Avoiding Gilligan's Island: How to Keep a Three-Hour Pre-Sub Meeting From Turning Into a Shipwreck

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Our Panel

- John Nealon, President & CEO, UroCure; former former President & CEO Kspine and SVP of Women's Health Business at American Medical Systems/ENDO
- Bob Paulson, President & CEO, VentureMed; former President & CEO, NxThera
- Tom Ressmann, former President & CEO; Amphora Medical and Entellus Medical

DuVal Client Alert--September 2013

The Pre-Sub Meeting and Gilligan's Island:

When a Three Hour Tour Can Turn Into a Shipwreck

You remember the tune from the popular television series, let us just rewrite the lyrics a bit to fit our story/critique:

> Just sit right back and you'll hear a tale, a tale of a fateful trip, that started from this medtech port, aboard this partnership. The creator was an innovative guy, the CEO brave and sure. Five other employees set sail that day for a three hour tour, a three hour tour. The dialogue started getting tough, the tiny firm was tossed. If not for the courage of the fearless crew, the idea would be lost, the idea would be lost. The firm set ground on the shore of this uncharted Pre-Sub Isle; with clinicals, animal studies too, bio, and some bench. Risk averseness reigns; standards change—here on Pre-Sub Isle.

Executive Summary

The Pre-Sub obviously is not perfect, but it's trying to be helpful. It is designed to allow industry to seek upfront input from FDA on both regulatory pathway and performance data (including clinical trial) issues. Both industry and FDA need to understand it was well-intentioned in scope and purpose, but it has its limitations for both parties. We think they work well for PMAs, not so much for 510(k)s, and they are somewhere in between for a de novo. For PMAs FDA still attempts to dictate the data it wants and yet is non-committal, but FDA feels the starting place with a PMA applicant is that the sponsor wants to work

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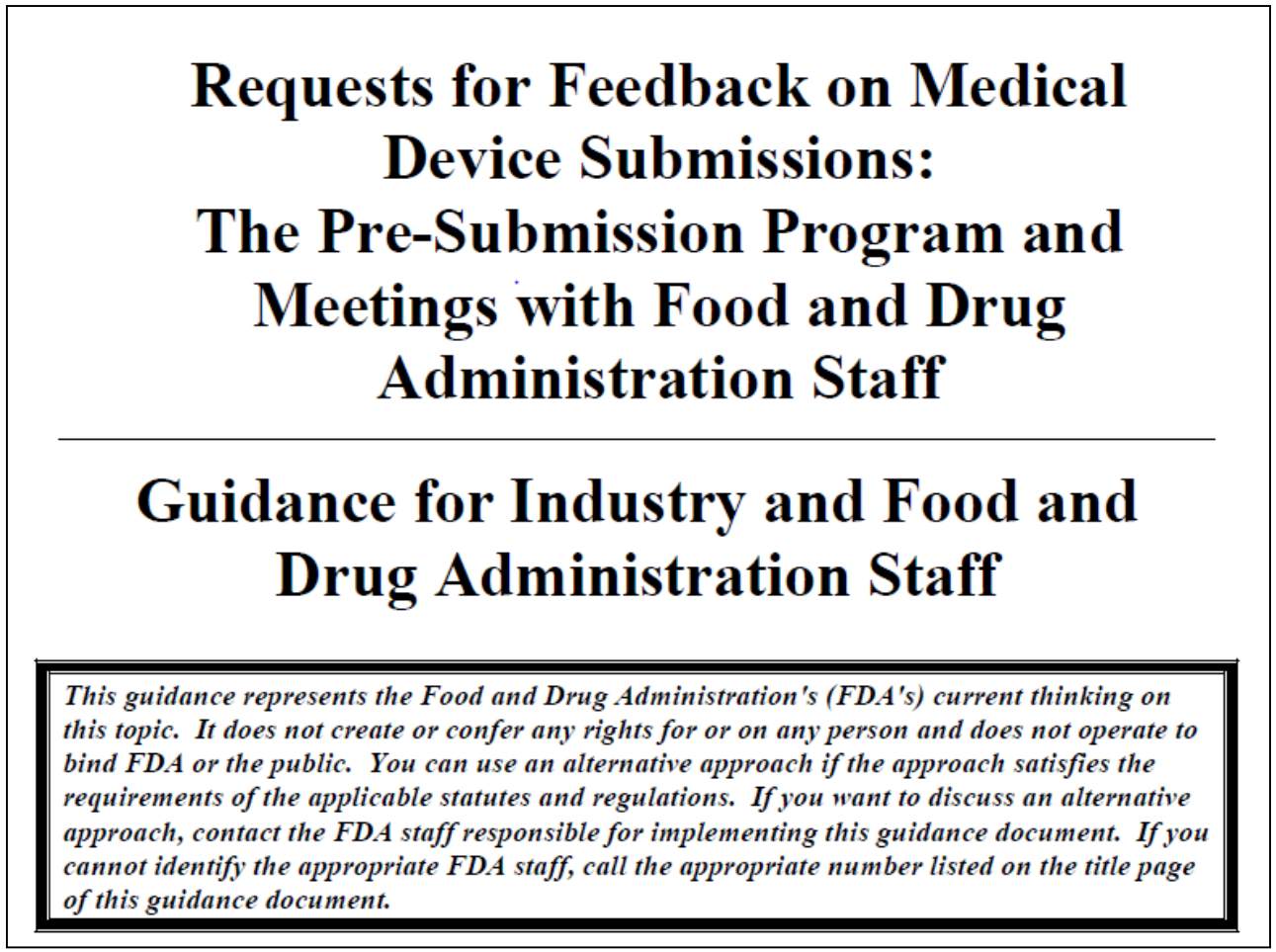
Where you find information on Pre-Sub Meetings



Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance document. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance document.

The feedback mechanisms contained in the Guidance—now all called "Q-Submission" or "Q-Sub" meetings

- **Pre-Submission Meetings**
- Informational Meetings
- Study Risk Determinations
- Formal Early Collaboration Meetings (i.e. Agreement and Determination Meetings under FDAMA)
- **Submission Issue Meetings**
- PMA Day 100 Meetings

The timing associated with different feedback mechanisms

III. Requests for FDA Feedback

As stated in the introduction, this guidance provides information regarding existing mechanisms for requesting FDA feedback, and also establishes several new mechanisms, all of which will now fall within the same organizational "Q-Sub" structure for tracking purposes. The various types of Q-Subs addressed in this guidance and the timeframes within which FDA intends to provide the requested feedback are described in Table 1 below.

Table 1

Q-Sub Type	Meeting as Method of Feedback?	Timeframe for Meeting/Teleconference (from receipt of submission)
Pre-Submission*	Upon request	75-90 days**
Informational Meeting	Yes	90 days
Study Risk Determination	No	N/A
Agreement Meeting	Yes	30 days or within time frame agreed to with sponsor
Determination Meeting	Yes	Date for meeting agreed upon within 30 days of request
Submission Issue Meeting	Yes	21 days
Day 100 Meeting	Yes	100 days (from PMA filing date)

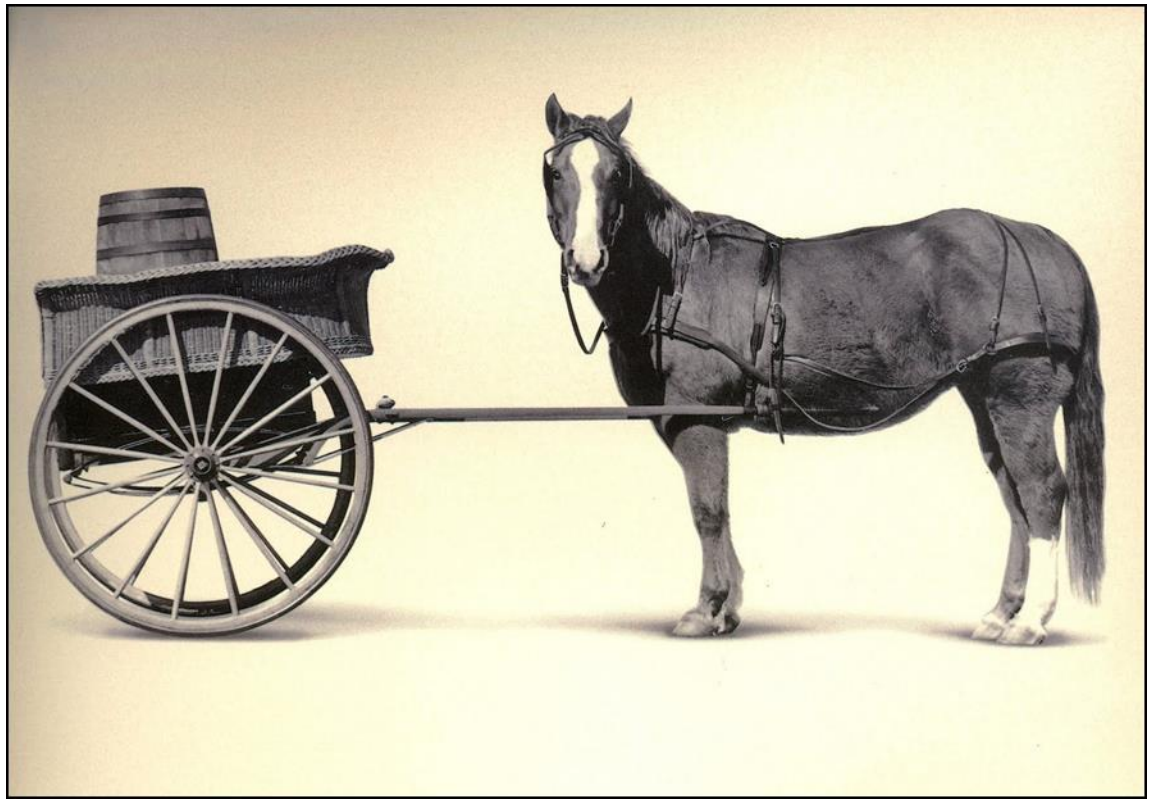
*As defined in MDUFA III Commitment Letter.
**21 days for urgent public health issues (see Section III.A.6.).

The Pre-Sub arises in several different contexts—first

A BONA FIDE NEGOTIATION

The Pre-Sub arises in several different contexts—second

CART BEFORE THE HORSE?



The Pre-Sub arises in several different contexts—third

THE DIVERSION PROGRAM

The Pre-Sub arises in several different contexts—third

OR THE TROJAN HORSE (GIFT)?

Some thoughts—Performance data and clinical study demands

A Pre-Sub allows FDA to pontificate about all the data requirements it can dream up and then some

Final thoughts—
Pre-Submission meetings

- Pre-Sub meeting is an asset in a PMA and de novo setting, not so much for a 510(k)
- In PMA or *de novo* FDA feels more part of team—FDA likes being on the development team
- With 510(k) (and even *de novo*) FDA's assumption is that company is trying to get away with as little as possible—leading to a polite, more edgy conversation
  - Attempts to hold them to a 510(k) standard or Least Burdensome requirements not always welcome

It can be frustrating; but don't let the FDA turn you into something you're not

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