Engaging with FDA: Communications and Relationships

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Do's and Don'ts

Do's	Don'ts
Do your homework (*e.g.*, check to see if the question is answered in a guidance document or webinar).	Don't ask FDA for business advice or to do something the Agency does not have the authority to do.
Submit thoughtful questions (*e.g.*, set forth a scientific and evidence-based approach and request feedback).	Don't ask broad or vague questions like "how do we get our product approved?"
Be a zealous advocate for positions that are supported by science, statute, and regulation.	Don't verbally attack Agency personnel, regardless of your level of frustration.
Make FDA's job easier.	Don't hide the ball.

Challenges

- Given the relative newness of FDA's tobacco products authority, there is bound to be uncertainty and/or confusion (both among industry and the Agency).
- In order to comply with Agency regulation, industry needs real-time feedback.
- FDA needs to speak with "one voice."
- Lack of successful examples upon which to model certain types of submissions.
- Long periods of time between interactions.

What's the Solution? A Few Suggestions.

- Live and virtual stakeholder discussions.
- "Ask an expert" (*e.g.*, social media town halls).
- Dedicated branch and office "call time" hours.
- Call center tracking.
- Prioritization of inquiries based on impending compliance deadlines.
- Customer service ratings.
- Dynamic frequently asked questions (FAQs) and answers documents.

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Questions?

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