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Opportunities to Resolve Scientific and Regulatory Disagreement

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Agenda

- Actions/Decisions Subject to Appeal
- Appeal Pathways
- Section 517A – Administrative Efficiency v. Company Rights
- Decision to Appeal/Accepting an “Improper Decision”
- Pursuing a 10.75 “Appeal”
- Conclusion

Appeal Pathways

- Administrative
  - 21 CFR 10.75 – Supervisory Review
  - 21 CFR 10.33 -- Reconsideration
  - 21 CFR Part 16 – Informal Regulatory Hearing
  - Section 517A – Review of Significant Decisions
  - Section 515(g) – Appeal of a PMA Approval or Denial
    - Expert Panel (But not a 513(b) Panel)
    - ALJ – Part 12 Formal Hearing
  - Section 562 – Dispute Resolution – Scientific Controversies where no specific right to review under the Act or Regulations
- Judicial Review – Section 517 – U.S. Court of Appeals
  - Classification, Reclassification or Performance Standard Regulations
  - Regulation Requiring PMAs for Preamendment Devices
  - Order Approving or Denying a PMA (After an Administrative Appeal)
  - Order Approving or Denying a GMP Exemption or Variance
  - NSE or SE Order

Actions/Decisions Subject to Appeal

- Any action, whether interim or final, *e.g.*,
  - By Statute – PMA Approval, Withdrawal or Denial, IDE Denial or Withdrawal, or Scientific Controversies (where no statutory authority to addresses the controversy)
  - By General Regulation (Supervisory Review) – Additional Information & Deficiency Letters, Warning Letters, De Novo decisions, Etc.
- Under 10.75 FDA Is To Entertain Supervisory Review Requests, Although Discretion Exists for Some
- Ombudsman's Office (Dave Buckles, Ph.D. and Jake Romanell)
  - Extensive CDRH experience, and about 1 complaint a day
  - Good ear, constructive advice
  - Arrange opportunities to discuss issues to avoid appeals
  - Not decision-makers

Sections 517A – Administrative Efficiency v. Company Rights

- Section 517A – "Agency Documentation and Review of Significant Decisions Regarding Devices"
- Purpose = Improve Documentation and Timeliness of Significant Decisions. Response to Deficiencies Not Strengths
- Documentation of Rationale for Significant Decisions
  - Statute – "The [FDA] shall provide a substantive summary of the scientific and regulatory rationale for any significant decision . . . Regarding submission or review of [a 510(k), PMA or IDE], including documentation of significant controversies or differences of opinion and the resolution of such controversies or differences of opinion"
  - CDRH Approach – In Draft Guidance FDA "Limits" "any significant decision" to SE and NSE Determinations, PMA/HDE Not Approvable and Approvable with Conditions Letters, and Approval (Not Denial) Letters, and IDE Approval and Disapproval Orders, and Protocol Agreement Disputes.
    - Although Administratively Neat, this Definition Does not Satisfy the Act
    - Section 517A Identifies "any significant decision . . . regarding the submission or review" of 510(k)s, PMAs and IDEs, neither of which is confined to final or near final orders (Cont'd)

Sections 517A – Administrative Efficiency v. Company Rights

- Section 517A Does Not Define What "Significant" Means, But Does Define a Scope of Actions That Could be "Significant" Decisions
  - The word "Submission[s]" Could Relate to the Acceptance/Filing Review, Including Whether Rejection of a Submission Was Based on Procedural or Substantive Grounds
  - Additional Information Letters are part of 510(k) reviews, and in that Context, for Example, Requiring a Prospective Well-Controlled Clinical Study to Demonstrate SE, Where No Predicate Had Such a Study Requirement Equivalence, Presents a Significant Issue
  - These Examples Could be Highly Significant Because in One CDRH Could Improperly Reject a Submission for Review and in the Other, the Center Would Create New Requirements That Could Undermine a Startup Company, or Unfairly Burden any 510(k) Submitter with an Ad Hoc and Arbitrary Requirement
- Moreover, the Purpose of the Provision Would be Frustrated
  - The Decision-Making Rationale Would Apply to too Few Matters
  - Application of the Beneficial Time Schedule Would be too Limited
  - CDRH Should Reconsider the Definition of Significant and Broaden It

(Cont'd)

Sections 517A – Administrative Efficiency v. Company Rights

- Timing for Significant Matters
  - To Benefit from Section 517A, the Statute Requires Requests for Review of Significant Matters Not Later than 30 Days after the Decision
  - In Draft Guidance, CDRH uses 30 Day Requirement to Foreclose All Appeals Related to Significant Matters if a Request is Late, But Will Accept Non-Significant Appeals at a Later Date. This Result is Illogical and Misinterprets the Purpose of Amendment
- Non- 517A Appeals, *i.e.*, 10.75 Reviews of Non-Significant Matters
  - Generally, 60 Days to Request Review
  - Historically, These Appeals at Times were Protracted
    - Long and Expensive Process
    - Startups Vulnerable and Some Cannot Survive, Even When They Prevail Because of Delay
  - Critical that this Process is Made More Transparent and Timely
  - Critical that Additional Information Requests Qualify as "Significant," Particularly When Clinical Data Requirements are at Issue

Decision to Appeal/Accepting "Improper Decision"

- Only Appeal Actions When the Failure to do so Presents a Potential Harm of Some Significance to a Company Either Presently or in the Future, *e.g.*, through the establishment of bad precedent
- "Improper Actions" Not Rooted in Violations of Laws or Regulations that Really Represent Disagreements and can be Remedied at an Acceptable Cost and are Isolated in Effect, typically should not be appealed, *i.e.*, acceptance would not create a precedent you could not live with. Acceptable Resolutions are Positive, because:
  - Process is Slow
  - It's Costly
  - It Diverts Your and FDA Staff's Time and Energy from Important Work, and
  - For this kind of issue -- Unlikely to do better than Informal Meeting, or Simply Doing Something You Don't like and Getting It Behind You
- If the Matter in Dispute is About a Principle or Practice, Make Sure It is Worth Challenging/Defending, *e.g.*, a reviewer who repeatedly requests data and then does not accept it to conclude the review and requests more.

Pursuing a 10.75 "Appeal"

- Next Level of Supervision, Unless a Reason to Skip a Level, *i.e.*, "The review will ordinarily follow the established agency channels of supervision or review for [the] matter" 10.75(b)(1)
- Based on the Administrative Record Existing at the Time of Decision
- Direct Review of Dispute by the Commissioner or Center Director Appropriate When, Among Other things, "[t]o resolve an issue that cannot be resolved at lower levels within the agency, *e.g.*, between two parts of a center . . ."
- Presentation of Review
  - Clear and Complete Statement of Appeal
    - Issue or Issues for Review
    - Complete Briefing of Legal/Regulatory and Scientific Issues with Expert Support for Each
    - Concise Presentation
    - Requested Relief

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Pursuing a 10.75 "Appeal"

- Meeting
  - Essential and Include Review Staff and Deciding Official
  - Avoid Teleconferences
    - Undermines Full Exchanges on Issues
    - Negates Expert Input
    - Minimizes Impact of Presentation
- Panel Review/Homework Assignment?
- Obtaining a Timely Decision

- Responding to Decision
  - Ensure Common Understanding and Expectations
  - If Unsatisfactory, Assess Next Steps

Conclusions

- Don’t Misuse Internal Agency Review Process – In the End There is No Net Benefit to Anyone from Inappropriate Appeals: Inappropriate Appeals are Resource Intensive and Misallocate Resources
- Understand the Role of the Ombudsman’s Office and Consider Using It to Seek Lower Cost, Informal Resolutions
- If You Decide to Seek Supervisory Review, Do It for the Right Reasons and Do It Right
- Consider Commenting on FDA’s Draft Guidance on Significant Decisions and the Processing of “Not Significant’ Decisions; You Can Comment at Any Time

QUESTIONS

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