Recall – Corrections & Removals

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Johnson & Johnson
Quality & Compliance Worldwide

Government Agencies

NHTSA
www.nhtsa.gov
National Highway Traffic Safety Administration
Our Mission: Save lives, prevent injuries, reduce vehicle-related crashes

FDA
U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

483 observations

- A violation of the FD&C Act involving a device which might present a risk to health was not reported to FDA.
- A report of the required information regarding device correction and removal actions was not sent to FDA within 10 days of initiating the correction and removal.
- The firm failed to identify all lots of products that may present a risk to health.

Warning Letters

- Our inspection also revealed that your device is misbranded under section 502(t)(2) of the Act, 21 U.S.C. 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. 360i, and 21 CFR Part 806 - Reports of Corrections and Removals regulation. Significant deviations include, but are not limited to, the following :
  - Failure to submit a written report to FDA of any correction or removal of a device initiated by the manufacturer where the correction or removal was initiated to reduce a risk to health posed by the device, or to remedy a violation of the act caused by the device which may present a risk to health, as required by 21 C.F.R. 806.10.

FDA Definitions

Recalls are actions taken by a firm to physically remove or correct a violative product. Recalls may be conducted voluntarily, by FDA request, or by FDA order under statutory authority.

- Removal is defined as the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.

- Correction refers to repair, modification, adjustment, relabeling, destruction or inspection without physically removing it.

FDA Definitions

- Risk to health: defined as a reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; temporary or medically reversible adverse health consequences; or an outcome in which the probability of serious adverse health consequences is remote.

- Market Withdrawal: occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation, ex: a product removed due to tampering, without evidence of manufacturing or distribution problems.

- Medical device safety alert: situations where a medical device may present an unreasonable risk of substantial harm. In some cases, these are also considered recalls.

FDA Recall Classifications

Class I: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death. Ex: food with undeclared allergen; defective heart valve.

Class II: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. Ex: less potent drug that is not for life-threatening treatment.

Class III: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences. Ex: defective container; off-taste or off-color; lack of English labeling in a retail food.

FDA Guidance & Regulations

- 21 CFR Part 7 – general requirements and guidance:

Product Information	Health Hazard assessment
Contacts for Recalling Firm	Volume of recalled product
Responsible Firm	Distribution pattern
Reason for Recall	Recall Strategy

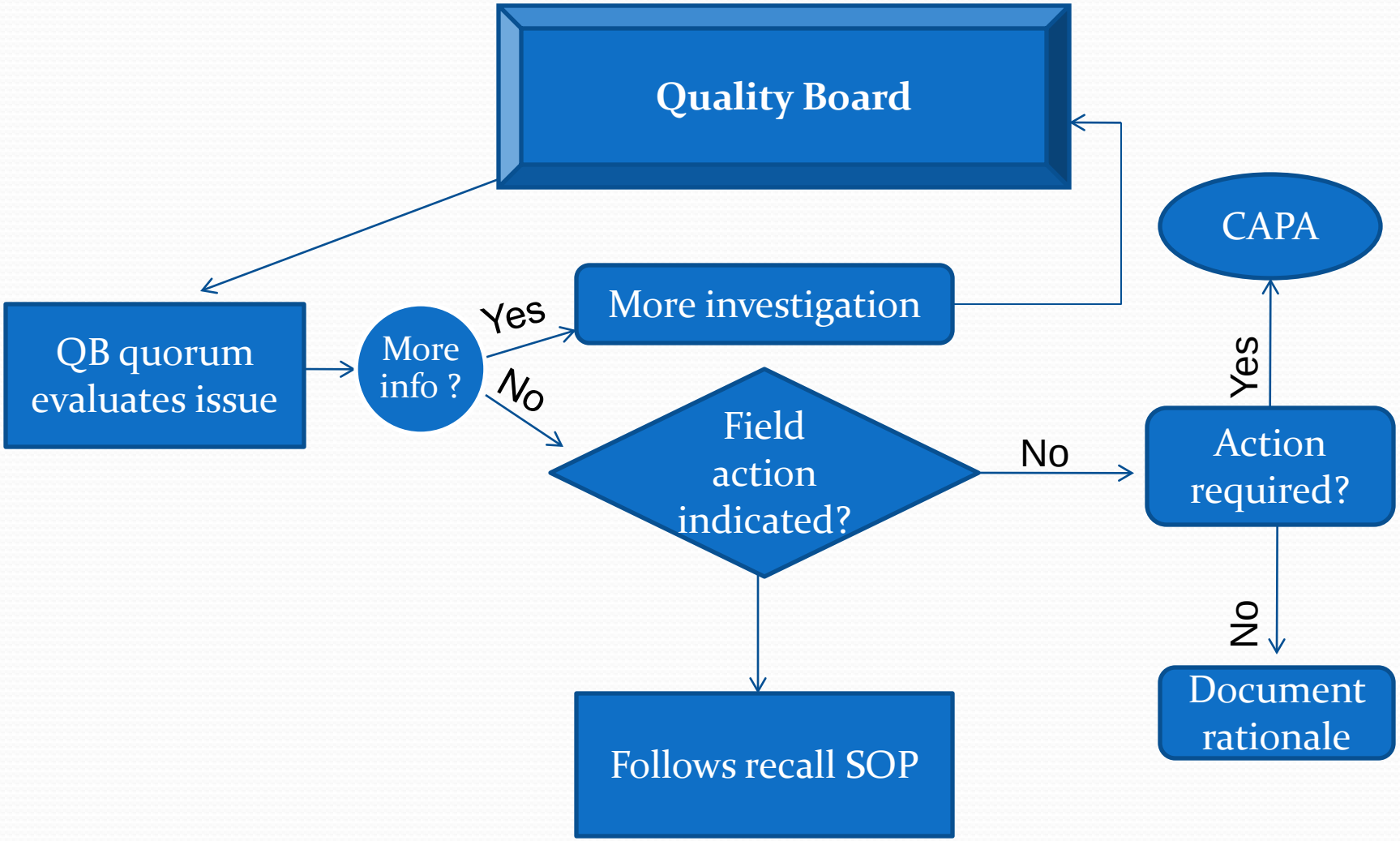
- 21 CFR Part 806 – describes the record and reporting requirements for device manufacturers and importers if the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the act caused by the device which may present a risk to health. Except if reported under 803 (MDR).

- 21 CFR Part 810 – Medical Device Recall Authority. FDA may issue a mandatory recall order when a manufacturer or importer fails to voluntarily recall a device that is a risk to health.

First Steps

Frequent	5				
Probable	4				
Occasional	3				
Remote	2				
Improbable	1				
		1	2	3	4
		Negligible	Marginal	Critical	Intolerable

Decision Process



When to notify FDA

21 CFR Part 806 – requires a written report of any correction or removal of a device if the action was prompted to reduce a risk to health or remedy a violation of the act caused by the device.

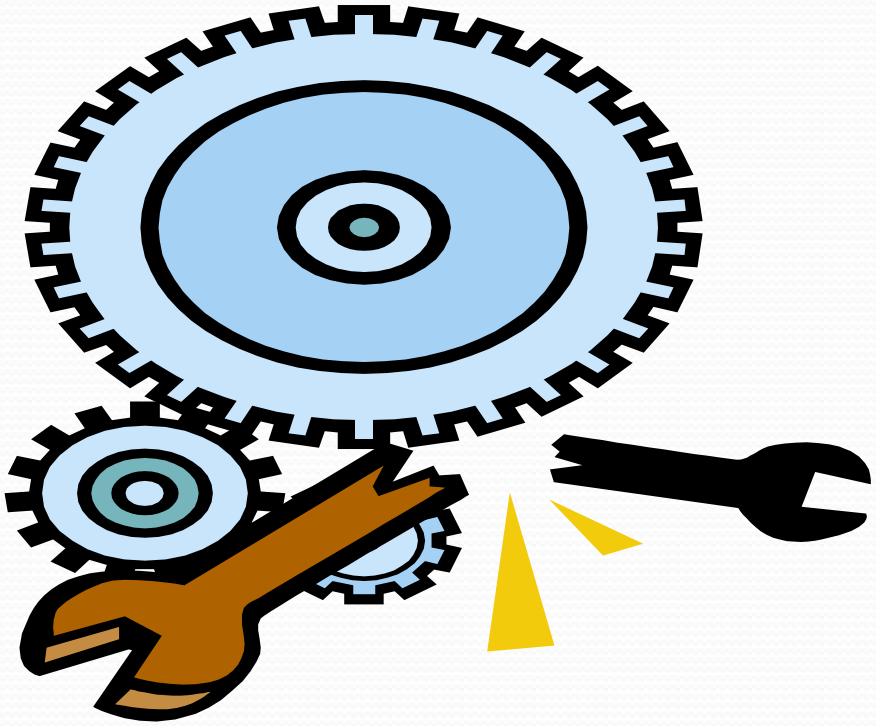
Notification of reportable events under 806.10 are required to be submitted within 10 working days of initiating the correction or removal.

Records are required to be maintained under 806.20.

Reporting exemptions

- 806.1 defines when reports are not required
  - Actions taken to improve the performance or quality of a device, but do not reduce the risk to health or remedy a violation of the act
  - Market withdrawals
  - Routine servicing (preventive maintenance; software updates)
  - Previously reported – MedWatch
  - Normal stock rotation
  - Stock recovery
  - Routine servicing

Correction or Removal?



Silent Recalls?

- Technical or Service Bulletins
  - Unanticipated repairs or parts replacement?
- Software upgrades
  - Updates or bug fixes?
- Medical Alert – “Dear user letters”
  - Information or alert to avoid potential risk?

J&J Field Action & Regulatory Reporting

Removal:

The physical removal of a marketed product (in commercial distribution) from the field because it failed to meet product specifications or labeling (including promotional materials) or, failed to perform as intended. Recalls and Market Withdrawals would be examples of Removals.

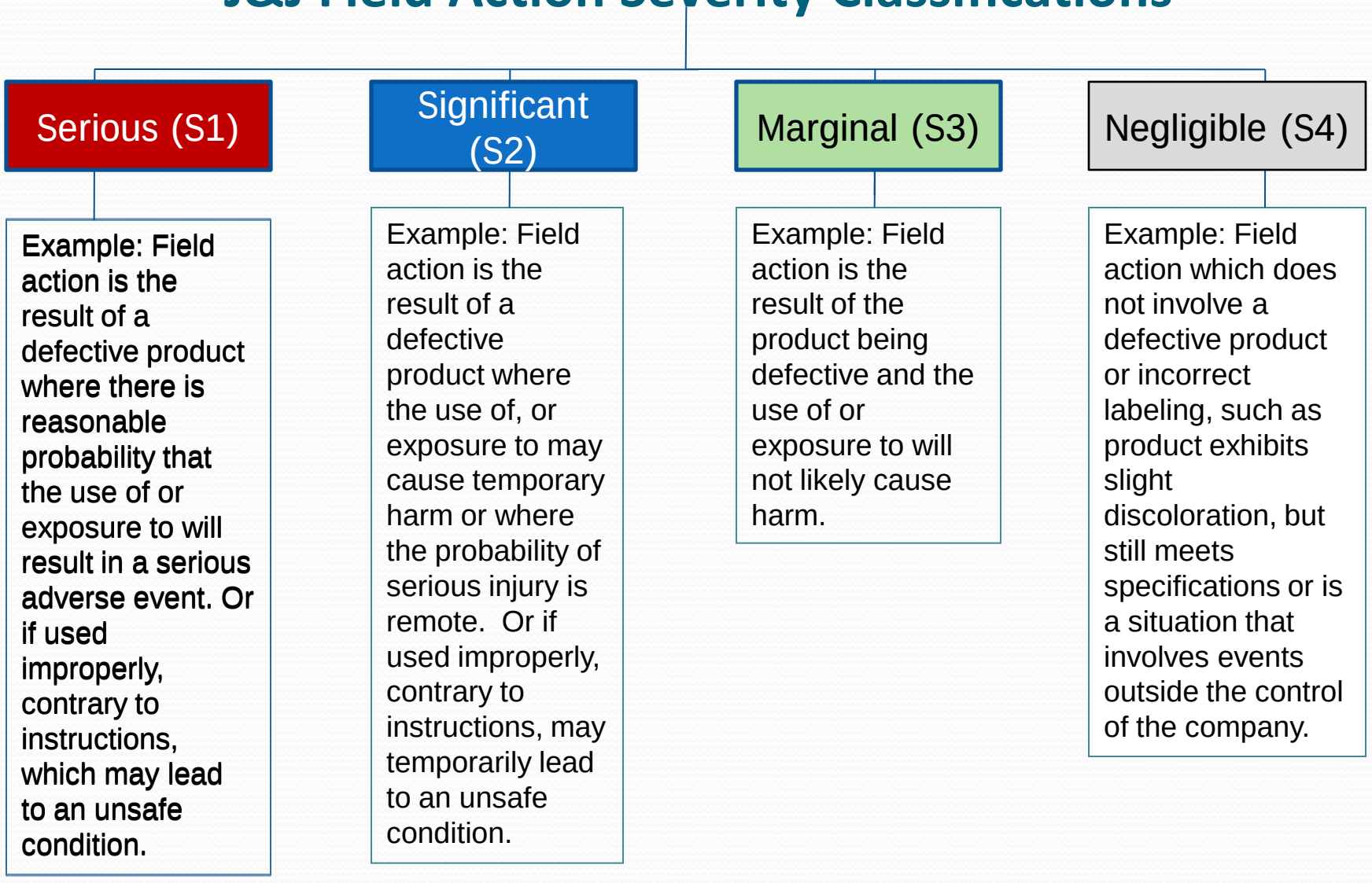
Field Correction:

The repair, modification, adjustment, re-labeling, destruction or inspection (including patient monitoring) of a marketed product because it failed to meet product specifications or labeling (including promotional materials) or, failed to perform as intended, without its physical removal from point of use. Some software updates, modifications and fixes may be considered field corrections, also non-routine servicing.

Field Alert:

Communication voluntarily issued by a manufacturer, distributor or other responsible person to inform health professionals and/or other persons of a situation that may present an unreasonable risk or substantial harm to the public health. It can also apply to potential product non-conformances or failure of a distributed product to meet any its established specifications. Examples would include new warnings or other safety information.

J&J Field Action Severity Classifications



Root cause analysis

Design	• Product specifications/Methods • Process – Design & Development
Supply Chain	• Human Factors/Behavioral • Equipment/Instrument/Malfunction • Supplier Control/Incorrect raw material
Others	• Special circumstances

Examples: Corrections & Removals