Refuse to Accept (RTA) & Additional Information Requests (AIR):

How to Avoid Problems with Your Medical Device Submission?

presented by:

Michael Drues, Ph.D.

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Carlsbad, California

and

Adjunct Professor of Regulatory Science, Medicine and Biomedical Engineering

Cornell University Graduate Dept. of Biomedical Engineering

GreenLight.Guru (March 23, 2023)

www.greenlight.guru/webinar/refuse-to-accept-additional-information-requests-avoid-problems-medical-device-submission

For questions or more information, call
(508) 887 – 9486 or e-mail mdrues@vascularsci.com

Refuse to Accept (RTA) and Additional Information Requests (AIR):

Why do so many medical device submissions have such avoidable problems?

presented by: ***Michael Drues, Ph.D.***

Despite FDA publishing multiple *Refuse-To-Accept* (RTA) guidance documents for all major medical device submission types including the 510k, de novo and PMA, ***more than two-thirds of all medical device submissions result in an Additional Information Request (AIR) and/or are rejected upon administrative review i.e., Refuse-to-Accept*** (see MDUFA statistics here). Regrettably, ***when a submission is rejected on administrative review, it is solely the fault of the company not the FDA!***

The purpose of this webinar is to review the available RTA checklists and most importantly to learn to design a submission that will pass administrative review and avoid receiving an Additional Information Request (AIR) or Refuse-to-Accept (RTA) determination which will undoubtedly lead to delays to market!

In his signature style, Dr. Michael Drues will use actual devices as case studies to discuss:

- The FDA review process: administrative review vs. substantive/scientific review
- Actual (not hypothetical) examples of AIRs and RTAs from real medical device submissions
- Practical and actionable advice on how to avoid RTA determinations
- Advice on using electronic tools to minimize RTA determinations
- Strategies on how to deal with AIRs and RTAs should you receive one

Simply put: whether we need them or not, FDA has published these RTA checklists… we might as well use them to our advantage!

About the Presenter

Michael Drues, Ph.D., is a regulatory strategy consultant specializing in designing novel regulatory strategies to bring new and innovative medical products to market and in developing effective communication strategies between companies and regulatory agencies to minimize time to market and avoid delays.

Dr. Drues received his B.S., M.S., and Ph.D. degrees in Biomedical Engineering from Iowa State University. He works with leading medical device, pharmaceutical and biotechnology companies ranging in size from start-ups to Fortune 100 companies. He also works on a regular basis for the U.S. Food and Drug Administration, Health Canada, the US and European Patent Offices, the Centers for Medicare and Medicaid Services and other regulatory and governmental agencies around the world.

Dr. Drues is an internationally recognized expert and featured keynote speaker on cutting-edge medical technologies and regulatory affairs. He conducts seminars and short courses for medical device, pharmaceutical and biotechnology companies, the FDA, Health Canada, the US and European Patent Offices, CMS and other regulatory and governmental agencies around the world.

Finally, Dr. Drues is an Adjunct Professor of Regulatory Affairs, Medicine and Biomedical Engineering at several universities and medical schools. He regularly teaches graduate courses in Regulatory Affairs and Clinical Trials, Product Development, Combination Products and Pathophysiology.

For additional information, contact Dr. Drues directly at (508) 887-9486, e-mail mdrues@vascularsci.com
or via LinkedIn at www.linkedin.com/in/michaeldrues.

Refuse to Accept (RTA) & Additional Information Requests (AIR):

How to Avoid Problems with Your Medical Device Submission?

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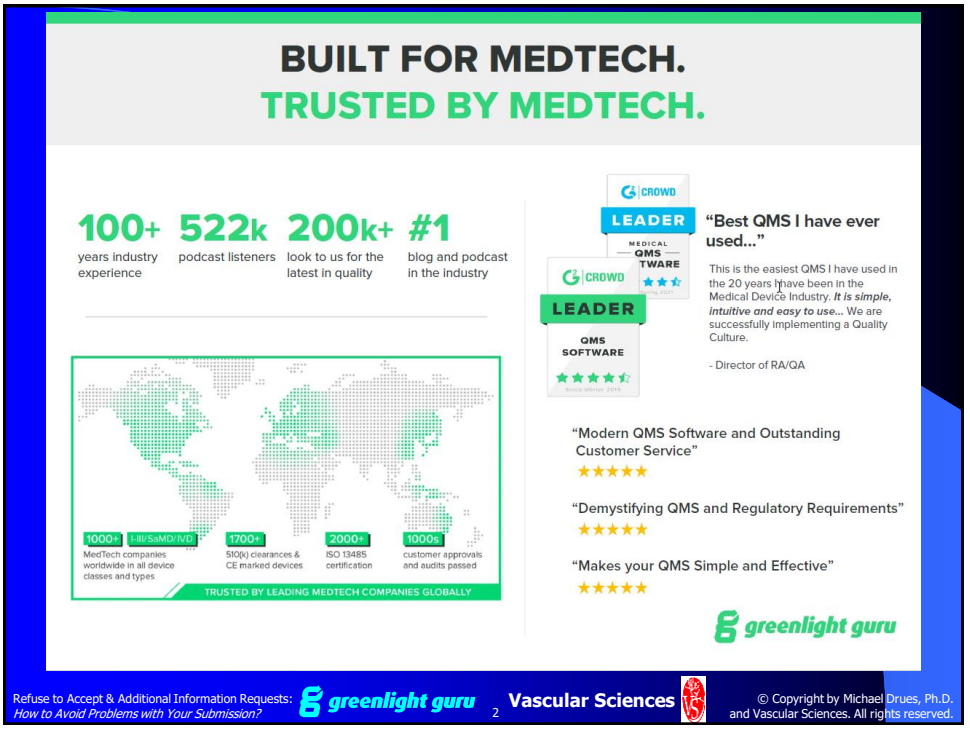

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GreenLight.Guru Webinar (March 23, 2023)

www.greenlight.guru/webinar/refuse-to-accept-additional-information-requests-avoid-problems-medical-device-submission

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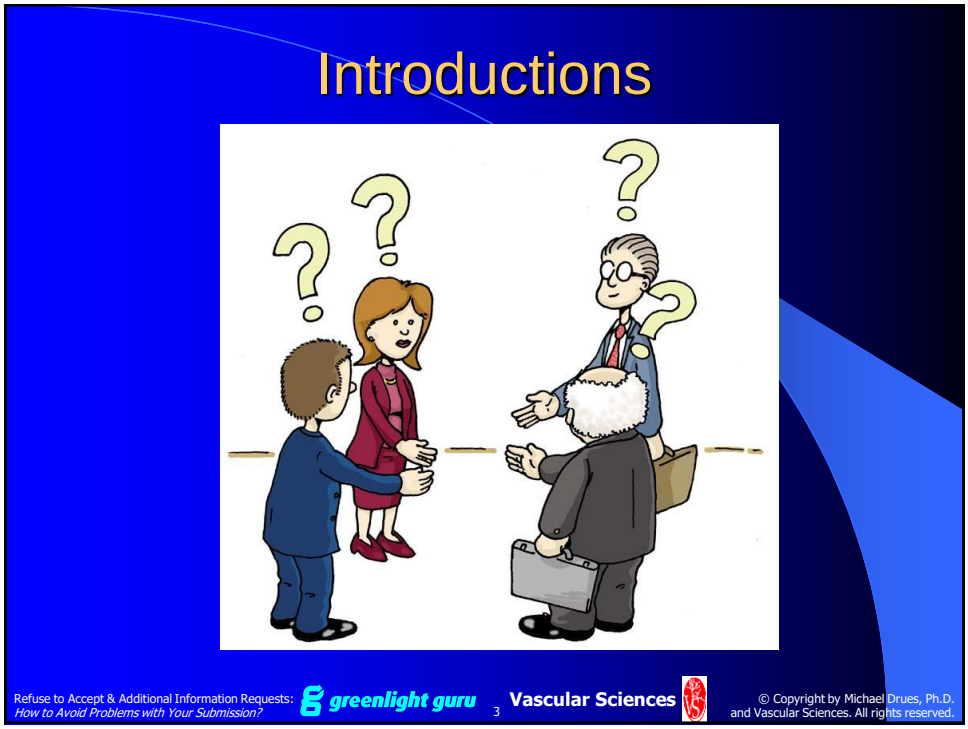

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First, an important disclaimer...

I can't make you an expert in a few minutes!

I'm not even going to try but…

Remember my philosophy of education:

To teach you how to think not what to think!

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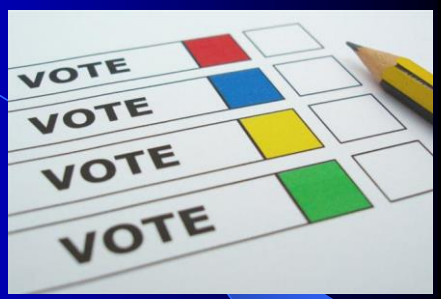
Before we begin…

Polling Questions



I received an AIR following an FDA submission? [y/n]

I received an RTA or MDL following an FDA submission? [y/n]

I was surprised to receive an AIR, RTA or MDL? [y/n]

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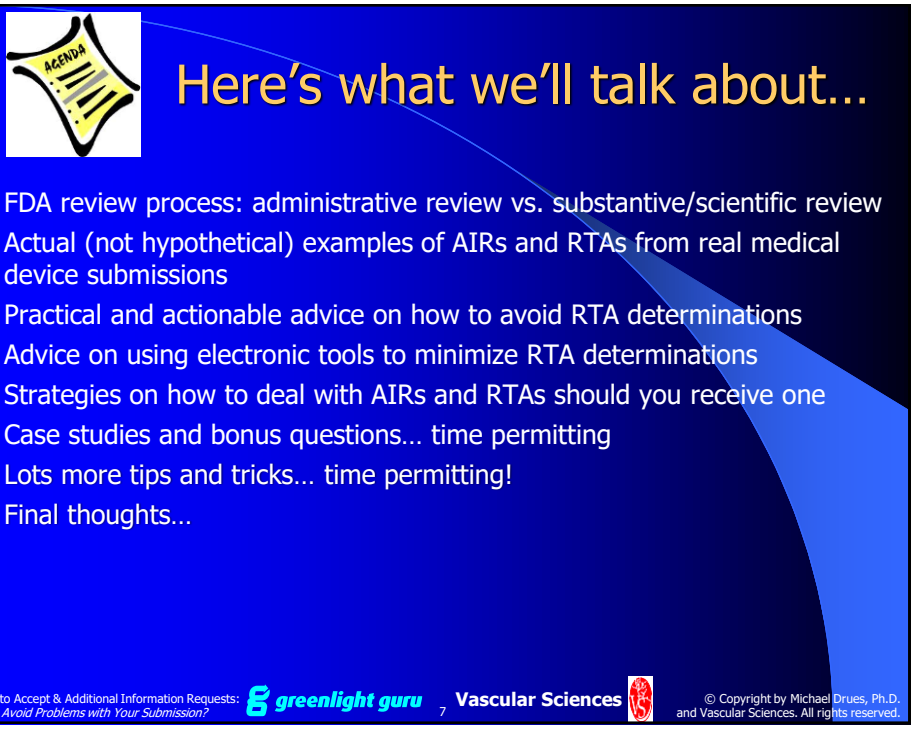

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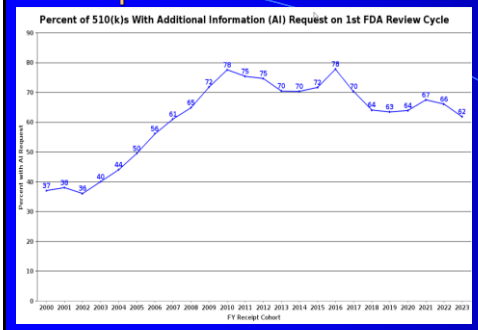
For additional information, www.linkedin.com/in/michaeldrues, call (508) 887-9486 or e-mail mdrues@vascularsci.com

Refuse to Accept (RTA) & Additional Information Requests (AIR):

How to Avoid Problems with Your Medical Device Submission?

What percent of submissions are kicked back upon first review?



MDUFA Quarterly Performance Report (March, 2023) here.

Bottom line:

~ 62 – 94% of 510k & PMA submissions are rejected upon first review!

85% specifically for substantial equivalence…

or the lack there of!

This should NEVER happen!

Should we be proud of this?

Why do we treat FDA as our elementary school teacher???

My goal:

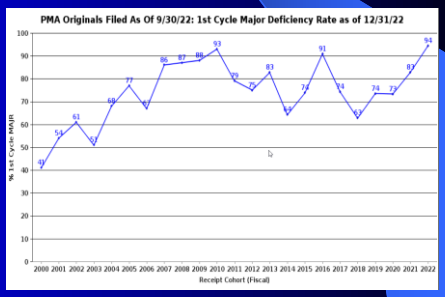
Not simply acceptance…

anyone can to that!

Acceptance upon first review…

or with the few number of questions/kickbacks as possible!

Any questions upon review → Failure



MDUFA Quarterly Performance Report (March, 2023) here.

How do you achieve this?

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Mikes Mantra

Repeat after me:

Tell don't ask…

lead don't follow…

learn don't bash!

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Refuse to Accept (RTA) & Additional Information Requests (AIR):

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Don't believe me… do your own fact checking!

March, 2023 available here.

Updated quarterly – our user fees hard at work! ☺

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Are we making progress?

Apparently not…

1994 (original guidance)

↓

2012 (updated guidance)

↓

2015 (yet another "updated" guidance)

↓

2022 (yet another "updated" guidance)

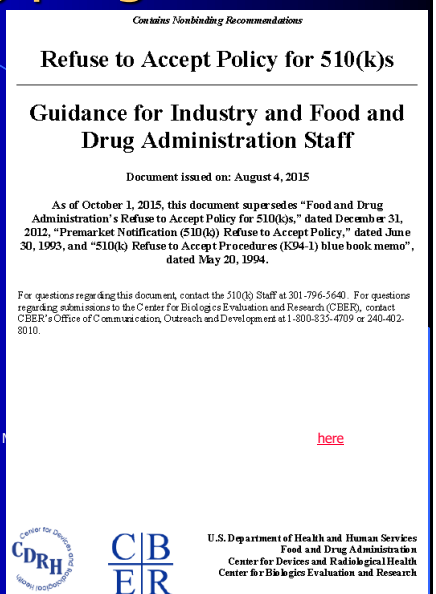
Note: at least no "final" guidance

And yet…

"As of September 2013, ~60% of all newly filed 510(k)s were refused under the RTA."

FDA News, Falls Church, VA Sept. 30, 2013

Refuse to Accept Policy for 510(k)s (December, 2012 available here)


Contains Nonbinding Recommendations

Refuse to Accept Policy for 510(k)s

Guidance for Industry and Food and Drug Administration Staff

Document issued on: August 4, 2015

As of October 1, 2015, this document supersedes "Food and Drug Administration's Refuse to Accept Policy for 510(k)s," dated December 31, 2012, "Premarket Notification (510(k)) Refuse to Accept Policy," dated June 30, 1993, and "510(k) Refuse to Accept Procedures (K94-1) blue book memo", dated May 20, 1994.

For questions regarding this document, contact the 510(k) Staff at 301-796-5640. For questions regarding submissions to the Center for Biologics Evaluation and Research (CBER), contact CBER's Office of Communication, Outreach and Development at 1-800-835-4709 or 240-402-8010.

here

CDRH CBER

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Checklist vs. Refuse to Accept

Use this to avoid RTA's…

but do we (should we?) really need it?

Organizational Elements

Failure to include these items alone generally should not result in an RTA designation

	Yes	No
a. Submission contains Table of Contents	☐	☐
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	☐	☐
c. All pages of the submission are numbered *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☐	☐
d. Type of 510(k) is identified– traditional, abbreviated, or special *If type of 510(k) is not designated, review as a traditional*	☐	☐
Comments:		

Refuse to Accept Policy for 510(k)s (April, 2022 available here)

Contains Nonbinding Recommendations

Refuse to Accept Policy for 510(k)s

Guidance for Industry and Food and Drug Administration Staff

Document issued on: April 21, 2022.

Document originally issued on May 20, 1994.

This document supersedes "Refuse to Accept Policy for 510(k)s" issued September 13, 2019.

For questions about this document regarding CDRH-regulated devices, contact ORP: Office of Regulatory Programs, DRP1: Division of Submission Support, Premarket Notification and Classification Team by email at 510K_Program@fda.hhs.gov or at 301-796-5640.

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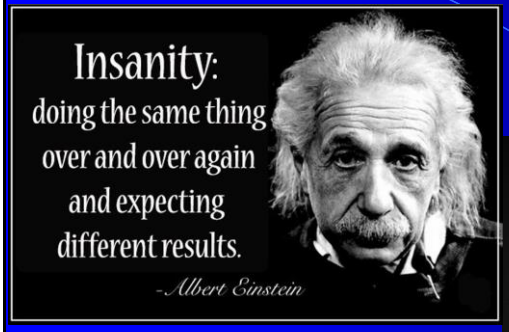
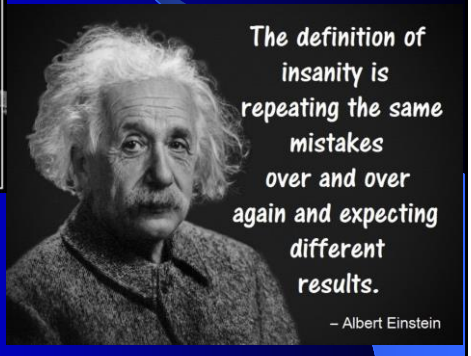
Are we making progress?



Better Definition



Or put another way…

Practice does not make perfect…

perfect practice makes perfect!

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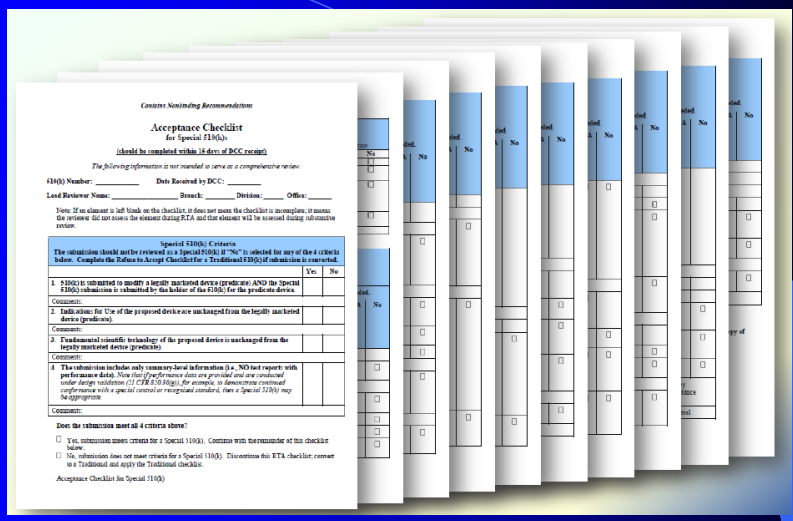
Use the RTA checklist to your advantage!



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Acceptance Checklist
for Special 510(k)s
(should be completed within 14 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) Number: _____ Date Received by DCC: _____

Lead Reviewer Name: _____ Branch: _____ Division: _____ Office: _____

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during RTA and that element will be assessed during substantive review.

Special 510(k) Criteria
The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.

	Yes	No
1. 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.		
Comment:		
2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).		
Comment:		
3. Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).		
Comment:		
4. The submission includes only summary-level information (i.e., NO test reports with performance data). Note that if performance data are provided and are conducted under design validation (21 CFR 820.30(g)), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.		
Comment:		

Does the submission meet all 4 criteria above?

☐ Yes, submission meets criteria for a Special 510(k). Continue with the remainder of this checklist below.
☐ No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist; convert to a Traditional and apply the Traditional checklist.

Acceptance Checklist for Special 510(k)

RTA guidance includes checklists for traditional (24 pages), special (10 pages) and abbreviated (26 pages) 510k…

What does that say?

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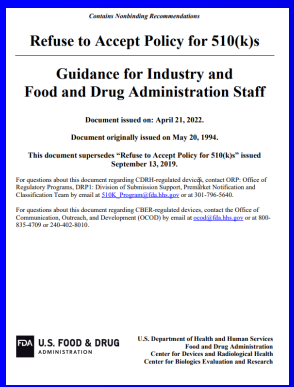
Meet the family…



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Refuse to Accept Policy for 510(k)s

Guidance for Industry and Food and Drug Administration Staff

Document issued on: April 21, 2022.

Document originally issued on May 20, 1994.

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Center for Devices and Radiological Health
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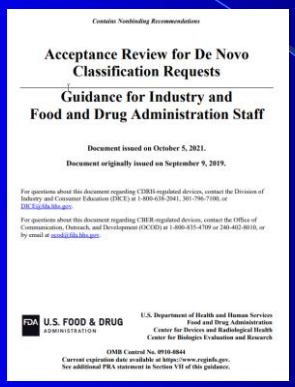
Refuse to Accept Policy for 510(k)s (April, 2022 available here)



Contains Nonbinding Recommendations

Acceptance Review for De Novo Classification Requests

Guidance for Industry and Food and Drug Administration Staff

Document issued on October 5, 2021.

Document originally issued on September 9, 2019.

For questions about this document regarding CDRH-regulated devices, contact the Division of Industry and Consumer Education (DICE) at 1-800-638-2041, 301-796-7100, or DICE@fda.hhs.gov.

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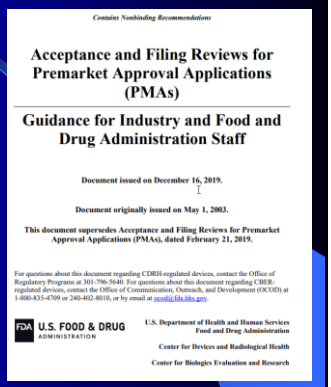
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

OMB Control No. 0910-0844
Current expiration date available at https://www.reginfo.gov.
See additional PRA statement in Section VII of this guidance.

Guidance: *Acceptance Review for De Novo Classification Requests* (Oct, 2021) here



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Acceptance and Filing Reviews for Premarket Approval Applications (PMAs)

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 16, 2019.

Document originally issued on May 1, 2003.

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Acceptance and Filing Reviews for Premarket Approval Applications (PMAs) (Dec, 2019) here

If you get an AIR or RTA, what's your excuse?

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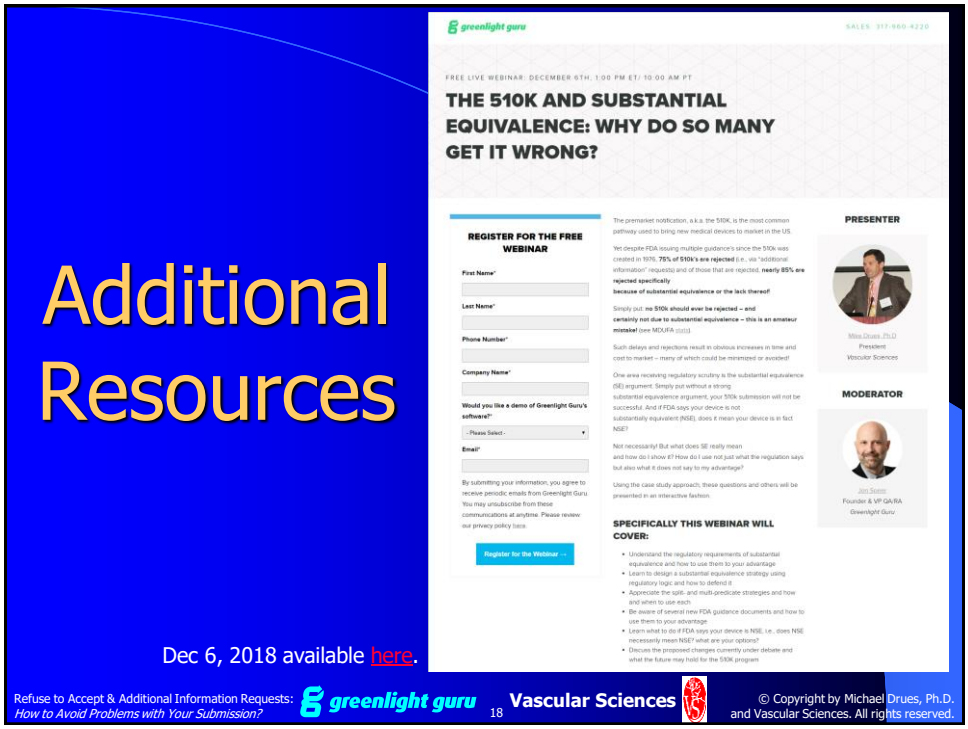

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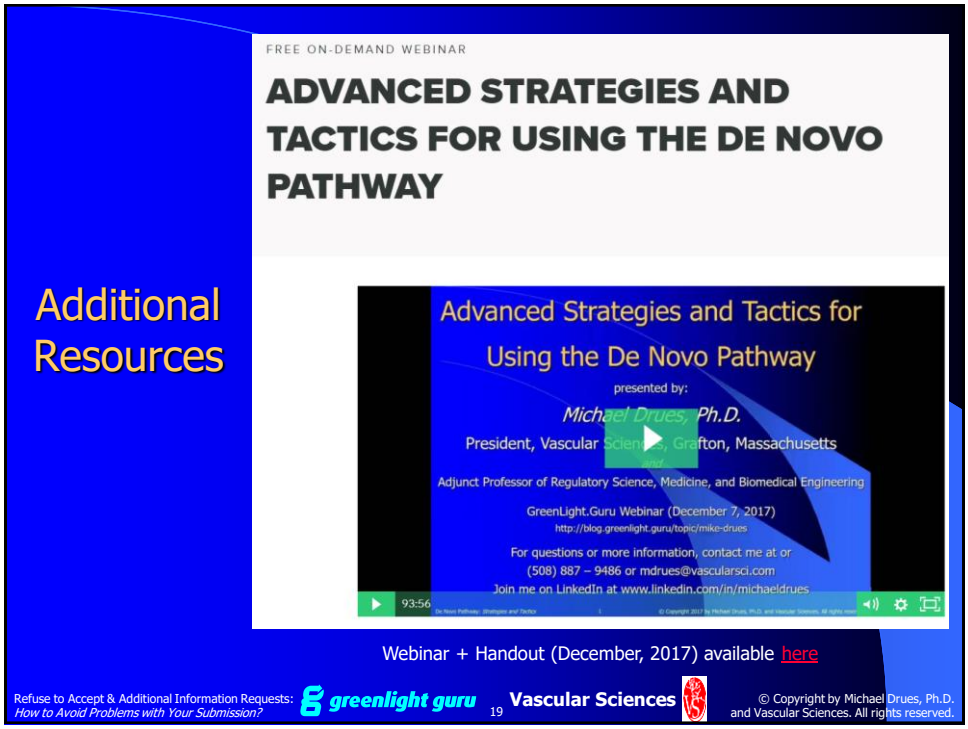

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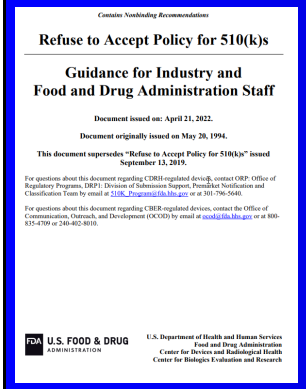
Comparison by Page Count?



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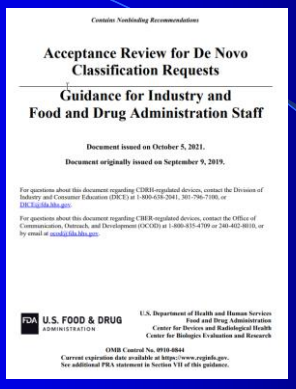
Refuse to Accept Policy for 510(k)s (April, 2022 available here)

102 pages



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OMB Control No. 0910-0844
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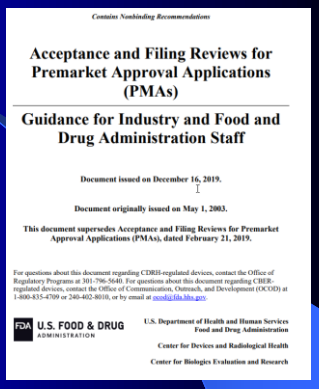
35 pages



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Acceptance and Filing Reviews for Premarket Approval Applications (PMAs) (Dec, 2019) here

36 pages

What does that say?

i.e., Novel (de Novo) and/or Riskier Devices (PMA) << Me-too (510k) Devices?

Does that make sense?

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Are they substantially equivalent?

We must always look for similarities…

even when no similarities appear to exist!

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Are these substantially equivalent?

Contains Nonbinding Recommendations

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Refuse to File: NDA and BLA Submissions to CDER
Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact Amalia Himaya at 301-796-0700.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

December 2017
Procedural

Refusal to file (RTF) is FDA's formal decision to deny review of an NDA or BLA due to application deficiencies.

Refuse to File: NDA and BLA Submissions to CDER Guidance (Dec, 2017 here)

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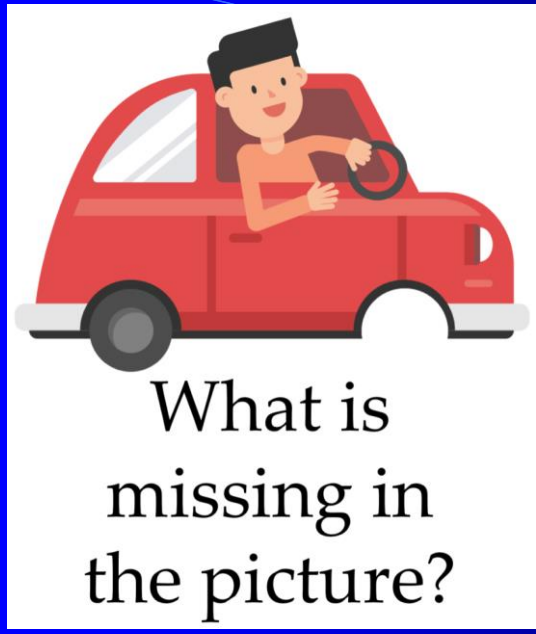

What RTA guidance's do we not have?

Is there an RTA guidance for pre-subs?

Nope!

Should there be?

But there are many resources available…

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GreenLight.Guru Webinar (March 23, 2023)

www.greenlight.guru/webinar/refuse-to-accept-additional-information-requests-avoid-problems-medical-device-submission

Mike's Pre-Sub Resources

2-hr Seminar: ***Conducting Effective FDA Pre-Submission Meetings*** (Med Device Tech Exchange, April, 2018) here.

Podcast: ***How to Properly Use the FDA Pre-Submission Process and Why It's So Important*** (August, 2016) here.

Column: ***How To Make The Most Of Your Pre-Sub Interactions with FDA*** (Med Dev Online, Feb, 2015) here.

Column: ***Communicating With FDA: How (And When) To Get It Right*** (Med Dev Online, June, 2015) here.

Editorial: ***3 Tips To Vastly Improve Your FDA Communication Strategy*** (MDDI, May, 2014) here.

Podcast: ***How To Make The Most Of Your Pre-Submission Interactions With FDA*** here.

Podcast: ***How to Properly Use the FDA Pre-Submission Process and Why It's So Important*** here.

Podcast: ***When And How To Interact With The FDA*** (MED Device Online, March, 2015) here.

Webinar: ***Communication With FDA: What Do We Say and How Do We Say It?*** (GWU, Jan, 2016) here.

Should you be interested... ☺

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Why did FDA reject 58% of all 510k submissions in 2013

Refuse-to-Accept (RTA) Policy

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Don't blame FDA… learn from others mistakes!

In 2013,

2,965 510k's received = 1,197 Accepted + 1,715 RTA [+ 53 MIA?]

Percent of Submissions Not Accepted under RTA = 58%

Why?

Some Reported Reasons for Refusal

- ✓ Failure to state whether a condom was patient contacting
  Recommendation: *Don't assume FDA understands your device!*
- ✓ Failure to comply with a *draft* guidance document
  Recommendation: *Draft vs. Final doesn't matter - you don't have to comply but you must justify!*
- ✓ Failure to indicate vinyl glove does not contain software or met electrical safety requirements
  Recommendation: *Don't leave something out because you think it doesn't apply!*
- ✓ Typos, misprints, duplicate pages, etc.
  Recommendation: *Do I really need to say… proof-read! AND don't ask FDA to be your β-tester!*

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How to avoid unnecessary delays?

Most delays are avoidable!

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How to avoid unnecessary delays?

Most delays are avoidable!

What's the review process?

Administrative Review

↓

Scientific Review

Remember,

Never OMIT a section!

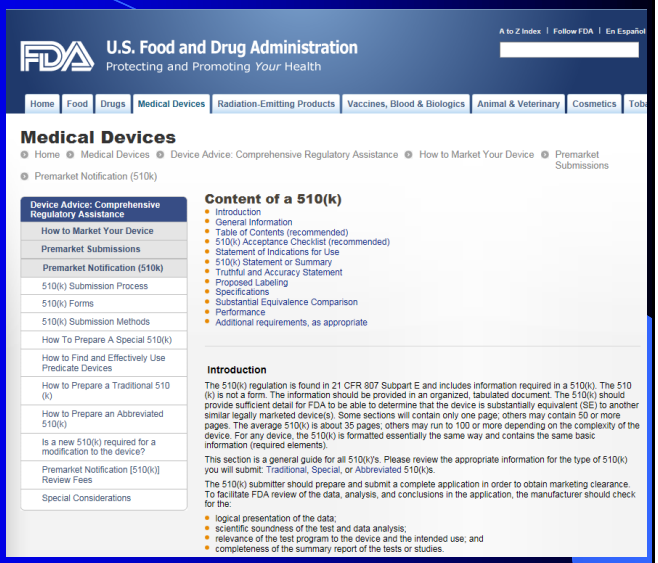
and

Always use the current forms!

Keeps the bureaucrats happy! ☺

Call DICE?

CDRH Premarket Review Submission Cover Sheet (FDA 3514) (June, 2023) here (online here)



https://www.fda.gov/medical-devices/premarket-notification-510k/content-510k

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How much detail must I provide in my submission

There is no answer... sorry!

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What kind of submission? How much detail?

Question: ***What kind of submission do I need for a class I device? How in depth?***

In a nut-shell:

if Class I Exempt → no 510k submission is required
(registration is still required in most cases)

if Class I non-exempt → 510k is required

Note:

General submission requirements are no different for Class I vs. Class II however…

Class II 510k is going to require more 'detail' than class I due to higher risk, etc.

Also, Design Controls apply to some Class I devices and all class II devices.

Here are a few resources you might find useful:

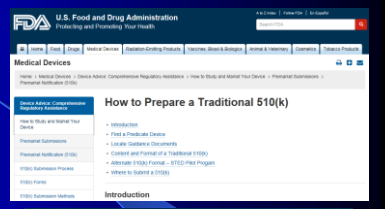
How to Prepare a Traditional 510(k) available here.

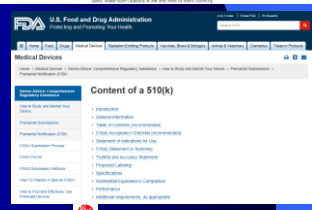
510(k) Format Tips available here.

Content of a 510(k) available here.

How much detail? My recommendation:

Put yourself in the shoes of the reviewer!





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Don't be penny wise and pound foolish!

Look how easy a 510k can be! →

If you needed surgery…

Would you want your surgeon following a template?

Even for simple devices…

Is it worth it?

Remember…

Most problems are predictable and preventable

and

Usually it costs more time and money to clean up other people's messes!

Screenshot (July, 2015) available here.

FDA 510(k) Templates

510(k) Templates Are Customizable for Traditional, Abbreviated, and Special 510(k)s and Are Made Compliant with the e-Copy and RTA Policy Requirements

510(k) Preparation Made EZ! – USE TEMPLATES!!!

- **510(k) Templates**
  1. For Traditional, Abbreviated and Special 510(k)s
  2. Documents in Word
  3. Prepared Section by Section
  4. Customizable
  5. Cover Letter Included
  6. eCopy Ready Format
  7. RTA Items-Made Easy to Address
  8. Support Available While Using the Template Forms
  9. *YOU SAVE TIME and EFFORTS!!!*
- **$119-149**
  - *Delivered Within 24 Hours of Purchase*

Customizable 510(k) Templates Are Available for Three 510(k) Types (Traditional, Abbreviated, and Special)

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Can I (should I) use e-tools to mitigate AIR and RTA risk

Short answer: *yes and no*

i.e., recognize their strengths and limitations

Suggestion: Think

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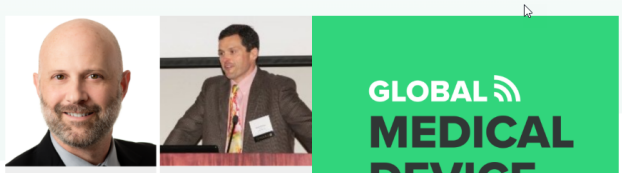
What is the eSTAR Pilot Program and How Will it Improve FDA's 510(k) Review Process?

Written by: NICK TIPPMANN

March 12, 2020



The FDA announced another new pilot program to improve the consistency and efficiency of its 510(k) review process. It's called, eSTAR, or electronic Submission Template And Resource.

www.greenlight.guru/blog/what-is-estar-pilot-program-and-how-will-it-improve-fda-510k-review-process

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How about some

Additional Information Request: *Usability* 510k AIR Hold Letter

Additional Information Request: *Biocompatibility*

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Want more on Usability?

Free Live Webinar by greenlight guru + Vascular Sciences

USABILITY TESTING: WHY CAN'T WE GET IT RIGHT?

REGISTER NOW →

September 22nd @ 1:00p ET / 10:00a PT

Presenter

MIKE DRUES
President, Vascular Sciences

Moderator

JON SPEER
Founder, Greenlight Guru

https://www.greenlight.guru/webinar/usability-testing

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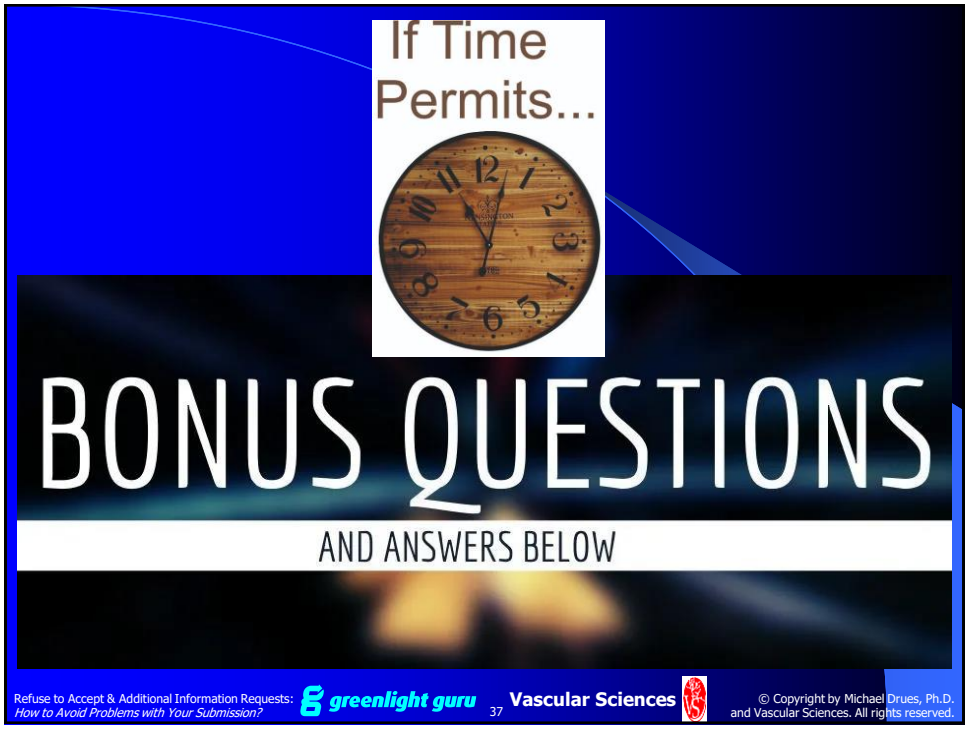

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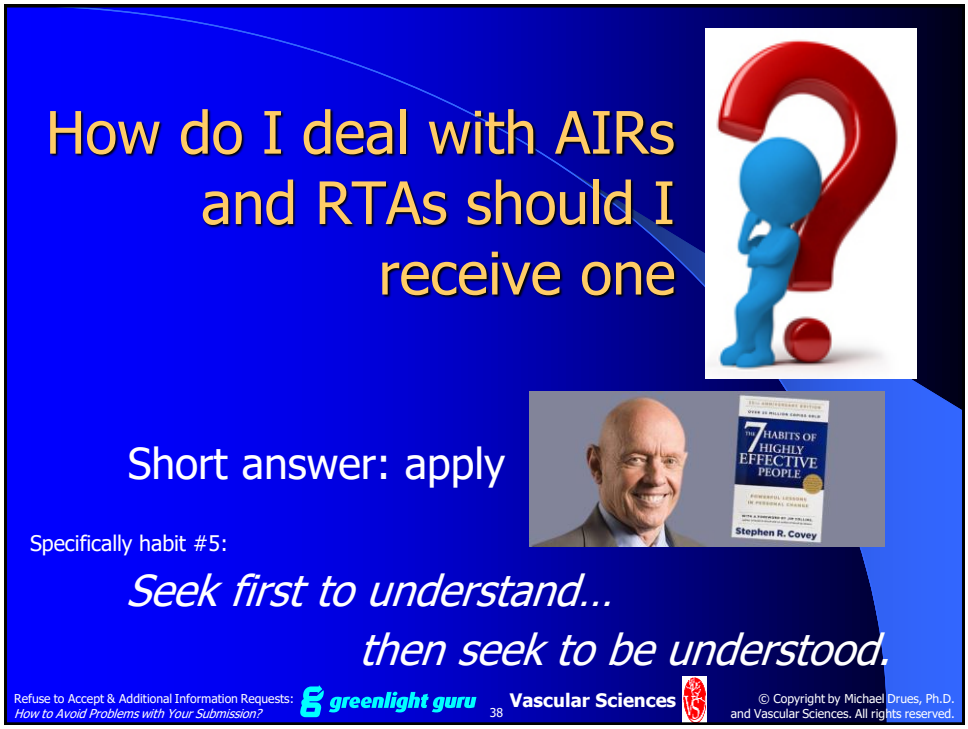

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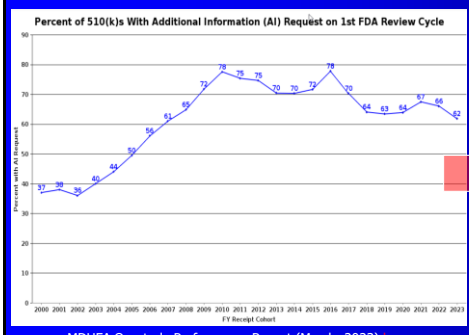
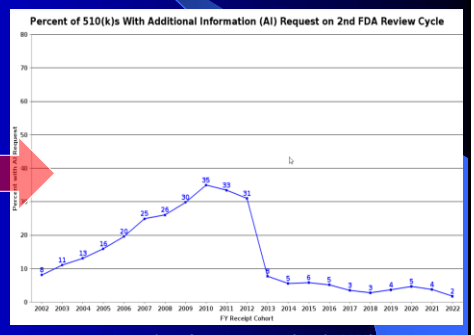
How do I measure the efficacy of my AIR response



MDUFA Quarterly Performance Report (March, 2023) here.



MDUFA Quarterly Performance Report (March, 2023) here.

Simple: *Did you get another incomplete?*

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What's the

- ✓ Put yourself in the shoes of the reviewer
- ✓ Don't treat the FDA as your β-tester
- ✓ Remember

If you get an AIR, you got an incomplete!

If you get an RTA or MDL, you got an F!

If you don't get an AIR, RTA or MDL, does that mean you got an "A" – *nope!*

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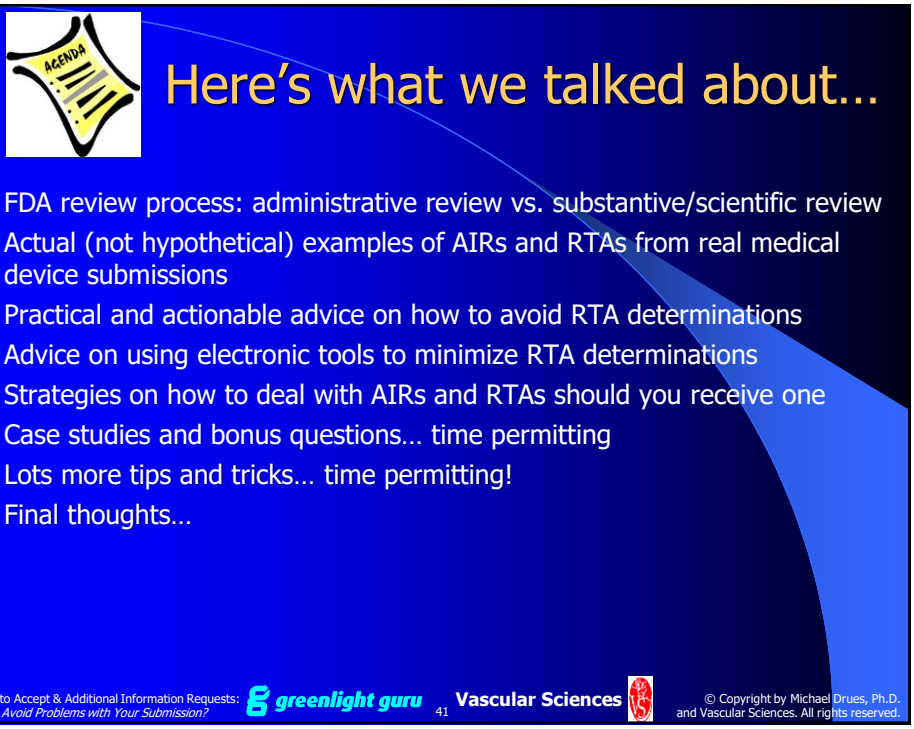

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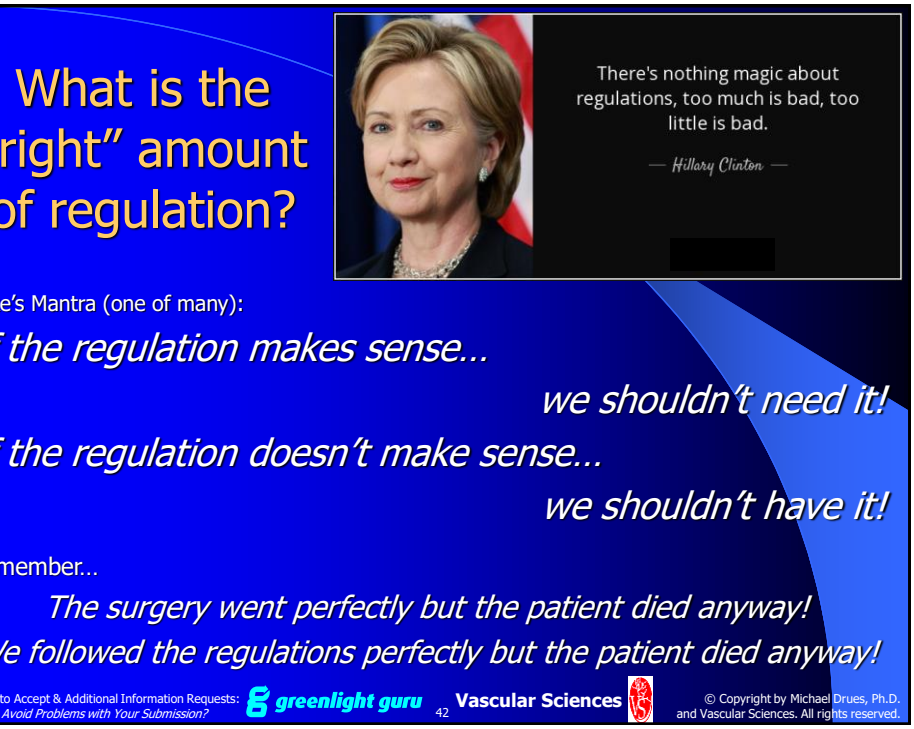

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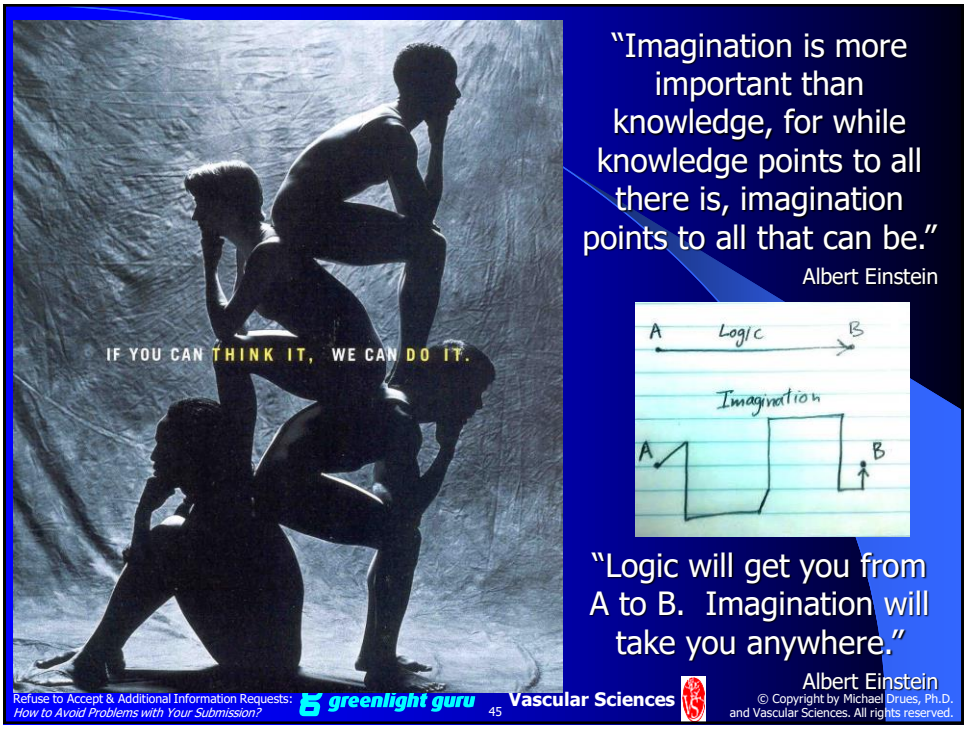
For additional information, www.linkedin.com/in/michaeldrues,
call (508) 887-9486 or e-mail mdrues@vascularsci.com



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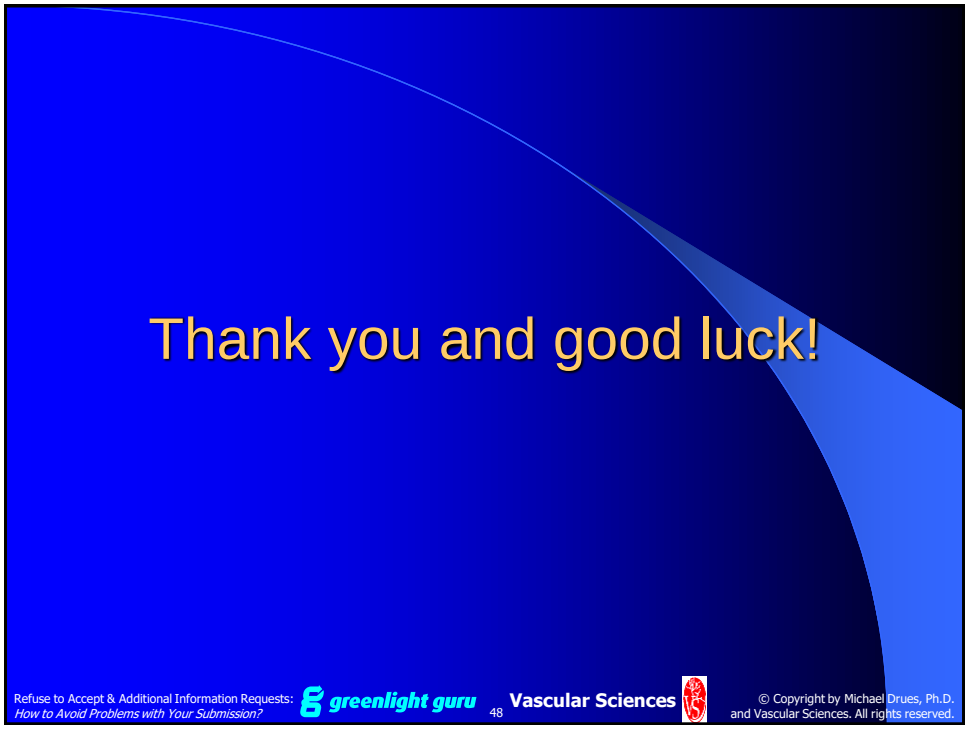

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