



TITLE:

**Adding District Use Codes for Veterinary Drug
and Medicated Feed Mill Facilities**

ORIGINAL EFFECTIVE DATE:
[DATE]

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1. Purpose/Scope

To establish a procedure to be followed by ALL district offices in updating District Use Codes (DUC) in FACTS using information received from the Center for Veterinary Medicine (CVM). This procedure summarizes field and headquarter responsibilities and ensures information that is in the Center files and the field's Official Establishment Inventory (OEI) and Registration files are aligned. Follow FMD-130 for additional instructions, including assigning Establishment Types.

2. Responsibility

- A. It is the responsibility of the District OEI Coordinator, District Veterinary Drug Program Monitor, or designee to manage assigning district use codes in accordance with this work instruction.
District includes both domestic and foreign areas.
- B. The National OEI Coordinator is the point of contact (POC) between CVM and ORA, and will route all communications and questions regarding the data in the spreadsheet/registration documents.

Note: The document refers to District Registration Monitor throughout, but is referring to the above statement.

3. Background

Previously, firms were identified as veterinary drug firms in Firm Management Services (FMS). CVM requested more granularity in identifying the types of veterinary drug products handled by each firm, to assist with work planning and



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expertise of investigator assigned to each firm. This procedure provides guidance for identifying veterinary drug types handled by each firm in FMS.

4. Procedure

4.1 Determination of Firm Activities for Assigning a District Use Code (DUC)

Step 1: Refer to the approved licensed medicated feed mills listed on these links

By company name:

<http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/UCM089532.pdf>

By state

<http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/UCM089534.pdf>

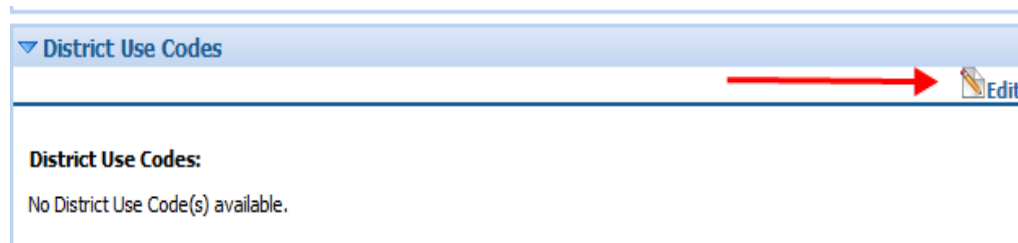
Step 2: Identify the activities of the firm (as described in Section 4.2 Step 4) from information received from inspections, investigations, registrations or other data sources.

4.2 Updating Firm Management System (FMS)

Step 1: Review the firm's registration information in eDRLS

Step 2: Search for the firm being updated in Firm Maintenance Services (FMS) in FACTS.

Step 3: Under "Firm Details", scroll to the bottom of the page and click "Edit" next to "District Use Codes".



Step 4: Identify the appropriate District Use Code (DUC). If there is no District Use Code defined within this procedure, the product is defined solely by establishment type, with no additional granularity needed for inventory breakdown.

District Use Code (DUC)	Explanation
LF	Licensed Medicated Feed Mill: must comply with the requirements of 21 CFR 515 and 21 CFR 225.1 - 225.115, and be registered in accordance with 21 CFR 207. An approved medicated feed mill license, Form FDA 3448 , is required for



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	<p>facilities that manufacture feed using Category II, Type A medicated articles or manufacture certain liquid and free-choice feed, using Category I Type A medicated articles that must follow proprietary formulas or specifications.</p> <p>The information in FMS is not the official determination for licensed establishments. CVM maintains the approved feed mill license database and unless a licensed establishment goes out of business or notifies the district and signs a request to withdraw their license, it remains licensed even if someone updates this field.</p>
PP	<p>Swine and Poultry Feed Mills: A feed mill (licensed or unlicensed) under the same management and in one general (but not necessarily contiguous) physical location as a primary production farm that uses prohibited material in manufacturing animal food, but only manufactures animal food intended to be fed to poultry or swine located on the primary production farm. DO NOT CODE AS UF or LF also, unless they manufacture products to be sold at locations not under their control.</p>
VC	<p>Firms that are operating as pharmacy compounding for veterinary use in accordance with Section 503A of the FD&C Act.</p>
VD	<p>Firms that manufacture, process, pack or hold finished dosage form veterinary drugs per Section 201(g) of the FD&C Act. This does not include pharmacy compounding, teat dips or medical gas.</p>
VM	<p>Firms that manufacture only teat dips and udder washes subject to CPG Sec 654.200.</p>
VX	<p>Firms that manufacturer Active Pharmaceutical Ingredient(s) for veterinary drugs.</p>
UF	<p>Unlicensed medicated feed mills: Firms that manufacture medicated feeds containing Category I Type A medicated articles, and do NOT manufacture certain liquid and free-choice feed, using Category I Type A medicated articles that must follow proprietary formulas or specifications.</p>

Step 5: Use the drop down menu and the “Right” Green Arrow to add the District Use Code.



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Enter Additional Firm Details

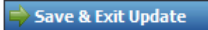

You may enter additional details by clicking on the different tabs below. Once done, press the 'Next' button to continue.

* Denotes required fields
** Denotes conditionally required fields

Required* Cross Ref Contact Program Risk **District Use Codes**

District Use Code: - Select an Option -  **No District Use Code(s) available.**

Drop down arrow  **"Right" Green arrow**

5. Glossary/Definitions

- A. **CVM:** Center for Veterinary Medicine
- B. **CFN:** Central File Number
- C. **CTS:** Center Tracking System
- D. **FEI:** Field Establishment identifier
- E. **FACTS:** Field Accomplishment Tracking System
- F. **FMS:** Facility Management Service
- G. **OEI:** Official Establishment Inventory

6. Supporting Documents

- A. CPG Sec. 654.200
- B. Compliance Policy Guidance Manual (CPGM) 7371.004 "Feed Manufacturing Compliance Program"
- C. CPGM 7456.002

7. Document History

Version #	Status* (D,I, R, C)	Date	Author Name and Title	Approving Official Name and Title
1.0	I		LORI S. LAWLESS, NATIONAL OEI COORDINATOR	Kate Bent, Director OPRM

* - D: Draft, I: Initial, R: Revision, C: Cancel

8. Change History

Version	Change
1.0	Initial

9. Attachments

None