KING & SPALDING

What is a Regulatory Meeting and How to Prepare for It

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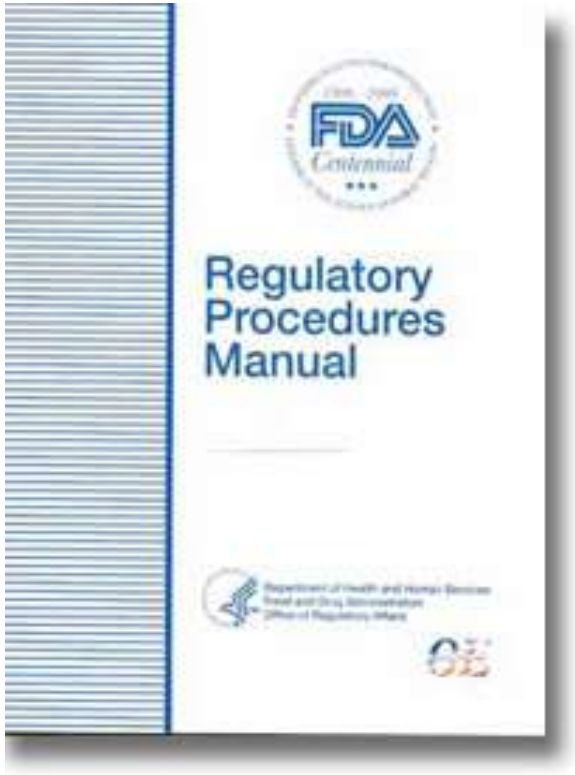
What is a Regulatory Meeting?

"*A Regulatory Meeting is a meeting requested by FDA management at its discretion, to inform responsible individuals or firms about how one or more products, practices, processes, or other activities are considered to be in violation of the law.*"

— FDA Regulatory Procedures Manual, Chapter 10, section 10.3



What are FDA's Obligations?

- FDA is not obligated to hold a Regulatory Meeting with the following exceptions:
  - Under the authority of Subchapter C - Electronic Product Radiation Control - FDA is required by law to provide a written notification to manufacturers when the agency discovers products that fail to comply with a performance standard or that contain a radiation safety defect.
- Any FDA organization with regulatory oversight over a firm or individual has the discretion to hold a Regulatory Meeting
  - Participation by both the affected Center and appropriate ORA Division are encouraged to participate
    - Depending upon the product center involved, a ORA division may or may not require Center concurrence to schedule a Regulatory Meeting
- When corporate wide situations arise, all affected Centers, Divisions shall be included, with the location to be negotiated by the involved parties.

*The Regulatory Meetings being discussed today are **not** to be confused with Regulatory Meetings with Sponsors an Applicants for Drug and Biologic Products*

When are Regulatory Meetings Used?

Regulatory Meetings can be an effective enforcement tool to obtain prompt voluntary compliance !

- As a follow-up to a Warning Letter, when the firm has corrected the majority of violative conditions as a means to provide additional encouragement, direction and assistance in achieving compliance
- As a follow-up to a Warning Letter to remind a firm or individual(s) that failure to make appropriate corrections in a timely manner may result in enforcement action
- To communicate documented violations that do not warrant a Warning Letter – but provides real-time two-way discussion of the violations and the appropriate corrective action

When are Regulatory Meetings Used?

Regulatory Meetings may also be used to initially communicate violations of regulatory significance!

- When an imminent health hazard exits and the necessity to undertake immediate corrective action to address violative product on the market
- When a Regulatory Meeting is held in conjunction with the issuance of Warning Letter to emphasize the importance of the violations
- When FDA wants the opportunity to have a frank face to face discussion with top management about the seriousness of violations observed, a continuing pattern of recidivism, or documentation of continuing observations of significance with no apparent effort made to improve
- When a firm is taking too long to implement corrective actions

CDER's Use of Regulatory Meetings

Regulatory Meetings are on the rise to meet performance goals!

- Regulatory Meetings are used by CDER to:
  - Achieve GDUFA II goals to communicate surveillance inspection classifications within 90 days of he end of the inspection
  - Achieve GDUFA/PDUFA timeframes for review of pre-approval inspections
- In FY 2019, FDA issued 87% of final facility classification letters within 90 days of inspection closing and **completed 74% of regulatory actions for OAI facilities** within 6 months of inspection closing – excusing those classified through the Mutual recognition Agreement (MRA)
- FDA can consider a Regulatory Meeting following an OAI classification as the regulatory action that meets the agreed upon 6-month deadline!

When a Regulatory Meeting is a Success!

It can be a "win-win" for both parties - as long as commitments continue to be executed and followed…

- A successful outcome of a Regulatory Meeting would include a commitment by the responsible individuals to correct the conditions or practices at their facility that are in violation of the law
- These commitment would typically be confirmed and verified through evaluation of subsequent evaluation and documentation and/or follow-up inspection.
- Inspection classifications would be modified based upon the outcome of FDA's evaluation
- Where corrective actions are not satisfactorily carried out – definitive plans should be made for follow-up action by FDA
- Generally, Regulatory Meetings are not subject to FOI

Successfully Preparing for a Regulatory Meeting

"You don't get a second chance to make a first impression"
- Oscar Wilde, or Will Rogers

- Preparation is critical to the successful outcome of a Regulatory Meeting
  - Evaluate the request and the scope of interest
  - Assemble the best team to provide background and current status
  - Determine who are your Subject Matter Experts (SMEs)
    - Can they can "think on their feet"? The smartest person is not always the best FDA facing person – *always have a Plan B*
  - Consider need for outside experts – Medical? Clinical? Engineering?
    - Consider if they should be local or nationally recognized or both!
  - Decide who will attend the meeting – *remember* –
    - Be sure to have top management on board – and whenever possible attend to demonstrate commitment and importance given to the Meeting
    - Remember - the more people you have, the more FDA will have.
    - If you bring counsel, they will bring counsel

Successfully Preparing for a Regulatory Meeting (con't)

- Develop your presentation
  - Regulatory Meetings are generally timebound – mostly 1 hour
  - Decide on who *may* be presenting and which portions
  - Get your message out early in your presentation
    - Resist spending half your time providing a history of your firm, or all the products you manufacture – *get your message out!*
    - Focus on the site(s)/issues in question
    - Leave time for discussion and Q & A
  - Provide an update on your progress – tout your accomplishments
    - Be up front about what remains
    - Discuss challenges that may have impacted progress –
      - Discuss reasons for any delays
        - Need for capital equipment, building modifications requiring permits
        - Supplier issues – geographic hindrances, pandemic, etc.

Successfully Preparing for a Regulatory Meeting (con't)

- Once you finalize your presentation, assign speaking roles
  - Not everyone needs to have a speaking role – may need scientific, medical or engineering support
- Know the "skeletons in your closet" and decide how to respond to any questions that may arise
  - FDA may reach back to past inspections with similar problems
  - Know your inspectional history and be prepared to discuss it
  - Be familiar with complaints, recent recalls, AE/MDR reports, journal articles
  - Know how your competitor is doing – *BUT* resist the temptation to use the defense that "they aren't doing it – why should we…"
    - File a complaint to raise the issue
    - You are not aware what FDA may be dong to your competitor
- Conduct "mock meetings" – run through your presentation and ask the challenging questions
  - Most beneficial when a third party with knowledge of issue(s) run the "mock"
- Be sure top management whenever possible be present and provide the overview
- Request a list of attendees from FDA in advance and seek info about them

At the Meeting…

- Assign a scribe and memorialize those in attendance.
- Be respectful of FDA's time – and seek any further clarification about what prompted the meeting
- Avoid making admissions, and do not over-commit
    - Avoid acknowledgement that you were not doing something incorrectly or not at all – rather present it that since the issue has been pointed out we have taken the following steps
    - If you disagree with FDA's position, respectfully and politely disagree – and provide documentation why
        - Avoid loud confrontation and accusation
            - There are other tools available to deal with contentious issues
- To the best you can – keep the meeting on track to get your messaging across
- At the conclusion of the meeting – come to an agreement about any Minutes – who will prepare them, by when
- In the off-chance that FDA surprises you with a hand delivered Warning Letter at the conclusion, advise you will review it and respond within the timeframes
- Caucus among yourselves upon return to your firm and assign any open issues or promises or commitments made to FDA

Questions?

Thank You