From	To	MEA
§ 95.6376 VOR Federal Airway V376 Is Amended To Read in Part		
RICHMOND, VA VOR/DME	*GRUBY, VA FIX	2000
*3000—MCA GRUBY, VA FIX, N BND.		
GRUBY, VA FIX	IRONS, MD FIX	*4500
*1700—MOCA.		
§ 95.6430 VOR Federal Airway V430 Is Amended To Read in Part		
IRONWOOD, MI VOR/DME	DINER, MI FIX	3600
DINER, MI FIX	IRON MOUNTAIN, MI VOR/DME	*5000
*4000—GNSS MEA.		
IRON MOUNTAIN, MI VOR/DME	VUKFI, MI FIX	3300
VUKFI, MI FIX	ESCANABA, MI VOR/DME	*3000
*2300—MOCA.		

Airway Segment		Changeover Points	
From	To	Distance	From
§ 95.8003 VOR Federal Airway Changeover Point V376 Is Amended To Add Changeover Point			
RICHMOND, VA VOR/DME	WASHINGTON, DC VOR/DME	53	RICHMOND

[FR Doc. 2019–06394 Filed 4–1–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 112, 117, and 507

[Docket Nos. FDA–2011–N–0920, FDA–2011–N–0921, and FDA–2011–N–0922]

RIN 0910–AG10, 0910–AG35, and 0910–AG36

Implementing the Food and Drug Administration Food Safety Modernization Act; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is correcting with technical amendments two final rules that published in the **Federal Register** of September 17, 2015, and one final rule that published in the **Federal Register** of November 27, 2015. The final rules published with editorial and inadvertent errors. This document corrects those errors.

DATES: Effective April 2, 2019.

FOR FURTHER INFORMATION CONTACT: Sylvia Kim, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–7599.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 17, 2015 (80 FR 55908 and 80 FR 56170), FDA published the final rules ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food'' and ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals'' with editorial and inadvertent errors in the regulatory text. In the **Federal Register** of November 27, 2015 (80 FR 74354), FDA published the final rule ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption'' with editorial and inadvertent errors in the regulatory text. This action is being taken to correct those editorial and inadvertent errors.

List of Subjects

21 CFR Part 112

Foods, fruits and vegetables, Incorporation by reference, Packaging and containers, Recordkeeping requirements, Safety.

21 CFR Part 117

Food packaging, Foods.

21 CFR Part 507

Animal foods, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

PART 112—STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION

■ 1. The authority citation for part 112 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 350h, 371; 42 U.S.C. 243, 264, 271.

■ 2. In § 112.4, revise paragraph (a) to read as follows:

§ 112.4 Which farms are subject to the requirements of this part?

(a) Except as provided in paragraph (b) of this section, a farm or farm mixed-type facility with an average annual monetary value of produce (as ''produce'' is defined in § 112.3) sold during the previous 3-year period of more than $25,000 (on a rolling basis), adjusted for inflation using 2011 as the baseline year for calculating the adjustment, is a ''covered farm'' subject to this part. Covered farms subject to this part must comply with all applicable requirements of this part when conducting a covered activity on covered produce.

* * * * *

■ 3. In § 112.5, revise paragraphs (a)(1) and (2) to read as follows:

§ 112.5 Which farms are eligible for a qualified exemption and associated modified requirements based on average monetary value of all food sold and direct farm marketing?

(a) * * *

(1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food (as defined in § 112.3) the farm sold directly to qualified end-users (as defined in § 112.3) during such period exceeded the average annual monetary value of the food the farm sold to all other buyers during that period; and

(2) The average annual monetary value of all food (as defined in § 112.3) the farm sold during the 3-year period preceding the applicable calendar year

was less than $500,000, adjusted for inflation.

* * * * *

■ 4. In § 112.161, revise paragraph (b) to read as follows:

§ 112.161 What general requirements apply to records required under this part?

* * * * *

(b) Records required under §§ 112.7(b), 112.30(b), 112.50(b)(2), (4), and (6), 112.60(b)(2), 112.140(b)(1) and (2), and 112.150(b)(1), (4), and (6), must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.

PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROS FOR HUMAN FOOD

■ 5. The authority citation for part 117 continues to read as follows:

Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

■ 6. In § 117.126, revise paragraph (b)(5) to read as follows:

§ 117.126 Food safety plan.

* * * * *

(b) * * *

(5) The written procedures for monitoring the implementation of the preventive controls as required by § 117.145(a);

* * * * *

PART 507—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR FOOD FOR ANIMALS

■ 7. The authority citation for part 507 continues to read as follows:

Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

■ 8. In § 507.31, revise paragraph (c)(5) to read as follows:

§ 507.31 Food safety plan.

* * * * *

(c) * * *

(5) The written procedures for monitoring the implementation of the preventive controls as required by § 507.40(a);

* * * * *

■ 9. In § 507.130, revise paragraph (c)(2)(ii) to read as follows:

§ 507.130 Conducting supplier verification activities for raw materials and other ingredients.

* * * * *

(c) * * *

(2) * * *

(ii) A statement that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety laws, including relevant laws and regulations of foreign countries.

* * * * *

Dated: March 26, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–06141 Filed 4–1–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 528, 556, and 558

[Docket No. FDA–2018–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Changes of Sponsorship

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during October, November, and December 2018. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to make technical amendments to improve the readability of the regulations.

DATES: This rule is effective April 2, 2019.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5689, *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Approval Actions

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during October, November, and December 2018, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the office of the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm.* Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: *https://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm.*

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING OCTOBER, NOVEMBER, AND DECEMBER 2018

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
October 1, 2018	200–490	Dragon Fire Holding Co., Inc., 2619 Skyway Dr., Grand Prairie, TX 75052.	Carprofen, Chewable Tablets.	Dogs	Original approval as a generic copy of NADA 141–111.	FOI Summary.