* * * * *

■ 3. In § 107.100, revise paragraph (a) to read as follows:

§ 107.100 Nutrient specifications.

(a) An infant formula shall contain the following nutrients at a level not less than the minimum level specified and not more than the maximum level specified for each 100 kilocalories of the infant formula in the form prepared for consumption as directed on the container:

Nutrients	Unit of measurement	Minimum level	Maximum level
Protein	Grams	1.8	4.5
Fat	Do.	3.3	6.0
	Percent calories	30	54
Linoleic acid	Milligrams	300	
	Percent calories	2.7	
Vitamins			
Vitamin A	International Units	250	750
Vitamin D	Do.	40	100
Vitamin E	Do.	0.7	
Vitamin K	Micrograms	4	
Thiamine (Vitamin B_1)	Do.	40	
Riboflavin (Vitamin B_2)	Do.	60	
Vitamin B_6	Do.	35	
Vitamin B_{12}	Do.	0.15	
Niacin [1]	Do.	250	
Folic acid (Folacin)	Do.	4	
Pantothenic acid	Do.	300	
Biotin [2]	Do.	1.5	
Vitamin C (Ascorbic acid)	Milligrams	8	
Choline [2]	Do.	7	
Inositol [2]	Do.	4	
Minerals			
Calcium	Do.	60	
Phosphorus	Do.	30	
Magnesium	Do.	6	
Iron	Do.	0.15	3.0
Zinc	Do.	0.5	
Manganese	Micrograms	5	
Copper	Do.	60	
Iodine	Do.	5	75
Selenium	Do.	2	7
Sodium	Milligrams	20	60
Potassium	Do.	80	200
Chloride	Do.	55	150

[1] The generic term ''niacin'' includes niacin (nicotinic acid) and niacinamide (nicotinamide).
[2] Required only for non-milk-based infant formulas.

* * * * *

Dated: June 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–15394 Filed 6–22–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2010–N–0155]

RIN 0910–AG95

Veterinary Feed Directive; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule entitled ''Veterinary Feed Directive'' that appeared in the **Federal Register** of June 3, 2015 (80 FR 31708). The rule amended FDA's animal drug regulations regarding veterinary feed directive (VFD) drugs. The document published with typographical and formatting errors. This document corrects those errors.

DATES: *Effective:* October 1, 2015.

FOR FURTHER INFORMATION CONTACT: Sharon Benz, Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5939, email: *Sharon.Benz@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In FR Doc. 2015–13393, appearing on page 31708 in the **Federal Register** of Wednesday, June 3, 2015, the following corrections are made:

§ 558.6 [Corrected]

■ 1. On page 31734, in the second column, in § 558.6 *Veterinary feed directive drugs,* in paragraph (b)(5), remove ''(b)(2)(vi),'' and add in its place ''(b)(3)(vi),''.

■ 2. On page 31734, in the third column, in § 558.6 *Veterinary feed directive drugs,* the introductory text of paragraph (c) ''Responsibilities of any person who distributes an animal feed containing a VFD drug or a combination VFD drug:'' is corrected as a paragraph heading to read ''*Responsibilities of any person who distributes an animal feed containing a VFD drug or a combination VFD drug.*''

Dated: June 18, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–15388 Filed 6–22–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2015–N–1297]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Vibrator for Climax Control of Premature Ejaculation; Republication

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order; republication.

SUMMARY: The Food and Drug Administration (FDA) is republishing in its entirety a final order entitled ''Medical Devices; Gastroenterology-Urology Devices; Classification of the Vibrator for Climax Control of Premature Ejaculation'' that published in the **Federal Register** on May 28, 2015 (80 FR 30353). FDA is republishing to correct an inadvertent omission of information. FDA is classifying the vibrator for climax control of premature ejaculation into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the classification of the vibrator for climax control of premature ejaculation. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective June 23, 2015. The classification was applicable on March 20, 2015.

FOR FURTHER INFORMATION CONTACT: Tuan Nguyen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G118, Silver Spring, MD 20993–0002, 301–796–5174, *tuan.nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device. On November 21, 2013, Auris Medtech Europe, Ltd., submitted a request for classification of the Prolong™ under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1). On June 17, 2014, the request for classification of Prolong™ was transferred from Auris Medtech Europe, Ltd., to Ergon Medical, Ltd., through an amendment to the request (Ref. 2).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on March 20, 2015, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 876.5025.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a vibrator for climax control of premature ejaculation will need to comply with the special controls named in this final order. The device is assigned the generic name vibrator for climax control of premature ejaculation, and it is identified as a device used for males who suffer from premature ejaculation. It is designed to increase the time between arousal and ejaculation using the stimulating vibratory effects of the device on the penis.

FDA has identified the following risks to health associated specifically with this type of device, as well as the measures required to mitigate these risks in table 1.