OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

DRUG TOLERANCE NOTIFICATION PROCESS

I. PURPOSE

This document describes how the Center for Veterinary Medicine (CVM) informs the U.S. Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) of pending approvals that either establish a new animal drug tolerance or change an existing tolerance. It also describes how the Office of New Animal Drug Evaluation (ONADE) notifies the Office of Surveillance and Compliance (OSC) of pending approvals involving the establishment or changes in an animal drug's tolerance set by ONADE's Division of Human Food Safety and how OSC then notifies FSIS of the pending approval.

II. BACKGROUND

CVM is currently working under a Memorandum of Understanding (MOU) between FSIS and CVM.[1] One item in this MOU addresses how CVM provides FSIS advance notice of new or changes in drug tolerances. Specifically, the MOU states:

"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…."

III. PROCESS DESCRIPTION

In addition to the process steps below, a flowchart is provided in Appendix 1. See standard operating procedure 1243.000.007 for information on grammar standards for final action packages that undergo a quality control review by the Quality Assurance Team.

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 primary reviewer (PR) determines if the NADA can be approved. If it 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

[1] 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.

tolerance.[2] The email template is on the ONADE Templates SharePoint Page. The ONADE review division emails the Director of the Division of Drug Compliance and the Director of the Division of Food Compliance in OSC.

3. The ONADE PR includes a PDF copy of the notification email sent by the reviewer to OSC in the approval package in Folder B as a supporting document and references the email in the Human Food Safety section of the Memorandum Recommending Approval (MRA).

4. OSC emails FSIS with the pending establishment or change in the drug tolerance and copies the ONADE PR. This email is solely to keep the PR 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 verify that the ONADE PR sent the notification email to OSC. If the notification email was not sent, the QA Team instructs the ONADE PR to send the email and requests 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 PR emails the Director of the Division of Drug Compliance and the Director of the Division of Food Compliance notifying them that the tolerance change was not approved. All relevant package information is included in this email as well; so, it is clear which package and subsequent changes are not being approved. It is OSC's responsibility 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. REFERENCES

CVM Policies and Procedures Manual- ONADE Reviewer's Chapter

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)

ONADE Standard Operating Procedures

1243.000.007 – Grammar Standards for Final Action Packages that Undergo a Quality Control Review by the Quality Assurance Team

V. VERSION HISTORY

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

[2] See Outlook template called Drug Tolerance Notification for OSC in SharePoint.

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

July 15, 2022 – Quality systems update for minor formatting updates.

June 12, 2023 – Section III 2. updated to reflect the reorganization in OSC and that an email should now be sent to the Director of the Division of Drug Compliance and the Director of the Division of Food Compliance and remove the wording about copying the CVM compliance mailbox. Email template name changed from Drug Tolerance Notification for Office of Drug Compliance to Drug Tolerance Notification for OSC. Also updated the flowchart to reflect the process change and to include the step of emailing OSC if the drug tolerance is not going to be approved. To bring all office quality system documentation into compliance with the FDA Visual Identity Program approved fonts, ONADE has adopted Arial 11-point font. The font of this document was changed from Verdana 10-point font to Arial 11-point font.

April 5, 2024 – Edited section III. to include reference to the SOP on grammar standards for final action packages that undergo a quality control review by the QA Team. Also, put the document into the current office template and format.

APPENDIX 1: FLOWCHART OF THE PROCESS

Notification to USDA/FSIS of Drug Tolerance Establishment or Change