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 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:


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

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


6. 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) * * * * (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.

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 approval-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/ProductsApprovedAnimalDrugProducts/default.htm.

II. Approval Actions

The following table provides information on animal drug applications (ANADAs and NADAs) approved during October, November, and December 2018.

<table>
<thead>
<tr>
<th>Approval date</th>
<th>File No.</th>
<th>Sponsor</th>
<th>Product name</th>
<th>Species</th>
<th>Effect of the action</th>
<th>Public documents</th>
</tr>
</thead>
</table>