

SUPPLEMENT NO. 4 TO PART 744—ENTITY LIST—Continued

Country	Entity	License requirement	License review policy	Federal Register citation
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PAKISTAN				
*	*	*	*	*
	Jalaluddin Haqqani, a.k.a., the following seven aliases: —General Jalaluddin; —Haqqani Sahib; —Maulama Jalaluddin; —Maulawi Haqqani; —Molvi Sahib; —Mulawi Jalaluddin; <i>and</i> —Mullah Jalaluddin. Miram Shah, Pakistan.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	77 FR 25055, 4/27/12.
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UNITED ARAB EMIRATES				
*	*	*	*	*
	Al Maskah Used Car and Spare Parts, Maliha Road, Industrial Area 6, Sharjah, U.A.E.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	77 FR 25055, 4/27/12.
*	*	*	*	*
	Feroz Khan, a.k.a., the following three aliases: —Haaje Khan; —Haaji Khan; <i>and</i> —Firoz. Maliha Road, Industrial Area 6, Sharjah, U.A.E.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	77 FR 25055, 4/27/12.
*	*	*	*	*
	Zurmat General Trading, Office No. 205, Platinum Business Center, Baghdad Street, Al-Nahda 2, Al-Qusais, Dubai, U.A.E.; <i>and</i> P.O. Box No. 171452, Dubai, U.A.E.; <i>and</i> 1st Street, Industrial Area 4th, Sharjah, U.A.E. (Behind the Toyota Showroom), <i>and</i> P.O. Box 35470, Sharjah, U.A.E.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	77 FR 25055, 4/27/12.
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Dated: May 8, 2012.
Bernard Kritzer,
Director, Office of Exporter Services.
 [FR Doc. 2012–11555 Filed 5–11–12; 8:45 am]
BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA–2012–N–0002]

Oral Dosage Form New Animal Drugs; Change of Sponsor; Griseofulvin Powder; Levamisole Hydrochloride Powder; Oxytetracycline Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for five abbreviated new animal drug applications (ANADAs) for griseofulvin powder, levamisole hydrochloride soluble powder, and oxytetracycline hydrochloride soluble powder from Teva Animal Health, Inc., to Cross Vetpharm Group, Ltd.

DATES: This rule is effective May 14, 2012.

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240-276-8300, steven.vaughn@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Teva Animal Health, Inc., 3915 South 48th St. Ter., St. Joseph, MO 64503, has informed FDA that it has transferred ownership of, and all rights and interest in, ANADA 200-391 for Griseofulvin Powder, ANADAs 200-146 and 200-247 for Oxytetracycline Hydrochloride Soluble Powder, and ANADAs 200-313 and 200-386 for Levamisole Hydrochloride Soluble Pig Wormer and Drench Powder to Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland. Accordingly, the agency is amending the regulations in part 520 (21 CFR part 520) to reflect the transfer of ownership and a current format.

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 520

Animal drugs.

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.1100 [Amended]

■ 2. In paragraph (b)(2) of § 520.1100, remove “059130” and in its place add “061623”.

■ 3. In § 520.1242, revise the section heading to read as follows:

§ 520.1242 Levamisole.

■ 4. In § 520.1242a, revise the section heading to read as set forth below, and in paragraph (b)(4) remove “059130” and in its place add “061623”.

§ 520.1242a Levamisole powder.

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§ 520.1660d [Amended]

■ 5. In § 520.1660d, in paragraphs (b)(5), (d)(1)(ii)(A)(3), (d)(1)(ii)(B)(3), (d)(1)(ii)(C)(3), and (d)(1)(iii)(C), remove “059130” and in its place add “061623”.

Dated: May 7, 2012.

Elizabeth Rettie,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 2012-11382 Filed 5-11-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2011-1172]

RIN 1625-AA00

Safety Zone; America’s Cup World Series, East Passage, Narragansett Bay, RI

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing two temporary safety zones in the navigable waters of the East Passage, Narragansett Bay, Rhode Island, during the America’s Cup World Series (ACWS) sailing vessel racing event.

DATES: This rule is effective June 13, 2012 until 5:00 p.m. on July 1, 2012.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG-2011-1172 and are available online by going to <http://www.regulations.gov>, inserting USCG-2011-1172 in the “Keyword” box, and then clicking “Search.” This material is also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Edward G. LeBlanc, Waterways Management Division at Coast Guard Sector Southeastern New England, telephone 401-435-2351, email Edward.G.LeBlanc@uscg.mil. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On February 10, 2012, we published a notice of proposed rulemaking

(NPRM) entitled “Safety Zones; America’s Cup World Series, East Passage, Narragansett Bay, RI” in the **Federal Register** (77 FR 7025). We received one comment on the proposed rule.

Basis and Purpose

The legal basis for this rule is 33 U.S.C. 1231; 46 U.S.C. chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05-1, 6.04-1, 6.04-6, 160.5; Public Law 107-295, 116 Stat. 2064; and Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to define safety zones.

This rule is necessary to provide for the safety of life and navigation for both participants and spectators involved with the America’s Cup World Series in the vicinity of Newport, RI.

Discussion of Comments and Changes

One comment was received, supporting this rule. The commenter believed the safety zones established by this rule will improve navigation safety for all mariners and facilitate a safe America’s Cup World Series event. No changes were made to the language contained in the NPRM.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Executive Order 12866 and Executive Order 13563

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

We expect the economic impact of this rule to be minimal. Although this regulation may have some impact on the public, the potential impact will be minimized for the following reasons: Vessels will only be restricted from the East Passage of Narragansett Bay by the designated safety zone for a maximum of six hours per day for a maximum of 10 days; there is an alternate route, the West Passage of Narragansett Bay, that does not add substantial transit time, is already routinely used by mariners, and will not be affected by these safety zones; many vessels, especially all recreational vessels, may transit in all