

R. Gil Kerlikowske,
Commissioner, U.S. Customs and Border
Protection.

Approved: October 5, 2015.

Mark J. Mazur,
Assistant Secretary of the Treasury.

[FR Doc. 2015-25729 Filed 10-9-15; 8:45 am]

**BILLING CODE 9111-14-P; 9111-15-P; 9111-16-P;
9111-17-P**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 107

[Docket No. FDA-2013-N-0067]

Infant Formula: The Addition of Minimum and Maximum Levels of Selenium to Infant Formula and Related Labeling Requirements; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of June 22, 2016, for the final rule that appeared in the **Federal Register** of June 23, 2015. The final rule amended the regulations on nutrient specifications and labeling for infant formula to add the mineral selenium to the list of required nutrients and to establish minimum and maximum levels of selenium in infant formula.

DATES: Effective date of final rule published in the **Federal Register** of June 23, 2015 (80 FR 35834) confirmed: June 22, 2016.

FOR FURTHER INFORMATION CONTACT: Carrie Assar, Center for Food Safety and Applied Nutrition (HFS-850), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1451.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 23, 2015 (80 FR 35834), we amended the regulations on nutrient specifications and labeling for infant formula to add 2.0 µg selenium per 100 kilocalories (/100 kcal) as the minimum level of selenium in infant

formulas and 7.0 µg/100 kcal as the maximum level of selenium in infant formulas.

We gave interested persons until July 23, 2015, to file objections or requests for a hearing. We received no objections or requests for a hearing on the final rule. Therefore, we find that the effective date of the final rule that published in the **Federal Register** of June 22, 2016, should be confirmed.

List of Subjects in 21 CFR Part 107

Food labeling, Infants and children, Nutrition, Reporting and recordkeeping requirements, Signs and symbols.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 343, 350a, 371) and under authority delegated to the Commissioner of Food and Drugs, we are giving notice that no objections or requests for a hearing were filed in response to the June 23, 2015, final rule. Accordingly, the amendments issued thereby will become effective June 22, 2016.

Dated: October 7, 2015.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2015-25960 Filed 10-9-15; 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, 556, and 558

[Docket No. FDA-2015-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of a New Animal Drug Application; Change of Sponsor; Change of Sponsor's Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) 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 July and August 2015. FDA is also 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 reflect a change of sponsor, a change of sponsor's address, a revised food safety warning, the voluntary withdrawal of approval of an NADA, and a technical amendment. This technical amendment is being made to improve the accuracy of the regulations.

DATES: This rule is effective October 13, 2015, except for the amendment to 21 CFR 558.460, which is effective October 23, 2015.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5689, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during July and August 2015, 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 Division of Dockets Management (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: <http://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: <http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm>.