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OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

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**DRUG TOLERANCE NOTIFICATION PROCESS**

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**I. PURPOSE**

The purpose of this document is to describe how the Center for Veterinary Medicine (CVM) will inform the Food Safety and Inspection Service (FSIS) within the U.S. Department of Agriculture (USDA), of pending approvals that either establish a new animal drug tolerance or change an existing tolerance. The document describes the process the Office of New Animal Drug Evaluation (ONADE) uses to notify the Office of Surveillance and Compliance (OSC) of pending approvals involving the establishment or changes in an animal drug's tolerance set by the Office of New Animal Drug Evaluation's (ONADE) Division of Human Food Safety. OSC will notify the FSIS/USDA of the pending approval.

**II. BACKGROUND**

The CVM is currently working under a Memorandum of Understanding (MOU) between FSIS and CVM.<sup>1</sup> One item in the current the MOU addresses how CVM will provide FSIS advance notice of new or changes in drug tolerances. Specifically, the MOU instructs the following:

"Notify USDA headquarters whenever it (FDA) intends to establish or amend a tolerance for an animal drug or a tolerance or action level for an environmental contaminant that may affect USDA's responsibilities under the FMIA [Federal Meat Inspection Act], PPIA [Poultry Products Inspection Act], or EPIA [Egg Products Inspection Act], and include a summary of the information and evaluation upon which such tolerance or action level is based and a method of analysis to be used to enforce such tolerance or action level...."

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<sup>1</sup> See the MOU on the ONADE Policy SharePoint site entitled: MOU with USDA (FSIS and AMS) and EPA Regarding Regulatory Activities Concerning Residues of Drugs, Pesticides, and Environmental Contaminants in Foods  
Internal information redacted.

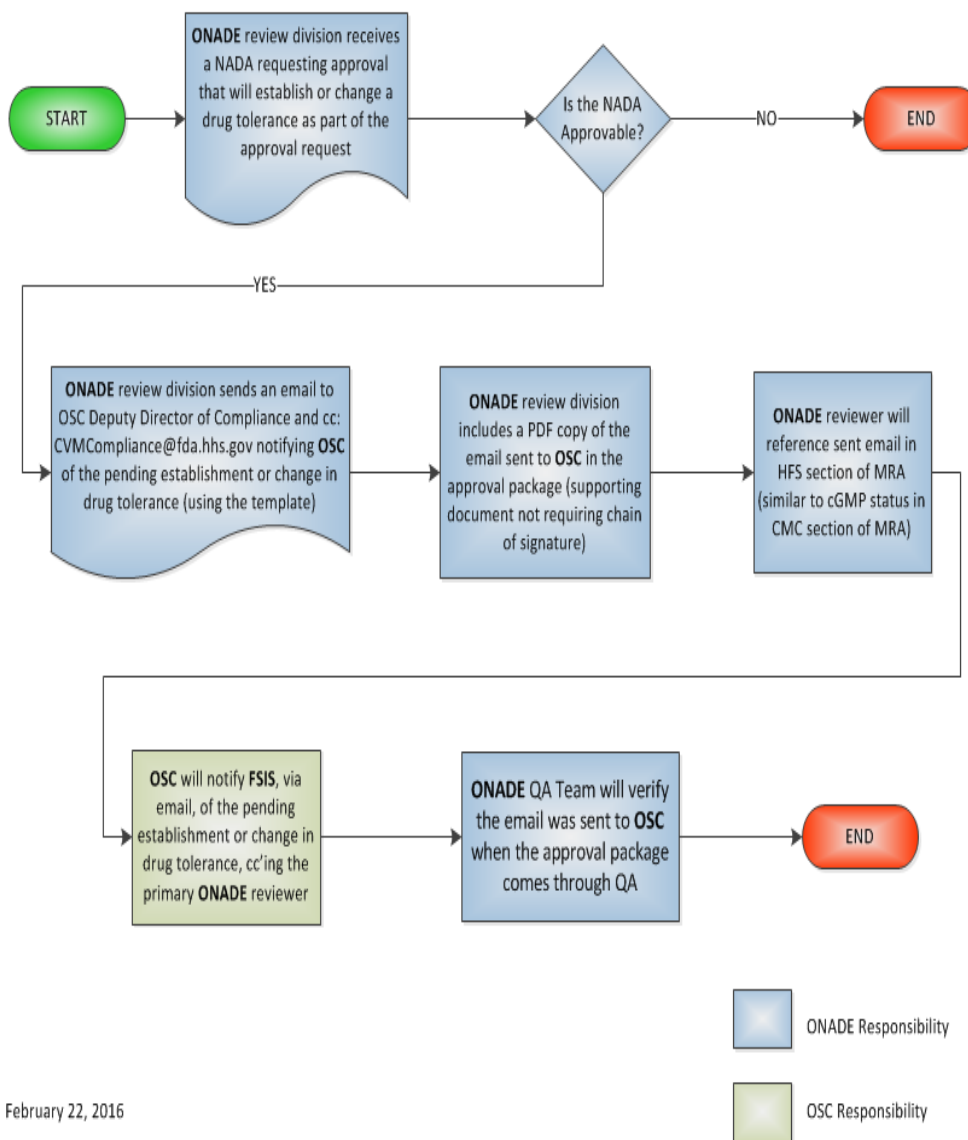
### III. PROCESS DESCRIPTION

1. An ONADE review division receives an original or supplemental new animal drug application (NADA) that would either establish or change the drug tolerance.
2. The ONADE review division determines if the NADA can be approved. If the NADA is approvable, the ONADE review division uses the Drug Tolerance Notification email template to notify OSC of the pending approval that establishes or changes a drug tolerance. The email template can be found on the ONADE Templates SharePoint Page. The ONADE/CVM review division sends the email to the Deputy Director of Compliance with a cc: to the CVM Compliance mailbox (CVMCompliance@fda.hhs.gov).
3. The ONADE review division includes a PDF copy of the notification email sent by the reviewer to OSC in the approval package in Folder B file as a supporting document and references the email in the Human Food Safety section of the Memorandum Recommending Approval (MRA).
4. The OSC will notify FSIS, via email, of the pending establishment or change in the drug tolerance and will copy the ONADE primary reviewer on the email to FSIS. This email is solely to keep the primary reviewer informed and does not need to be included in the approval package.
5. When the draft approval package is reviewed by ONADE's Quality Assurance (QA) Team, they will verify the ONADE review division sent the notification email to OSC. If the notification email was not sent, the QA Team will instruct the ONADE review division to send the email and request a second review of the draft approval package to verify the email was sent.
6. If for some reason, the approval package is not approved, the ONADE primary reviewer should send an email to the CVM Compliance mailbox notifying them that the tolerance change was not approved. All the relevant package information should be included in this email as well so it is clear which package and subsequent changes are not being approved. It is the responsibility of CVM OSC to notify FSIS when there has been a change in the status of an approval package and the new or revised tolerance(s) is not approved.

**Important note:** OSC and FSIS have requested the earliest possible notification once it has been determined that the establishment or change in drug tolerance will occur. ONADE review divisions should endeavor to send the notification email well before the draft approval package is sent to the QA Team for review.

IV. FLOWCHART OF THE PROCESS

Notification to USDA/FSIS of Drug Tolerance Establishment or Change



V. REFERENCES

CVM Program Policies and Procedure Manual

1243.3800 Reviewing, Preparing, and Routing Approval Packages for Certain Abbreviated and New Animal Drug Applications

1243.5741 Memorandum Recommending Approval (MRA) for Original and Supplemental (Abbreviated) New Animal Drug Applications ((A)NADA)

**VI. VERSION HISTORY**

July 14, 2017 – Original version. Redacted internal information for version that will be on the internet. Redactions appear as greyed out boxes.

June 18, 2020 – Revised to current P&P format.