

Common Deficiencies (Filing Considerations)

Complex vs Non-Complex ANDAs

Any Difference in Types or Frequency of
Deficiencies?

Top 3 Deficiencies

- Stability
 - 180-day hold-time
 - Missing altogether (orientation)
- Non-Q/Q-sameness
 - Disclaimer
- Improper or no signature (356h)

Case Study on Justification

Deviating from a guidance recommendation: Not an evaluation of merit, just a confirmation of if one was provided

A Note on Controlled Correspondence

Note the Disclaimer Language

Advice

Double Check the Submission before sending
through

