DISPUTE RESOLUTION AT CDRH

HIMA Device Submissions Workshop

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Presentation Outline

- Most-common areas of disagreement.
- Overview of options for resolving disputes.
- CDRH's proposed process for resolving scientific disputes.
- How to reduce the potential for disagreement.
- What to do when you disagree with CDRH.
- A few parting assurances.

Most-Common Areas of Disagreement

PMA / PMA Supplement –

- Primarily scientific disagreements.
- “Not filing” decisions.

PDP

- Only one appeal so far.

Most-Common Areas of Disagreement

510(k) –

- NSE decisions.
- Requests for additional information.
- Competitors unhappy with SE decisions.
- Which Center should regulate a product.

IDE –

- Scope, restrictions on studies.

Options for Resolving Disputes

Examples of less-formal processes:

- Appeal through the supervisory chain.
- Citizen petition.
- Petition for administrative reconsideration.
- IDE Review Committee.
- Review of product jurisdiction.

Options for Resolving Disputes

Examples of more-formal processes:

- Formal evidentiary public hearing.
- Public hearing before a Board of Inquiry.
- Public hearing before an advisory committee.
- Public hearing before the Commissioner.
- Regulatory hearing.

Resolution Scorecard — 510(k)

Of 76 appeals filed since January 1993 —

- 41 decisions upheld.
- 31 decisions reversed in whole or in part.
  - 23 found substantially equivalent.
  - 6 more achieved *some* clearance.
- 4 appeals still in process.
- Typical appeal decided in 30-60 days.

Resolving Scientific Disputes

– CDRH's Newest Dispute Resolution Process –

- Prompted by FDAMA (FD&C § 562).
- Provides a means of obtaining timely review of certain scientific controversies.
- Draft Guidance published April 27, 1999.
- Uses new Dispute Resolution Panel.
- Administered by new CDRH Ombudsman.

Subject Matter Jurisdiction of the Dispute Resolution Panel

Four statutory rights of appeal —

- PMA and PDP decisions.
- Establish, amend performance standards.
- Postmarket surveillance > 36 months.
- Any other “scientific controversy” where the FD&C Act or FDA regulations do not provide a right of review.

Organization of the Dispute Resolution Panel

- Five standing members:
  - Three members with general scientific and clinical expertise, one of whom serves as Chair.
  - Two non-voting members representing industry and consumer interests.
  - Four-year term of service.
- Three temporary members:
  - Appointed to review a particular appeal.
  - Term expires when decision is rendered.

Role of the CDRH Ombudsman

- Provide information on dispute resolution and appeals processes.
- Preliminary review of requests for Dispute Resolution Panel review.
- Mediate disputes when both sides consent.
- Provide staff support to the Dispute Resolution Panel.
- Monitor the processing of appeals.

Reducing the Potential for Disagreement

- Select the most-appropriate review mechanism and be sure you understand its requirements.
- Make sure your submission is complete, well-organized, and based on solid science.
- Anticipate probable CDRH concerns and address them in your submission.
- Frequent communication with CDRH.

What to Do When You Disagree with CDRH

- Define the problem, what you're willing to do, and what you want CDRH to do.
- Try to reach agreement at the lowest level possible.
- Document your concerns.
- Appeal through the supervisory chain before invoking a more formal process.
- Consider all the options before choosing.

Appeals Have Their Uses

- Appeals *aren't* a waste of time.
- Supervisors *want* feedback when you believe we've made an incorrect decision.
- Appeals are *routine*. You won't be "marked for life" if you appeal a decision.
- CDRH *does not* tolerate retribution.
- Our starting point: *Any* dispute can be resolved when both sides keep an open mind.

Appendix: Selected References

- Guidance: *Medical Device Appeals and Complaints – Guidance on Dispute Resolution* (February 1998).
- Draft guidance: *Resolving Scientific Disputes Concerning the Regulation of Medical Devices* (April 1999).
- CDRH WWW site (www.fda.gov/cdrh/resolvingdisputes) provides basic information and links to reference materials, other useful sites.
- 21 CFR 10.75 – Internal agency review of decisions.
- 21 CFR 10.33 – Administrative reconsideration of action.
- 21 CFR 10.30 – Citizen petition.