONS?