

- 3. Revise Part 1230 to read as follows:

PART 1230—PROTECTION OF HUMAN SUBJECTS

Sec.
1230.101 Scope.
1230.102 Applicability.
1230.103 Policy.

Authority: 5 U.S.C. 301; 45 CFR part 46.

§ 1230.101 Scope.

This Part establishes general policy for the protection of human subjects, which is of primary importance in the conduct of any human research, as specified under 5 U.S.C. 301; 45 CFR part 46, subpart A.

§ 1230.102 Applicability.

This Part applies to NASA Headquarters and NASA Centers, including Component Facilities, and Technical and Service Support Centers for all research involving humans subjects conducted, supported, or otherwise subject to regulations by any Federal department or agency which takes appropriate administrative action to make the policy applicable to such research.

§ 1230.103 Policy.

It is the National Aeronautics and Space Administration's (NASA) policy to comply with 45 CFR part 46, subpart A, Protection of Human Subjects, which applies to all research conducted involving human subjects. To implement the provisions of 45 part 46, subpart A, NASA promulgated the following internal policies and requirements:

(a) NPD 7100.8, Protection of Human Research Subjects, describes the Agency's policy for human research conducted or supported, whether on the ground, in aircraft, or in space. NPD 7100.8 can be accessed at <http://nodis3.gsfc.nasa.gov/>; and

(b) NPR 7100.1, Protection of Human Research Subjects, describes the requirements for the Agency to conduct or support research involving human subjects. NPR 7100.1 can be accessed at <http://nodis3.gsfc.nasa.gov/>.

- 4. Revise Part 1232 to read as follows:

PART 1232—CARE AND USE OF ANIMALS IN THE CONDUCT OF NASA ACTIVITIES

Sec.
1232.100 Scope.
1232.101 Applicability.
1232.102 Policy.

Authority: 51 U.S.C. 20102, 51 U.S.C. 20113; Pub. L. 89–544, as amended; 7 U.S.C. 2131; 39 U.S.C. 3001; and Pub. L. 99–158, Sec. 495.

§ 1232.100 Scope.

This part establishes general policy for the care and use of vertebrate animals in the conduct of NASA activities.

§ 1232.101 Applicability.

This part applies to NASA Headquarters and NASA Centers, including Component Facilities, and Technical and Service Support Centers and will be followed in all activities using animal subjects that are supported by NASA and conducted in NASA facilities, aircraft, or spacecraft, or activities, using animal subject conducted under a contract, grant, cooperative agreement, memorandum of understanding, or joint endeavor agreement entered into by NASA and another Government agency, private entity, non-Federal public entity, or foreign entity which are included within the scope of this part.

§ 1232.102 Policy.

It is the National Aeronautics and Space Administration's (NASA) policy to comply with the Animal Welfare Act of 1966 (Pub. L. 89–544) which requires that minimum standards of care and treatment be provided for certain animals bred for use in research. To implement the provisions of this Act, NASA promulgated the following internal policies and requirements:

(a) NASA Policy Directive (NPD) 8910.1, Care and Use of Animals, describes the policy and responsibilities for conducting activities involving vertebrate animals. NPD 8910.1 is accessible at <http://nodis3.gsfc.nasa.gov/>; and

(b) NASA Procedural Requirements (NPR) 8910.1, Care and Use of Animals, delineates the responsibilities and implements requirements for the Agency's use of animals in research, testing, teaching, and hardware development activities. NPR 8910.1 is accessible is access at <http://nodis3.gsfc.nasa.gov/>.

Charles F. Bolden, Jr.,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2012–N–0002]

New Animal Drugs for Use in Animal Feeds; Bambermycins

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 remove dairy replacement heifers from the pasture cattle class for which free-choice, loose-mineral medicated feeds containing bambermycins are approved. This action is being taken because a level of selenium for inclusion in such feeds has not been established for dairy cattle under the food additive regulation for selenium.

DATES: This rule is effective December 16, 2013.

FOR FURTHER INFORMATION CONTACT: Amey L. Adams, Center for Veterinary Medicine (HFV–120), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8108, email: amey.adams@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA has noticed that the animal drug regulations for bambermycins free-choice, loose-mineral Type C medicated feeds for pasture cattle (slaughter, stocker, and feeder cattle; and dairy and beef replacement heifers) specify formulations including trace mineral premixes that include selenium. However, the food additive regulation for selenium in salt-mineral mixtures for free-choice feeding (21 CFR 573.920(c)(3)) does not provide for use in dairy cattle. For this reason, FDA is revising the regulations to remove dairy replacement heifers from the pasture cattle class for which free-choice medicated feeds containing bambermycins are approved. This action is being taken to improve the accuracy of the regulations.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under

authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 2. In § 558.95, revise the introductory text in paragraphs (d)(4)(iii) and (d)(4)(iv), and the first sentence in paragraph (d)(4)(iii)(d) to read as follows:

§ 558.95 Bambermycins.

* * * * *

(d) * * *

(4) * * *

(iii) Used as a free-choice Type C medicated loose-mineral feed for pasture cattle (slaughter, stocker, and feeder cattle; and beef replacement heifers) as follows:

* * * * *

(d) *Limitations.* For free-choice feeding to pasture cattle (slaughter, stocker, and feeder cattle; and beef replacement heifers). * * *

(iv) Use free-choice Type C medicated feeds for pasture cattle (slaughter, stocker, and feeder cattle; and beef replacement heifers) as follows:

* * * * *

Dated: December 11, 2013.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2013-29810 Filed 12-13-13; 8:45 am]

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DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 334

Pacific Ocean off the Pacific Missile Range Facility at Barking Sands, Island of Kauai, Hawaii; Danger Zone.

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Final rule.

SUMMARY: The Corps of Engineers is amending its regulations for the danger zone in waters of the Pacific Ocean off the Pacific Missile Range Facility at Barking Sands, Island of Kauai, Hawaii. The U.S. Navy conducts weapon systems testing and other military testing and training activities at the Pacific Missile Range Facility. The amendment expands the boundaries of

the existing danger zone to include an area necessary to protect the public from potential hazards associated with weapon systems testing, other military testing and training activities, and increased threat conditions. Similar to the original danger zone, the expanded danger zone prohibits any activity by the public within the danger zone during range operations, weapon systems testing, other military testing and training activities, increases in force protection and other mission-essential evolutions without first obtaining permission from the Commanding Officer, Pacific Missile Range Facility to ensure public safety and/or installation good order. The expanded danger zone extends along approximately seven miles of shoreline adjacent to the Pacific Missile Range Facility, with its seaward extent ranging between 2.96 and 4.16 nautical miles offshore. Only the portions of the danger zone necessary to safely conduct range operations will be activated.

DATES: *Effective date:* January 15, 2014.

FOR FURTHER INFORMATION CONTACT: Mr. David Olson, Headquarters, Operations and Regulatory Community of Practice, Washington, DC at 202-761-4922, or Ms. Susan Meyer, Corps of Engineers, Honolulu District, Regulatory Branch at 808-835-4599 or by email at susan.a.meyer@usace.army.mil.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to its authorities in Section 7 of the Rivers and Harbors Act of 1917 (40 Stat. 266; 33 U.S.C. 1) and Chapter XIX of the Army Appropriations Act of 1919 (40 Stat. 892; 33 U.S.C. 3), the Corps of Engineers is amending the regulations at 33 CFR 334.1390 by expanding the boundaries of the existing permanent danger zone in the waters of the Pacific Ocean off the Pacific Missile Range Facility at Barking Sands, Island of Kauai, Hawaii.

The proposed rule was published in the July 1, 2013 issue of the **Federal Register** (78 FR 39198; docket number COE-2013-0007). Comments and statements were received from nine commenters in response to the **Federal Register** notice and the Corps of Engineers local Public Notice. The majority of the commenters opposed the expansion of the existing danger zone based on concerns that public access to the beach fronting the Pacific Missile Range Facility and the off-shore waters used by waterborne recreationalists, such as surfers, boaters, and fishermen, would be further restricted as a result of the amended danger zone.

The expansion of the danger zone boundaries will not increase the frequency with which the danger zone is activated for public safety and military security during range operations, weapon systems testing, other military testing and training activities, increases in force protection, and other mission-essential evolutions. Residents and visitors who typically use these waters off Pacific Missile Range Facility should not see any change in practice; the danger zone will continue to be activated only in limited circumstances and on a temporary basis. The intent of the danger zone is to ensure public access is controlled during the infrequent times of increased force protection, range operations, weapon systems training, and other military testing and training activities to minimize the potential for injury to individuals and property.

In addition, the State of Hawaii, Coastal Zone Management Program commented that the proposed federal action to amend the danger zone is subject to federal consistency review under the Coastal Zone Management Act of 1972 and therefore, requires the U.S. Navy to obtain concurrence from the state that the federal activity is consistent with the policies of the Hawaii Coastal Zone Management Program.

The U.S. Navy prepared a federal consistency determination for the proposed federal action and coordinated the document with the State of Hawaii Coastal Zone Management Program. In a letter dated September 13, 2013, the Hawaii Coastal Zone Management Program office concurred with the U.S. Navy's consistency determination, indicating the proposed activity is consistent to the maximum extent practicable with the enforceable policies of the Hawaii Coastal Zone Management Program.

Procedural Requirements

a. Review Under Executive Order 12866

This final rule is issued with respect to a military function of the Defense Department and the provisions of Executive Order 12866 do not apply.

b. Review Under the Regulatory Flexibility Act

This final rule has been reviewed under the Regulatory Flexibility Act (Pub. L. 96-354) which requires the preparation of a regulatory flexibility analysis for any regulation that will have a significant economic impact on a substantial number of small entities (i.e., small businesses and small governments). The Corps determined