MFRPS Audit Staff Review of Key Decision Memos and Documentation Expectation

Kathleen Close

Consumer Safety Officer - Auditor

U.S. Food & Drug Administration

Monday, February 1, 2021

2:45 PM – 3:00 PM ET

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Real Impact

- MFRP Alliance Survey – May 2020

Impact on State Programs		
May 31	14/22	63.64%
September 30	15/22	68.18%
December 31	18/22	81.82%

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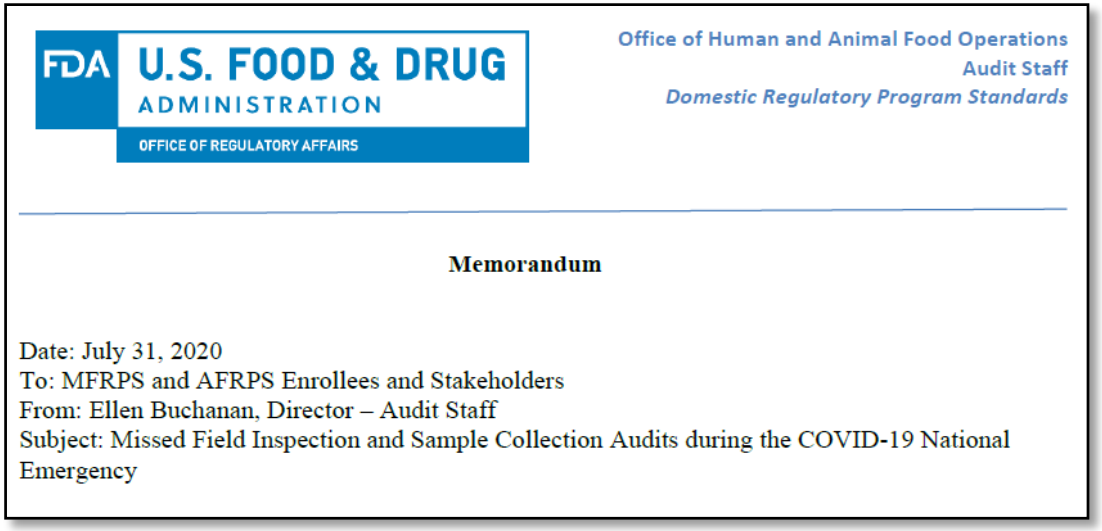
Decision Memorandum

- No findings for missed audit cycles



FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

Office of Human and Animal Food Operations
Audit Staff
Domestic Regulatory Program Standards

Memorandum

Date: July 31, 2020
To: MFRPS and AFRPS Enrollees and Stakeholders
From: Ellen Buchanan, Director – Audit Staff
Subject: Missed Field Inspection and Sample Collection Audits during the COVID-19 National Emergency

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Why?

- Program standards do not address missed timelines

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State regulatory programs

- manage the risk of missed program timelines

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Audit Program

A minimum of two **field inspection audits** of each inspector is conducted every 36-months

4.3.2.1

Standard 4

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Example:

Inspector Joe

Second Field Inspection

Audit: Scheduled for 10/5/2020

36-month cycle ends: 11/20/2020

Issue: The State has not resumed normal operations and work duties

Standard 4

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Example:

Inspector Joe

Identify gap: Joe will not have two field inspection audits completed during his 36-month cycle ending on 11/20/2020

Document gap: Strategic Improvement Plan or other record form

Standard 4

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What's on the horizon?

- Active proposal

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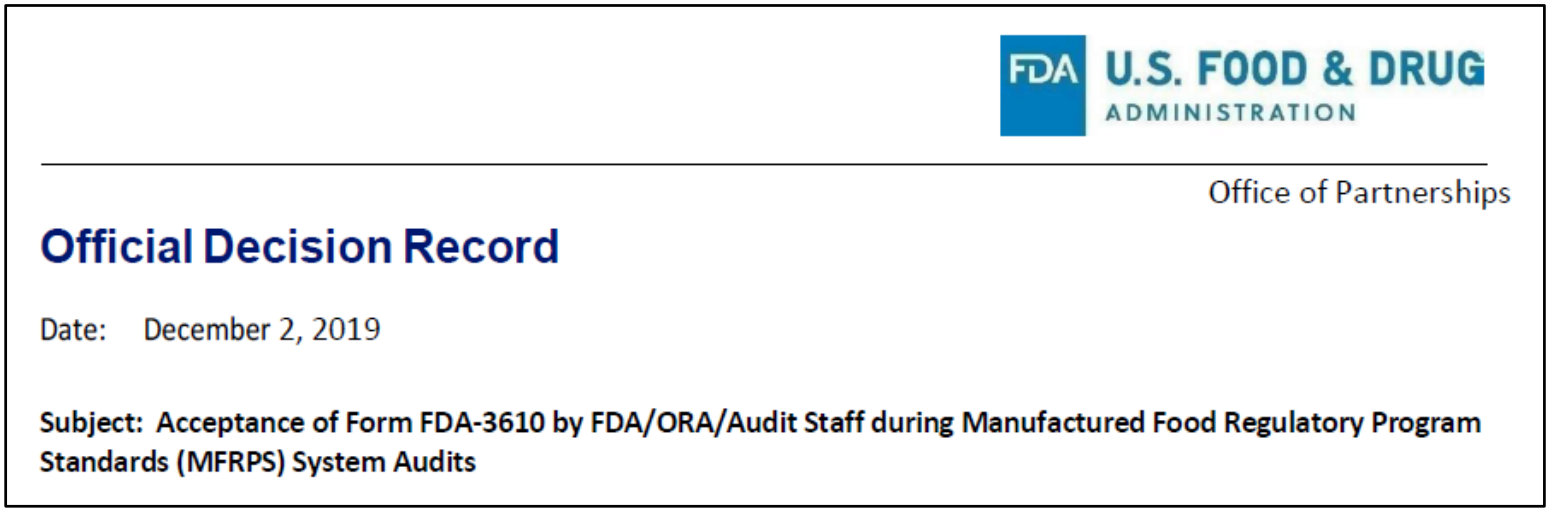
Decision Memorandum

- Acceptance of FDA-3610 from fmd-76 revisions 3 and 4



FDA U.S. FOOD & DRUG ADMINISTRATION

Office of Partnerships

Official Decision Record

Date: December 2, 2019

Subject: Acceptance of Form FDA-3610 by FDA/ORA/Audit Staff during Manufactured Food Regulatory Program Standards (MFRPS) System Audits

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Why?

- FDA-3610 from FMD-76 Revision 4 is not comparable to MFRPS Appendix 4.5 (2019)

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What's on the horizon?

- FMD-76 Revision 5

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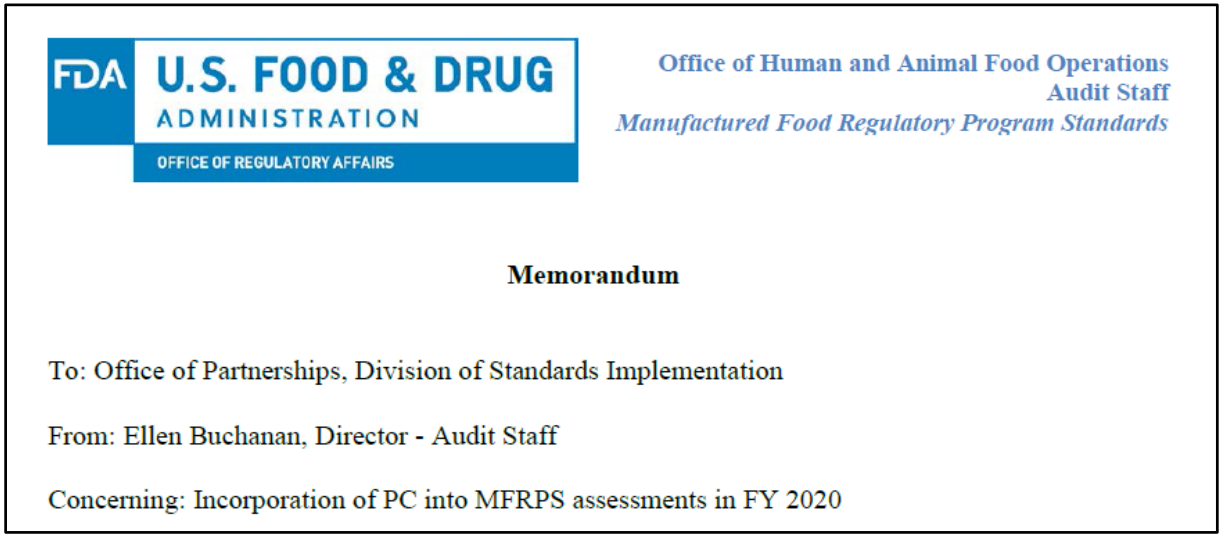
Decision Memorandum

- Incorporation of Preventive Controls



FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

Office of Human and Animal Food Operations
Audit Staff
Manufactured Food Regulatory Program Standards

Memorandum

To: Office of Partnerships, Division of Standards Implementation

From: Ellen Buchanan, Director - Audit Staff

Concerning: Incorporation of PC into MFRPS assessments in FY 2020

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If....

PC Rule Adoption (in whole or in part)

Then....

evaluation for PC Rule inclusion in Appendix 1.2

Standard 1

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If....	Then....
PC Rule Adoption (in whole or in part)Evidence	evaluation for PC Rule inspections

Standard 3

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If....

PC Rule Inspections Are Conducted

Then....

evaluation of training plan for PC Rule inspections

Standard 2

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If....

PC Rule Inspections Are Conducted

Then....

evaluation of Training Records for PC Rule inspections

Standard 2

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If....

Field Inspection Audits Are Conducted During PC Rule Inspections

Then....

evaluation of Training Records of the Qualified Trainer

Standard 2

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Why?

- Resources

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Contact Information

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