Premarket Notification [510(k)] Process Overview, New Policies and Pilots

FDA Small Business
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ONE DOES NOT SIMPLY
SUBMIT A 510(K)
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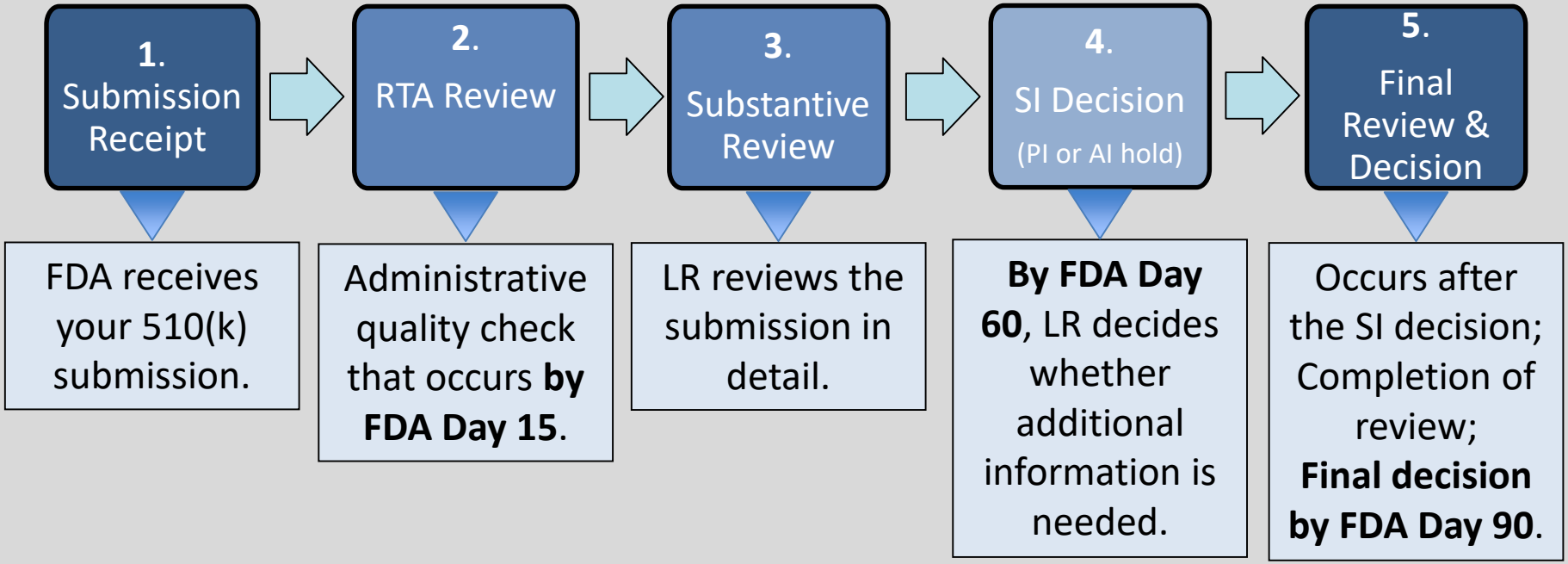
Learning Objectives

- Review a summary of the 510(k) Review Process
- Explain why FDA develops pilots and new policies
- Describe the new 510(k) policies
- Describe the ongoing 510(k) pilots

Summary of the 510(k) Review Process

High-Level Process Overview

510(k) Submission Core Process



Acronyms:

RTA = Refuse to Accept
LR = Lead Reviewer
SI = Substantive Interaction
PI = Proceed Interactively
AI = Additional Information

Why Develop Pilots and New Policies?

Goals of Pilots and New Policies

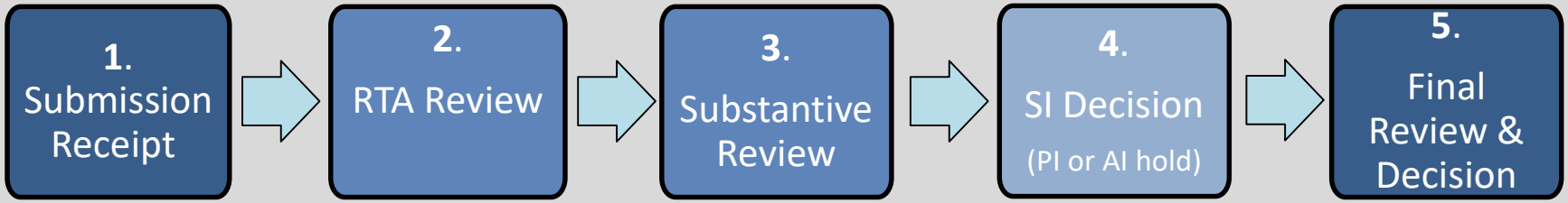
Improve Efficiency

Decrease the Total Time to Decision

New 510(k) Policies

New 510(k) Policies

510(k) Submission Core Process



Safety and Performance Based Pathway

Benefit-Risk Assessment

RTA Addendum

First Round NSE (FR-NSE)

Day-10 Call

Least Burdensome (LB) Flag

DHT-level SE

TPLC Key:
DHT = Division of Health Technology (formerly Branch)

New 510(k) Policies

1. Safety and Performance Based Pathway
2. Benefit Risk Assessment
3. RTA Addendum
4. First Round NSE
5. Day-10 Call
6. Least Burdensome Flag
7. DHT (First-level Manager) SE sign-off

1 – Safety and Performance Based Pathway: Overview

- Optional program
- Expands on existing Abbreviated 510(k) Program
- Removes requirement for direct predicate comparison testing for some performance characteristics
- Supports least burdensome provisions

Link to Guidance

www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway

1 – Safety and Performance Based Pathway: Eligibility Criteria

- Predicate is an eligible device type
- New device meets all FDA-identified performance criteria
- Performance criteria align with performance of at least one legally marketed device of the same device type

1 – Safety and Performance Based Pathway: Things to Note

- Not yet implemented
- Industry may suggest device types for consideration
- Once implemented:
  - You can meet FDA-identified performance criteria to demonstrate that the device is as safe and effective as predicate device
  - FDA intends to maintain a list of device types and testing methods recommended in guidance when appropriate

2 – Benefit Risk (B-R) Assessment

510(k) Benefit Risk Guidance

What It Is

- **An aid** for evaluating B-R factors to determine SE in a 510(k)
- **Improves predictability, consistency, and transparency** of the 510(k) premarket review process

What It Is Not

- **A change in** 510(k) premarket **review standard**
- **Extra burden** on a submitter to provide additional performance data from what has typically been expected for 510(k)s

When Is It Used?

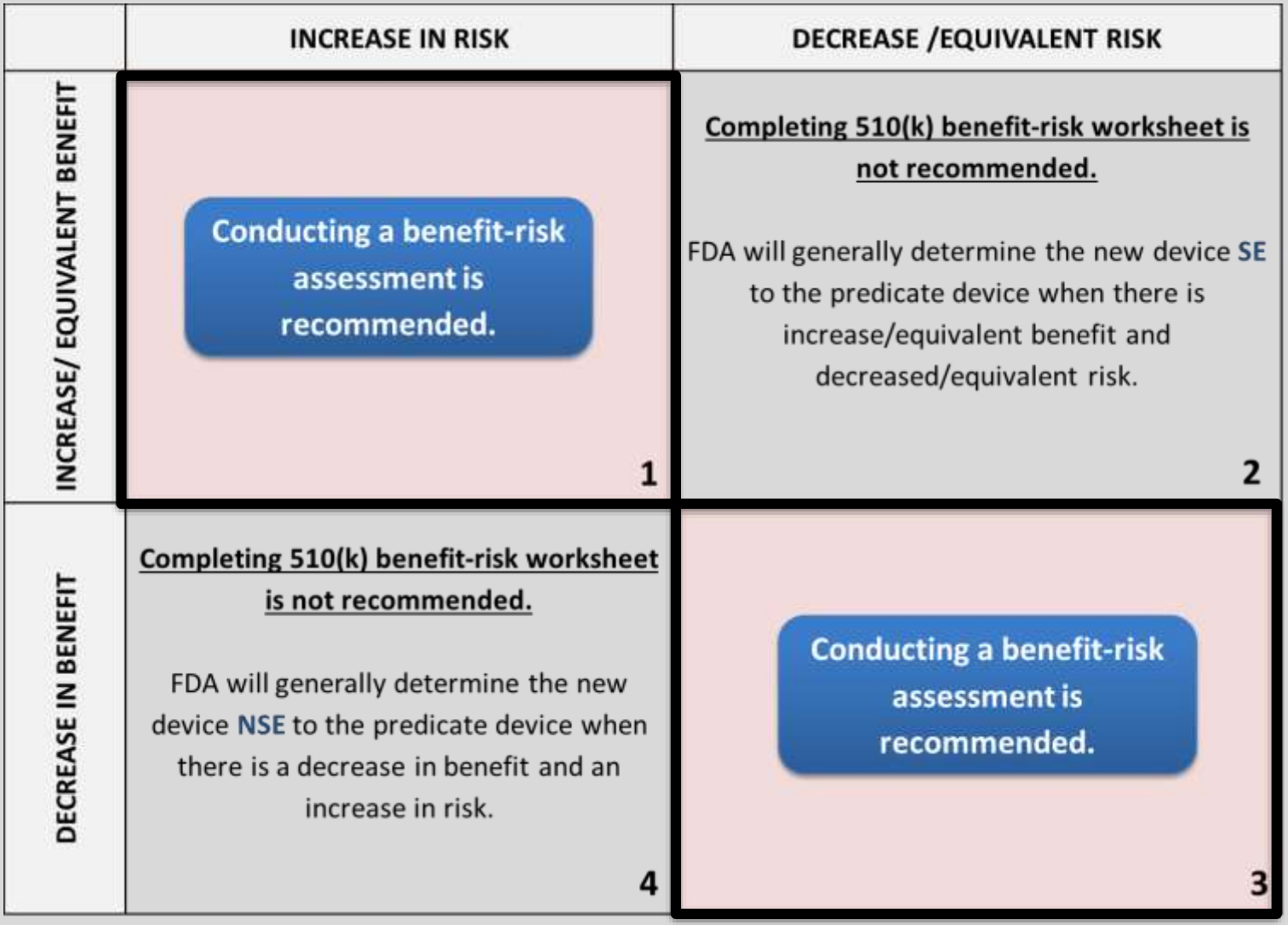
When the B-R profile of a new device differs from the predicate device

2 – Benefit Risk (B-R) Assessment

Table serves as a guide for when benefit-risk assessment is recommended in a 510(k). This table should be used with the guiding principles provided in the rest of the guidance.

	INCREASE/EQUIVALENT IN RISK	DECREASE /EQUIVALENT RISK
INCREASE/ EQUIVALENT BENEFIT	**INCREASE RISK & INCREASE/EQUIVALENT BENEFIT** FDA evaluates the nature of the increased risk and considers whether additional measures may help to mitigate the increased risk. **1**	**DECREASE/EQUIVALENT RISK & INCREASE/EQUIVALENT BENEFIT** FDA will generally determine the new device **SE** to the predicate device when there is increase/equivalent benefit and decreased/equivalent risk. **2**
DECREASE IN BENEFIT	**INCREASE/EQUIVALENT RISK & DECREASE BENEFIT** FDA will generally determine the new device **NSE** to the predicate device when there is a decrease in benefit and an increase in risk. **4**	**DECREASE/EQUIVALENT RISK & DECREASE BENEFIT** If the aggregate benefit and the risk level is decreased, FDA evaluates whether the differences impact whether the new device is at least "as safe and effective". **If there is a decrease in benefit without a decrease in risk, FDA would likely find a device NSE to the predicate.** **3**

2 – When will a B-R Assessment be performed?



3 – RTA Addendum

What It Is

- An attachment to RTA checklist embedded into PDF
- Early notification of "observations" made during initial RTA review
- An opportunity to address issues interactively during substantive review

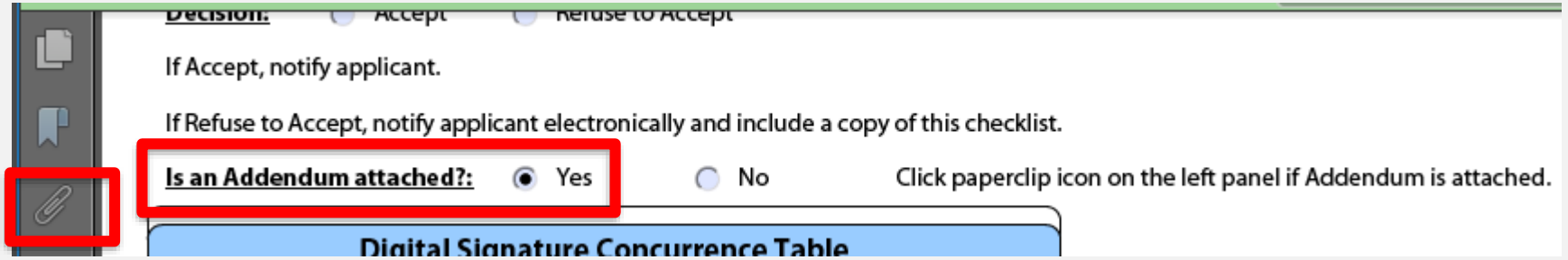
What It is Not

- Substantive review of submission
- In place of an additional information hold
- An official "ask" for additional information
- A delay in RTA review or decision

What Is An Observation?

Issue noted during administrative review that doesn't determine acceptability of submission, but would result in a deficiency during substantive review (Example: Missing a required animal or engineering test.)

Where Do I Find It?



4 – First Round (FR-NSE)

Description: A submission does not have to go on hold before a high level NSE recommendation is issued as long as the submitter has an opportunity to resolve the NSE issue interactively

What It Is

- Opportunity to resolve NSE issue interactively

What It Is Not

- An automatic NSE decision

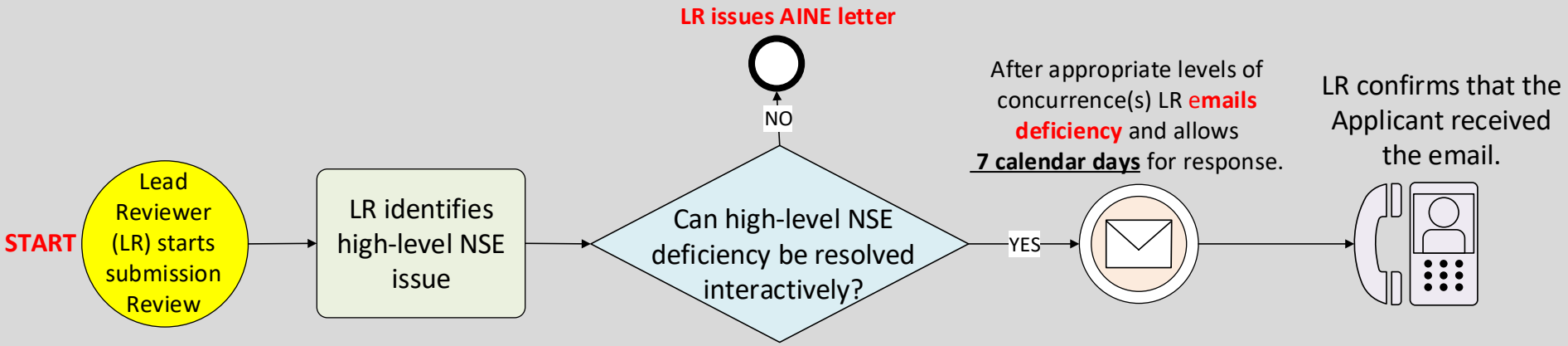
FR-NSE is reserved for High-level NSE reasons:

- No valid predicate
- New intended use
- Different technological characteristics that raise different questions of safety and effectiveness when compared to predicate

NOTE

Potential NSE letter can still be issued if FR-NSE was attempted and the deficiency cannot be adequately resolved interactively

4 – First Round (FR-NSE): Process Flow



AINE = AI Potential NSE decision

4 – First Round (FR-NSE): Responses and Outcomes

Responsive Submitter	**Cannot meet timeframe**	NSE letter is issued within 30 calendar days from email issuance.
	Can meet timeframe	LR reviews response and addresses minor clarification questions when appropriate.

Late Responder	**An NSE letter is issued within 30 calendar days after email issuance.** The LR is not obligated to review a late response if there is insufficient time for an adequate review.

Non-responsive Submitter	NSE letter is issued no sooner than one day after response was due.

5 – Day-10 Call

Description: Voluntary call offered by FDA that occurs within ten (10) days after issuance of an AI letter. The purpose of the call is to address clarification questions pertaining to the deficiencies in the letter.

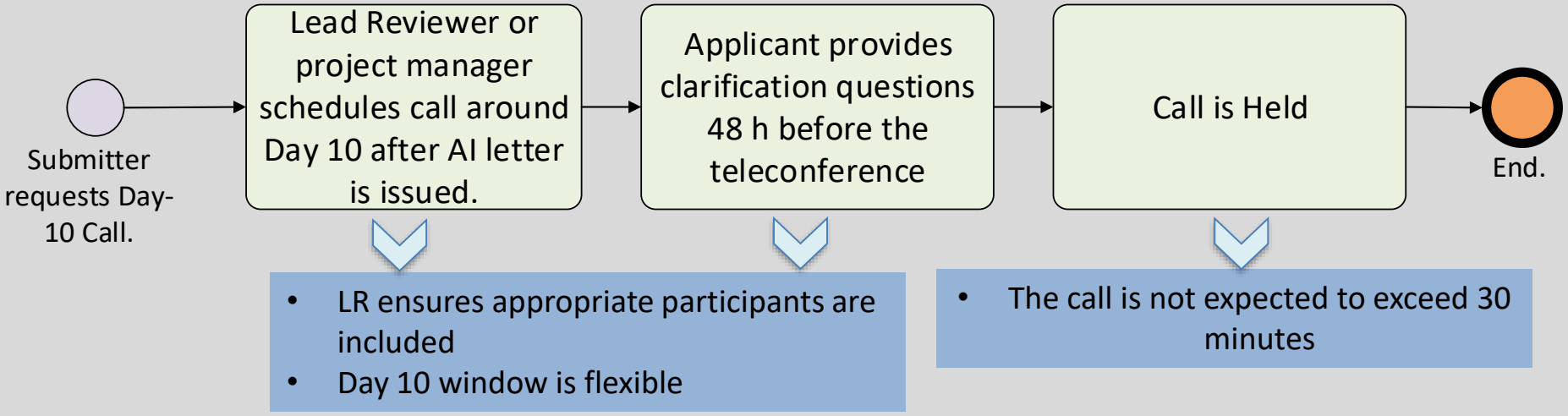
What It Is

- Teleconference
- Confirmation that submitter understands deficiencies in the letter
- Can be used to determine whether a Submission Issue Request is needed.

What It Is Not

- Review of additional information provided by submitter
- Discussion of issues unrelated to deficiencies in the AI letter
- A Submission Issue Request meeting

5 – Day-10 Call: Process Flow



6 – Least Burdensome (LB) Flag

What It Is

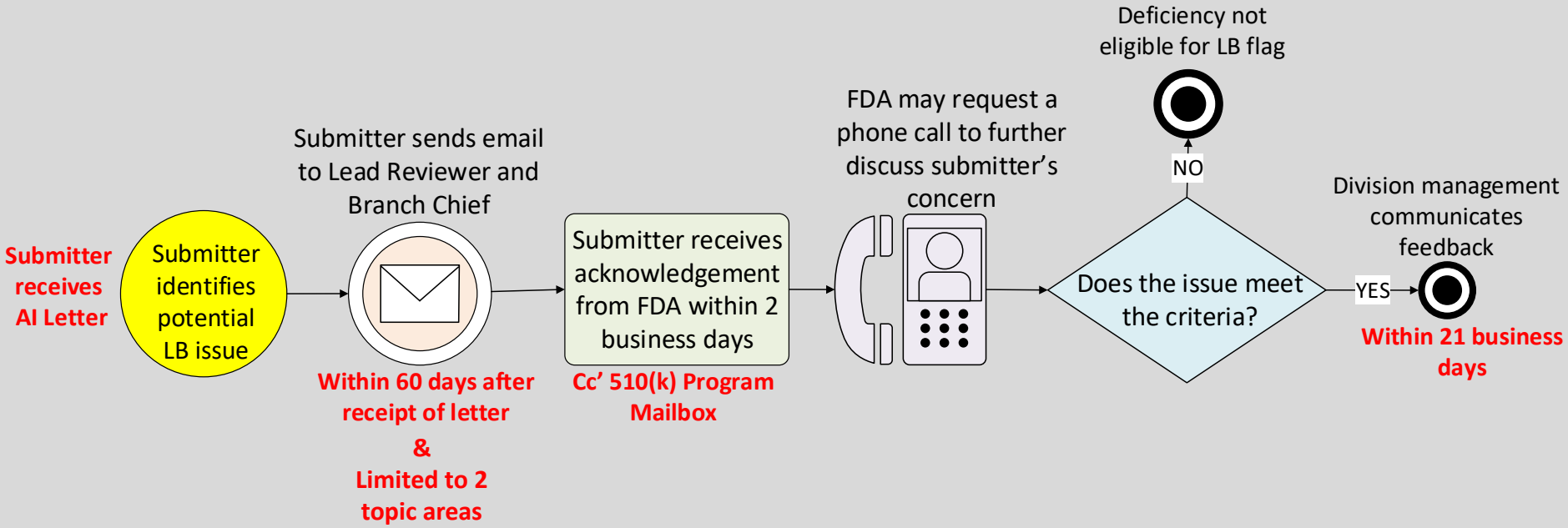
- Opportunity to address LB discrepancies in an AI letter
- Opportunity for submitters to address situations when they feel they are being held to a different standard

What It is Not

- An Appeal Meeting
- Change to 180 Response deadline

The Least Burdensome Provisions: Concept and Principles Guidance for Industry and FDA (February, 2019)

6 – Least Burdensome (LB) Flag: Process Flow



7 – DHT (First-Line Manager) SE Final Concurrence

Description: DHT AD signs out straightforward SE letters. This approach reduces time spent waiting for OHT Director's review and concurrence.

When Is It Applicable?

- The review team has reviewed similar devices with similar regulatory requirements
- DHT has extensive knowledge of product area
- The device or submission is not complex from a regulatory or performance data standpoint
  - Example: Clinical data needed for a change in indication and/or technology might not be appropriate for DHT-level SE concurrence.
- SE recommendation is not controversial and/or does not have potential to be controversial.
  - Example: A 510(k) claiming equivalence to a recalled device might not be appropriate.

TPLC Key: Branch Chief = Division of Health Technology Assistant Director (DHT AD); OHT = Office of Health Technology

Summary: New Policies

7 New Policies

1. Safety and Performance Based Pathway
2. Benefit Risk Assessment
3. RTA Addendum
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7. DHT SE sign-off

New 510(k) Pilots

2 Ongoing Pilot Programs

510(k) Pilot Webpage

Special 510(k) Pilot

Purpose: Expand types of changes eligible for program to improve efficiency of 510(k) review.

Remains the same:

Proposed change is made and submitted by the manufacturer authorized to market the existing device

Existing Special 510(k) Policy	Policy in Pilot
• Changes(s) do not affect intended use; AND • Change(s) do not alter fundamental scientific technology	• Performance data are unnecessary, **OR** if performance data are necessary, well-established methods are available to evaluate the change; **AND** • All data necessary to support substantial equivalence can be reviewed in summary or risk analysis format

Special 510(k) Pilot: What is a well-established method?

- Those used in the previously cleared 510(k)
- Methods in an FDA-recognized consensus standard
- Widely available and accepted methods, or those in another of the manufacturer's premarket submission

Things to Note

- All methods used in new 510(k) should be well-established
- If no well-established method exists, FDA intends to convert submission to a Traditional 510(k)

Quality in 510(k) Review Pilot

Purpose: Determine whether use of FDA's free eSubmitter software will produce well-organized submissions that can be reviewed more efficiently to help promote timely access to safe, effective, and high-quality medical devices.

- **Eligibility (must meet all):**
  - Specific product codes
  - Required use of eSubmitter to construct 510(k) submission
  - Not a combination product
  - Traditional and Abbreviated 510(k)s (no Specials)
- **No RTA review**
- **Interactive review**
- **Final decision expected by FDA Day 60**
- **If ineligible, submission is converted to 90 FDA Day timeframe**
  - Example: Complex issues could render the file ineligible for the pilot

Summary: Pilot Programs

2 On-going Pilots

1. Special 510(k)

2. Quality in 510(k) Review

Resources

Guidance Documents

- Deciding When to Submit a 510(k) for a Change to an Existing Device
- User Fees and Refunds for Premarket Notification Submissions (510(k)s)
- Refuse to Accept Policy for 510(k)s
- The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]
- The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications
- FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals
- Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions
- Procedures for Class II Device Exemptions from Premarket Notification
- Bundling Multiple Devices or Multiple Indications in a Single Submission
- The Least Burdensome Provisions: Concept and Principles
- Medical Device Classification Product Codes

Summary

- FDA has established a series of 7 policies and 2 pilots
  - to improve the review process
  - while maintaining safety and effectiveness review standard

Further Questions About the 510(k) Program

Contact:

- 510k_Program@fda.hhs.gov
- DICE@fda.hhs.gov
  Division of Industry and Consumer Education

Questions

Your Call To Action

- Use these policies and pilots when developing your next 510(k)

Clarity.fm

Thank you!