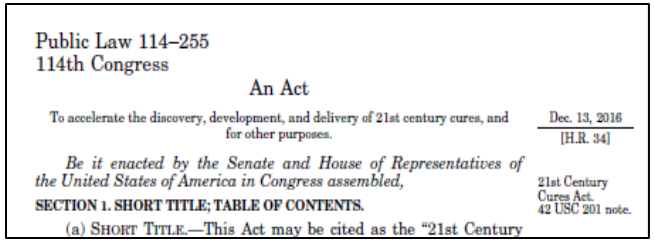
Least Burdensome: Training and Deficiency Guidance Update

Robert Sauer
Chief, Premarket Policy and Operations
Division of Program Operations and Management
OIR

21st Century Cures and MDUFA IV commit FDA to updating LB implementation



Public Law 114–255
114th Congress

An Act

To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes.

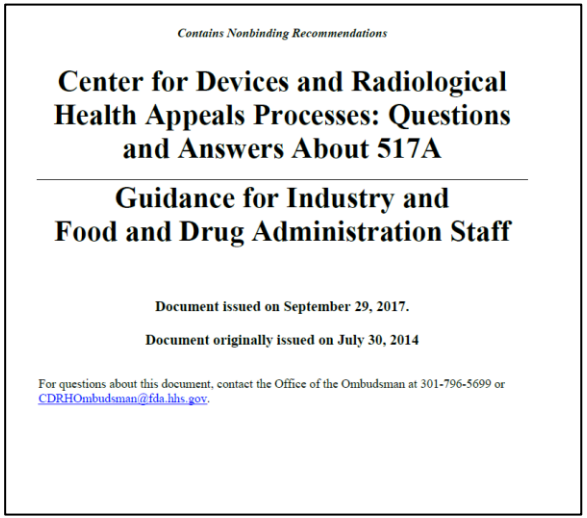
Dec. 13, 2016
[H.R. 34]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

21st Century Cures Act.
42 USC 201 note.

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "21st Century



Contains Nonbinding Recommendations

Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 29, 2017.

Document originally issued on July 30, 2014

For questions about this document, contact the Office of the Ombudsman at 301-796-5699 or CDRHOmbudsman@fda.hhs.gov.

Section 3058 of Cures:

Least Burdensome Device Review

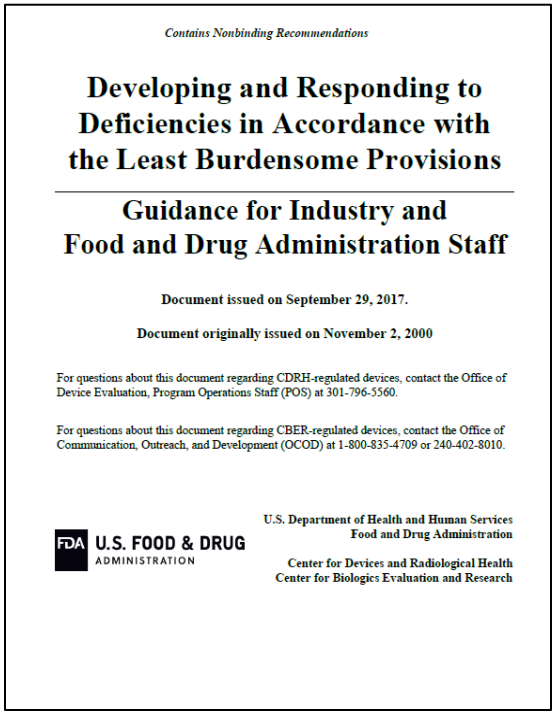
- Premarket Application Provisions
- Training & Assessment
- Audit by Ombudsman
- Rationale for Significant Decisions

There are now six major LB themes

1. 510(k) requests must be relevant to SE determination
2. PMA requests must consider LB means to demonstrate a Reasonable Assurance of Safety and Effectiveness
3. Requests for Clinical Data must be necessary for establishing device effectiveness
4. Postmarket Information shall be considered
5. Only ask for the minimum required information
6. Review Standards remain unchanged

Training was completed in September

In MDUFA IV, FDA committed to updating the deficiency guidance



Contains Nonbinding Recommendations

Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 29, 2017.

Document originally issued on November 2, 2000

For questions about this document regarding CDRH-regulated devices, contact the Office of Device Evaluation, Program Operations Staff (POS) at 301-796-5560.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

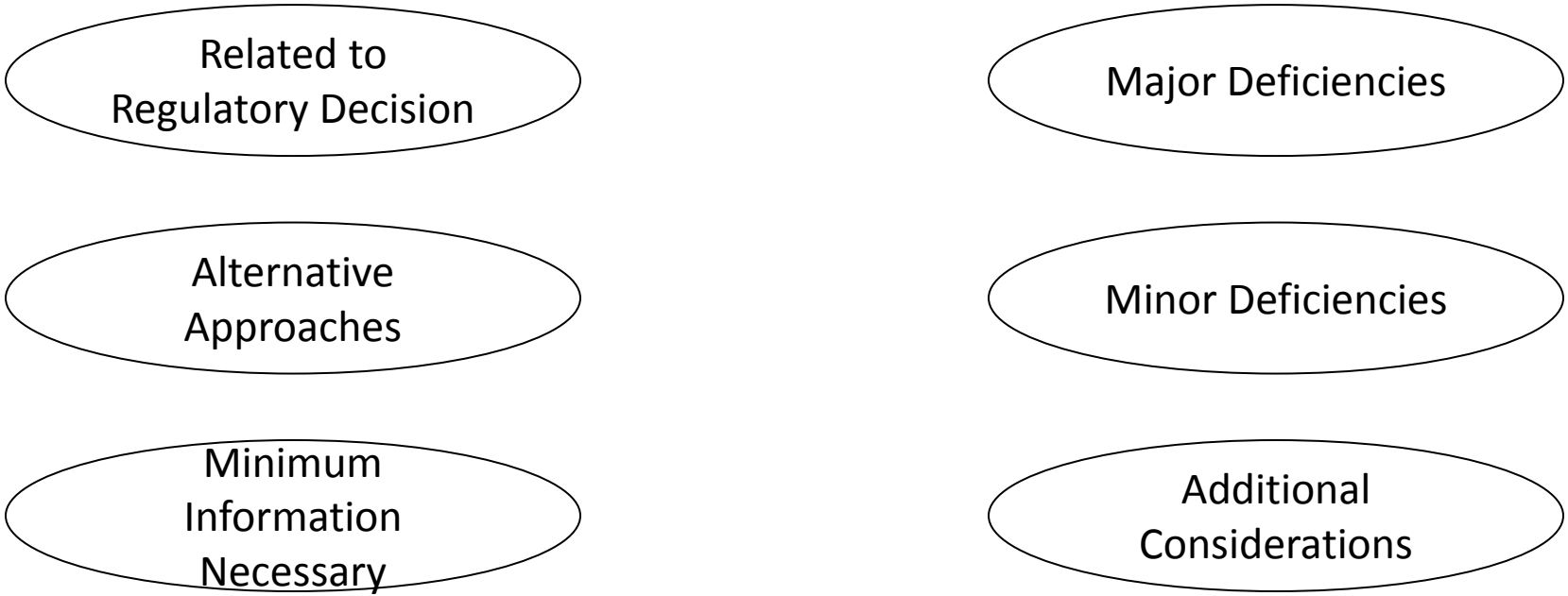
U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

- Scope: Marketing Applications
- Online and in-person training made available and completed in September 2017
- Introduces Guiding Principles
- Clarifies deficiency format

New Guiding Principles

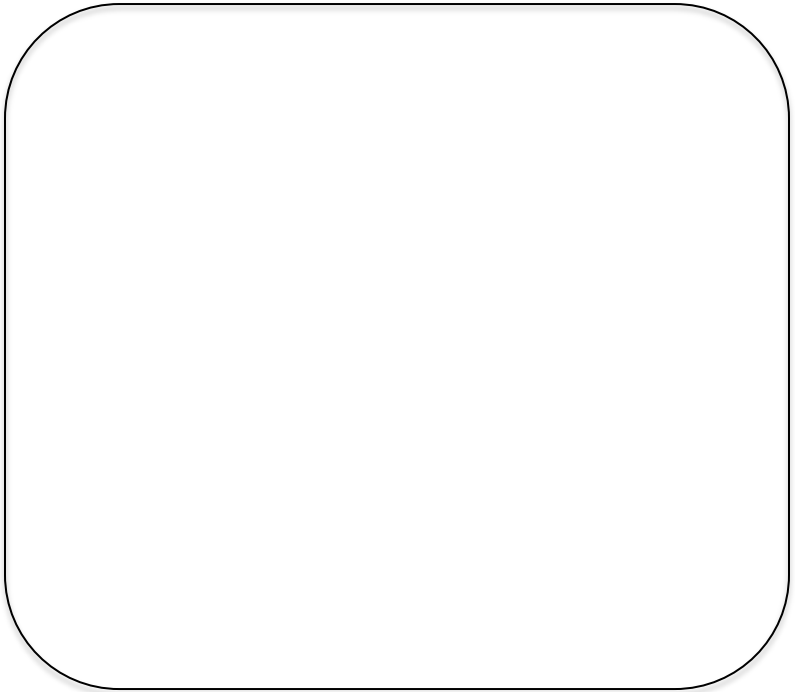


The first three Guiding Principles frame our requests

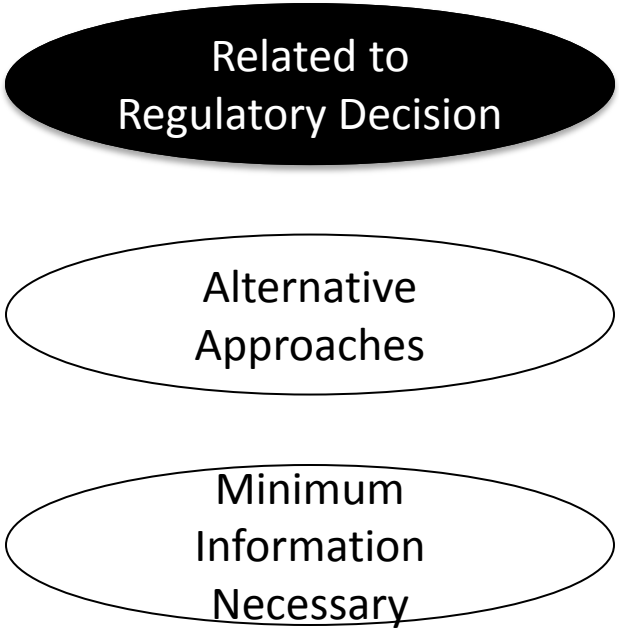
Related to Regulatory Decision

Alternative Approaches

Minimum Information Necessary

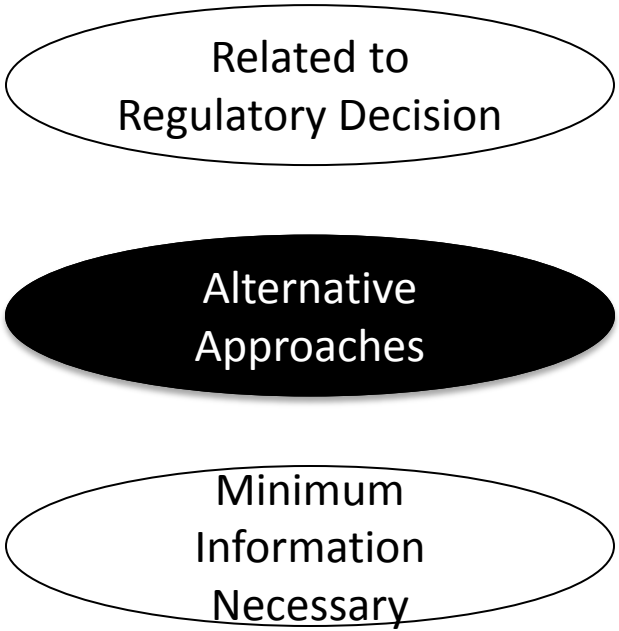


Related to Regulatory Decision



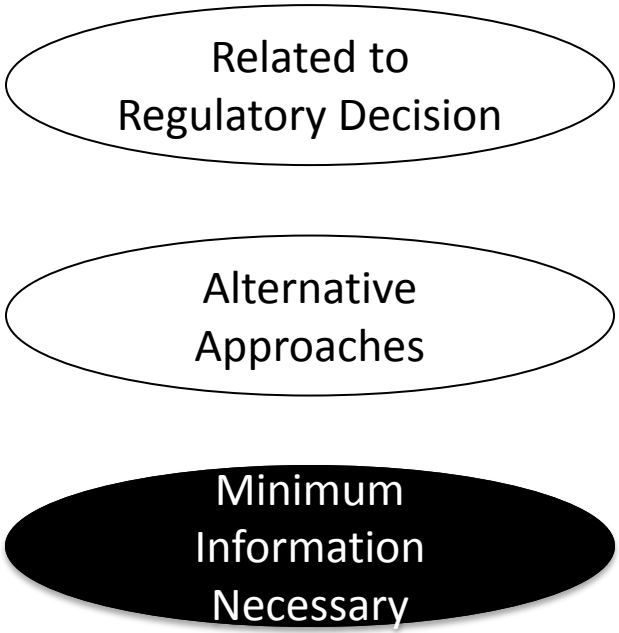
Information unrelated to the regulatory decision should not be part of the decision-making process.

Alternative Approaches



Alternative approaches to resolving regulatory issues should be considered to optimize the necessary time, effort, and resources involved in developing a response.

Minimum Information Necessary



Deficiencies should request the minimum (i.e., least burdensome) amount of information necessary to adequately address the identified issue in the most efficient manner at the right time. The balance between premarket and postmarket should be considered to determine when information should be provided to address the identified issue.

New Guiding Principles

Related to Regulatory Decision

Alternative Approaches

Minimum Information Necessary

Major Deficiencies

Minor Deficiencies

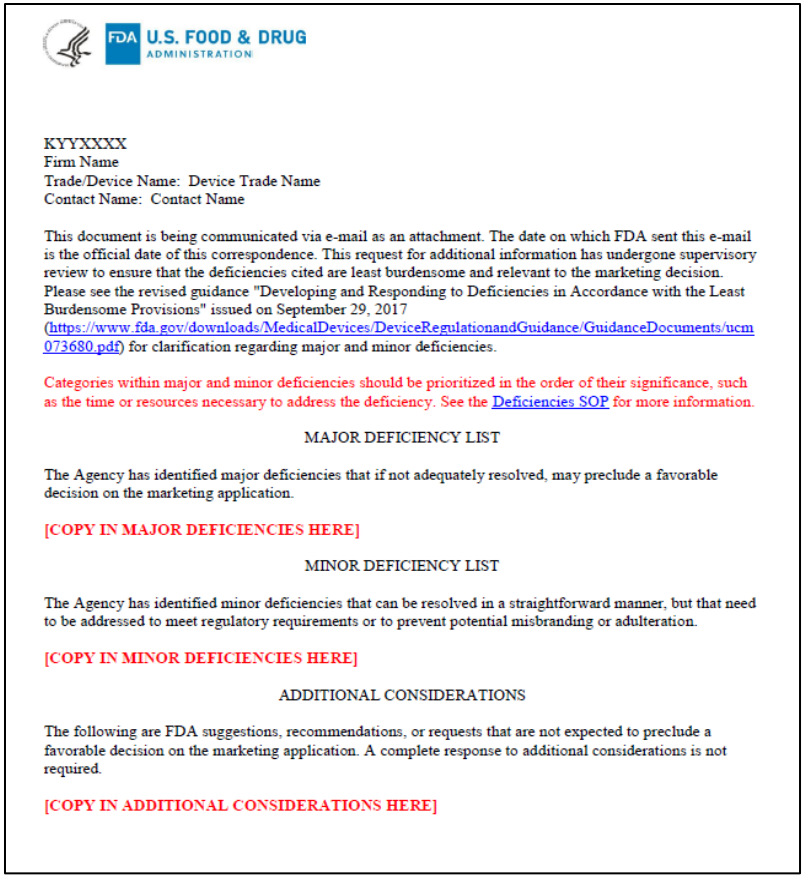
Additional Considerations

Categorizing deficiencies improves overall clarity

Major Deficiencies

Minor Deficiencies

Additional Considerations



U.S. FOOD & DRUG ADMINISTRATION

KYYXXXX
Firm Name
Trade/Device Name: Device Trade Name
Contact Name: Contact Name

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence. This request for additional information has undergone supervisory review to ensure that the deficiencies cited are least burdensome and relevant to the marketing decision. Please see the revised guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" issued on September 29, 2017 (https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073680.pdf) for clarification regarding major and minor deficiencies.

Categories within major and minor deficiencies should be prioritized in the order of their significance, such as the time or resources necessary to address the deficiency. See the Deficiencies SOP for more information.

MAJOR DEFICIENCY LIST

The Agency has identified major deficiencies that if not adequately resolved, may preclude a favorable decision on the marketing application.

[COPY IN MAJOR DEFICIENCIES HERE]

MINOR DEFICIENCY LIST

The Agency has identified minor deficiencies that can be resolved in a straightforward manner, but that need to be addressed to meet regulatory requirements or to prevent potential misbranding or adulteration.

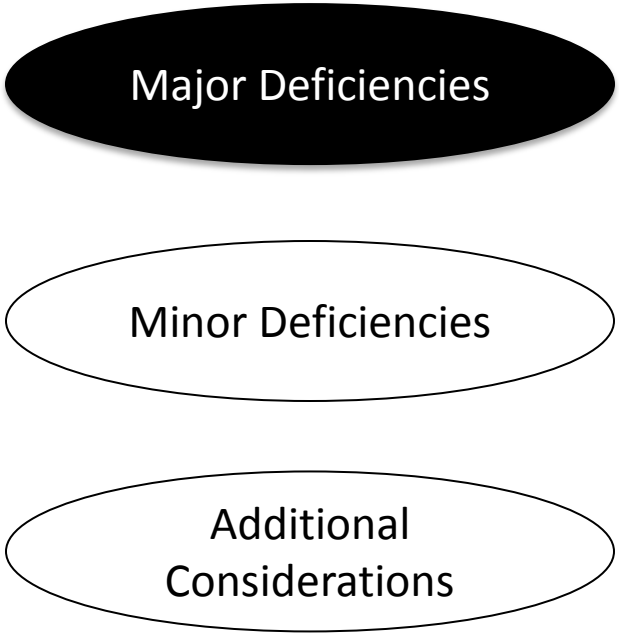
[COPY IN MINOR DEFICIENCIES HERE]

ADDITIONAL CONSIDERATIONS

The following are FDA suggestions, recommendations, or requests that are not expected to preclude a favorable decision on the marketing application. A complete response to additional considerations is not required.

[COPY IN ADDITIONAL CONSIDERATIONS HERE]

Major Deficiencies



Major deficiencies are those based on least burdensome principles that, **if not resolved, will preclude a favorable decision** on the marketing application. Major deficiencies should only be included if their resolution is necessary in order to reach a final decision regarding the marketing authorization.

Minor Deficiencies

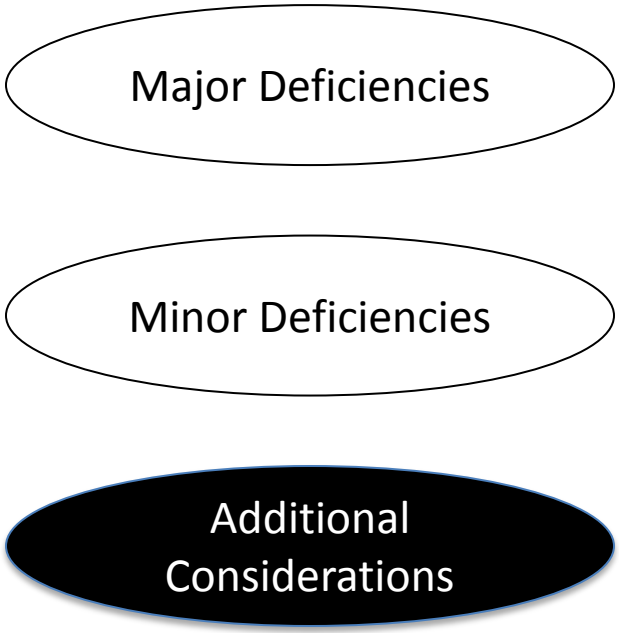
Major Deficiencies

Minor Deficiencies

Additional Considerations

Minor deficiencies are FDA requests that **can be resolved in a straightforward manner, but that need to be addressed** to meet regulatory requirements or to prevent potential misbranding or adulteration. In general, the Agency should not issue a formal deficiency letter if only minor deficiencies remain, but instead should attempt to resolve them interactively.

Additional Considerations



FDA may also include additional considerations that are suggestions, recommendations, or requests that are not expected to preclude a favorable decision on the marketing application. Because additional considerations are not expected to preclude a favorable decision, **they do not require an applicant response**.

New deficiency elements clarify "what" is deficient

1. Acknowledgment of the information submitted by the applicant, including references to sections, page numbers, or tables where appropriate.
2. Explanation of why the current information does not adequately address the issue (i.e., what is deficient).

New deficiency elements clarify "what" is deficient

1. Acknowledgment of the information submitted by the applicant, **including references to sections, page numbers, or tables where appropriate.**
2. Explanation of why the current information does not adequately address the issue (i.e., what is deficient).

New deficiency elements clarify "why" information is deficient

3. Explanation of the request's relevance to the PMA RASE determination, 510(k) SE determination, HDE safety and probable benefit determination, or De Novo classification determination, including, where appropriate, reference to an applicable section of a final rule, final guidance, and/or an FDA-recognized standard (unless the entire or most of the document is applicable). When the deficiency cannot be traced in the manner above and relates to a scientific or regulatory issue pertinent to the determination, FDA will cite the specific scientific issue and the information to support its position.

4. Explicit request for the additional information needed to address the issue and potential alternate ways of satisfying the issue, if applicable.

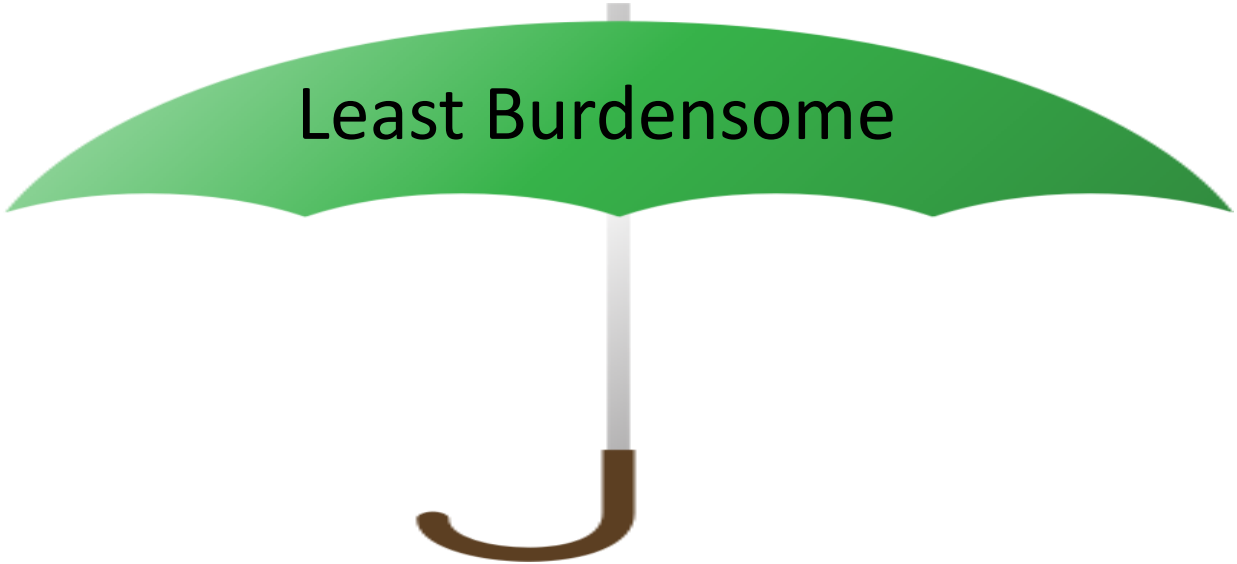
New deficiency elements clarify "why" information is deficient

3. Explanation of the request's relevance to the PMA RASE determination, 510(k) SE determination, HDE safety and probable benefit determination, or De Novo classification determination, **including, where appropriate, reference to an applicable section of a final rule, final guidance, and/or an FDA-recognized standard** (unless the entire or most of the document is applicable). When the deficiency cannot be traced in the manner above and relates to a scientific or regulatory issue pertinent to the determination, **FDA will cite the specific scientific issue and the information to support its position**.

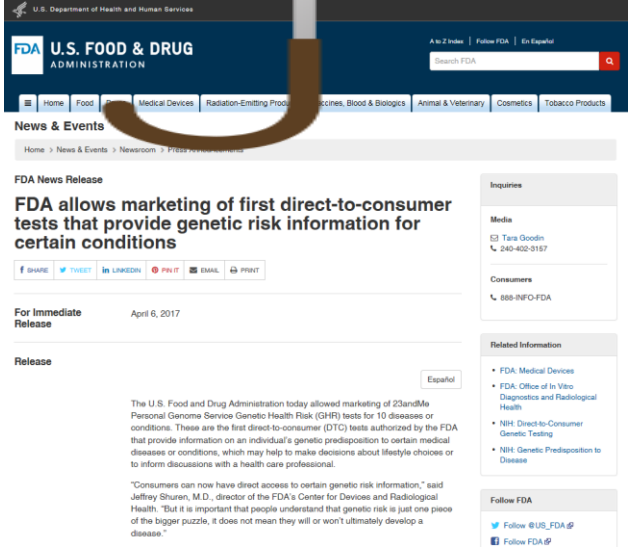
4. Explicit request for the additional information needed to address the issue and potential alternate ways of satisfying the issue, if applicable.

The format for responding to deficiencies didn't change

1. Restate the identified Agency issue; and
2. Provide one of the following:
    a. the information or data requested;
    b. an explanation why the issue is not relevant to the marketing authorization decision; or
    c. alternative information and an explanation describing why the information adequately addresses the issue.


Least Burdensome

Least Burdensome



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FDA News Release

FDA allows marketing of first direct-to-consumer tests that provide genetic risk information for certain conditions

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For Immediate Release April 6, 2017

Release

Español

The U.S. Food and Drug Administration today allowed marketing of 23andMe Personal Genome Service Genetic Health Risk (GHR) tests for 10 diseases or conditions. These are the first direct-to-consumer (DTC) tests authorized by the FDA that provide information on an individual's genetic predisposition to certain medical diseases or conditions, which may help to make decisions about lifestyle choices or to inform discussions with a health care professional.

"Consumers can now have direct access to certain genetic risk information," said Jeffrey Shuren, M.D., director of the FDA's Center for Devices and Radiological Health. "But it is important that people understand that genetic risk is just one piece of the bigger puzzle, it does not mean they will or won't ultimately develop a disease."

Inquiries

Media

Tara Goodin
240-402-3157

Consumers

888-INFO-FDA

Related Information

- FDA: Medical Devices
- FDA: Office of In Vitro Diagnostics and Radiological Health
- NIH: Direct-to-Consumer Genetic Testing
- NIH: Genetic Predisposition to Disease

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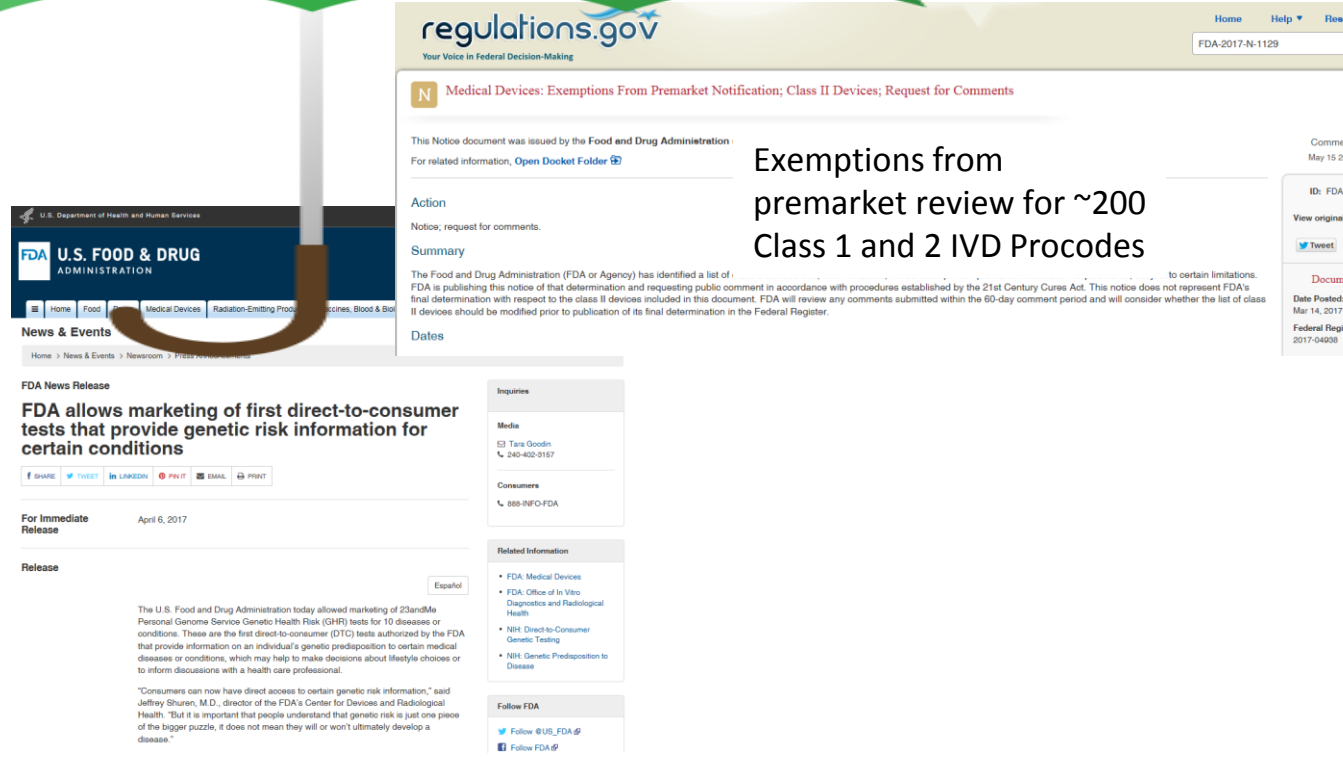

Exemptions from premarket review for ~200 Class 1 and 2 IVD Procodes

Least Burdensome

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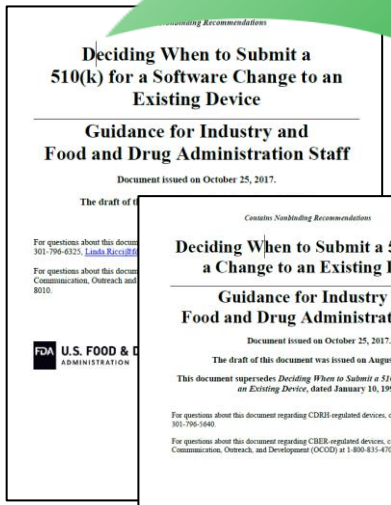
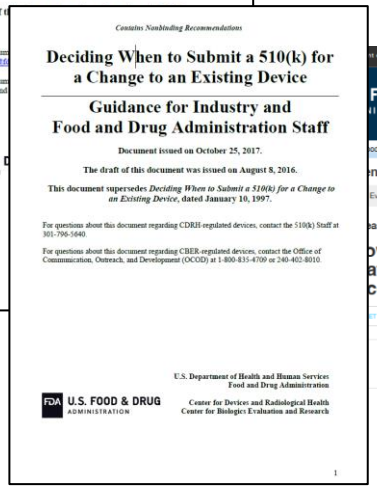

Deciding When to Submit a 510(k) for a Software Change to an Existing Device

Guidance for Industry and Food and Drug Administration Staff

Document issued on October 25, 2017.


Contains Nonbinding Recommendations

Deciding When to Submit a 510(k) for a Change to an Existing Device

Guidance for Industry and Food and Drug Administration Staff

Document issued on October 25, 2017.

The draft of this document was issued on August 8, 2016.

This document supersedes *Deciding When to Submit a 510(k) for a Change to an Existing Device*, dated January 10, 1997.

For questions about this document regarding CDRH-regulated devices, contact the 510(k) Staff at 301-796-5640.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration

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Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

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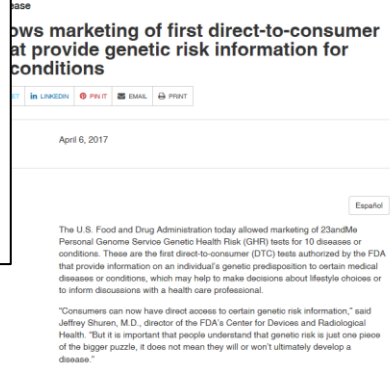
ows marketing of first direct-to-consumer
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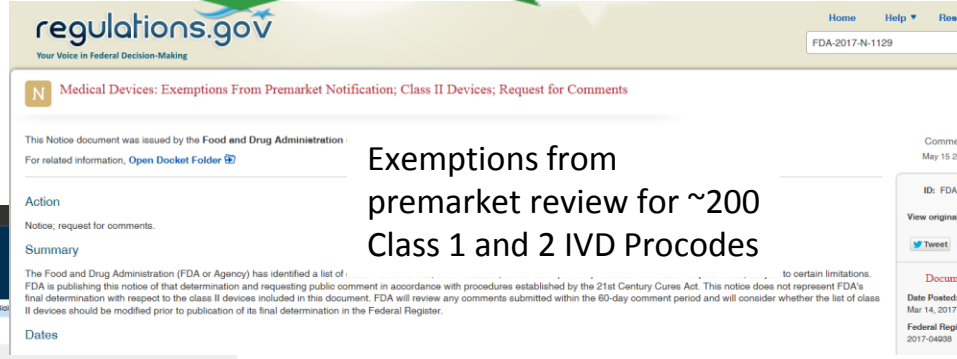
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FDA-2017-N-1129

Medical Devices: Exemptions From Premarket Notification; Class II Devices; Request for Comments

This Notice document was issued by the Food and Drug Administration

For related information, Open Docket Folder

Action

Notice; request for comments.

Summary

The Food and Drug Administration (FDA or Agency) has identified a list of to certain limitations. FDA is publishing this notice of that determination and requesting public comment in accordance with procedures established by the 21st Century Cures Act. This notice does not represent FDA's final determination with respect to the class II devices included in this document. FDA will review any comments submitted within the 60-day comment period and will consider whether the list of class II devices should be modified prior to publication of its final determination in the Federal Register.

Dates

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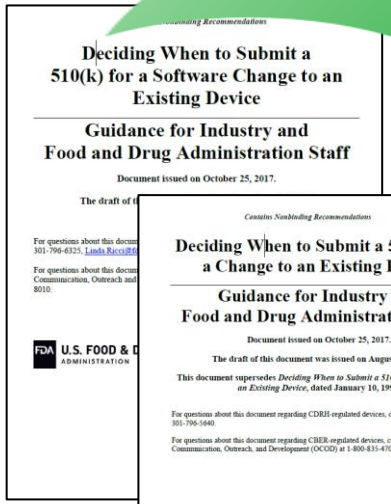
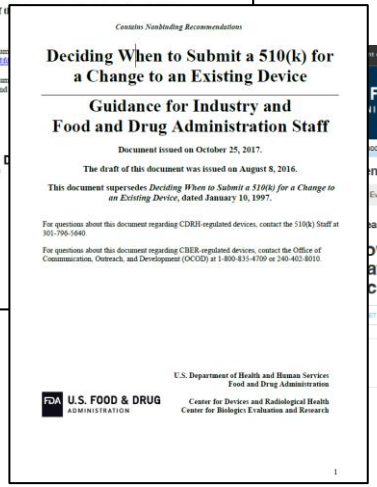
Date Posted:
Mar 14, 2017

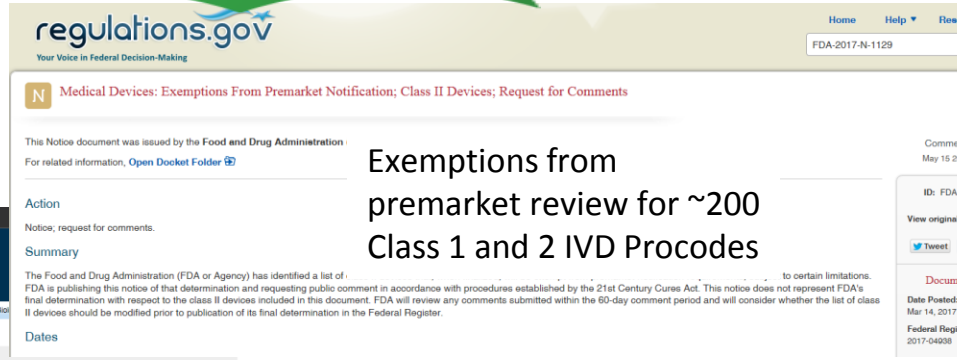
Federal Regi
2017-04938

Exemptions from premarket review for ~200 Class 1 and 2 IVD Procodes

Least Burdensome







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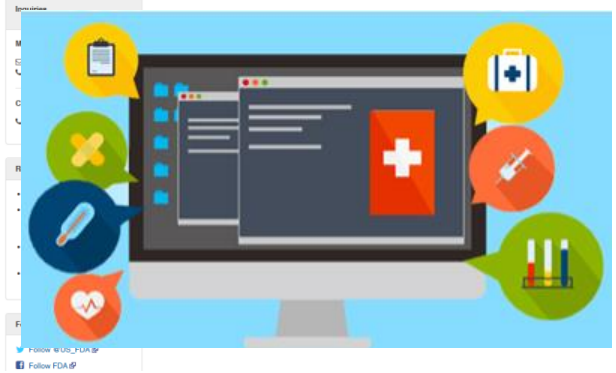

Coming soon:

- New RR guidance

Questions?

CDRH-OIR-Policy@fda.hhs.gov