Avoiding Pitfalls in Regulatory Submissions

• A Summary -
  – 4 Pitfalls
  – 4 Solutions (common sense)

• But first...... a quiz -
What’s a Pitfall?

pit-fall (pit’fol’) n. 1. a lightly covered and unnoticeable pit prepared as a trap for people or animals. 2. any trap or danger for the unwary.

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Webster’s American Dictionary (2001)
And the Answer is: 

#2

A trap or danger for the unwary
Pitfall #1

Not Setting the Stage Early – for Where You Want to be at the End

• What kind of product – regulatory category?
• Where will I sell?
• Who regulates and when?
• What are the claims?
Solutions

- Plan, Plan, Plan Ahead
- Talk to ALL potential regulators – EPA – PMRA - CADPR
  Identify and address the differences
  Pre-registration Meetings
  Follow-up to Confirm...and Update
Pitfall #2

Your submission is technically complete and accurate – but virtually unreadable.

The regulator’s would rather have a root canal than work on your submission!
Solution

DO whatever it takes to:

MAKE IT USER FRIENDLY

• Make the transmittal letter a *roadmap*
• Use tabs, tables of contents, cross-references, etc.
• Provide submission on CD - with handy hyper-links for easy access
• If the US Tax Code is more readable than your submission - keep working!
Pitfall #3

Unstated and/or Unrealistic Expectations

“You need a decision by when??#@#!!”
Solutions

When discussing timeframes:

• Be clear – from the start
• Be fair
• Be consistent
Pitfall #4

Too Many Assumptions:

• Our product is “perfect”
• “They’ll remember”
• “They’ll understand”
• “It’s obvious; It’s self evident”
Solutions

ASSUME NOTHING

• Put yourself in the regulator’s shoes…
• Give regulators the documentation they need to stand behind a decision
• Make sure all parties understand & agree – on timeframes, process issues, next steps, etc.
• Check …..double check…..monitor – within reason
Bonus Solution…. 

After you’ve done everything you can think of to compile the perfect submission……..

then its time for:
Pitfalls – Be Gone®

• A new revolutionary product!!
• Guaranteed to rid your submission of all those Pesty Pitfalls!!
• USEPA – PMRA – CADPR Approved!!*
• “Safe” and “All-Natural”
• CALL NOW: 1 - 800 - R E G - E A S Y

* Conditional Registration Expires: 11 - 12 - 01