7A994 Other navigation direction finding equipment, airborne communication equipment, all aircraft inertial navigation systems not controlled under 7A003 or 7A103, and other avionic equipment, including parts and components, n.e.s.

* * * * *

List of Items Controlled

Unit: * * *
Related Controls: N/A.
Related Definitions: * * *
Items: * * *

* * * * *

■ 9. Supplement No. 1 to Part 774 (the Commerce Control List), Category 9—Propulsion Systems, Space Vehicles, and Related Equipment, ECCN 9A106, List of Items Controlled Section is amended by revising the ''Items'' paragraph to read as follows:

9A106 Systems or components, other than those controlled by 9A006, usable in ''missiles'', as follows (see List of Items Controlled), and specially designed for liquid rocket propulsion systems.

* * * * *

List of Items Controlled

Unit: * * *
Related Controls: * * *
Related Definitions: * * *
Items:

a. Ablative liners for thrust or combustion chambers;

b. Rocket nozzles;

c. Thrust vector control sub-systems;

Technical Note: Examples of methods of achieving thrust vector control controlled by 9A106.c includes:

1. Flexible nozzle;
2. Fluid or secondary gas injection;
3. Movable engine or nozzle;
4. Deflection of exhaust gas steam (jet vanes or probes); or
5. Thrust tabs.

d. Liquid and slurry propellant (including oxidizers) control systems, and specially designed components therefor, designed or modified to operate in vibration environments of more than 10 g rms between 20 Hz and 2000 Hz.

Note: The only servo valves and pumps controlled by 9A106.d, are the following:

a. Servo valves designed for flow rates of 24 liters per minute or greater, at an absolute pressure of 7 Mpa or greater, that have an actuator response time of less than 100 ms;

b. Pumps, for liquid propellants, with shaft speeds equal to or greater than 8,000 rpm or with discharge pressures equal to or greater than 7 Mpa.

e. Flight control servo valves designed or modified for use in ''missiles'' and designed or modified to operate in a vibration environment of more than 10g RMS over the entire range between 20Hz and 2KHz.

Dated: September 12, 2003.

Matthew Borman,

Acting Assistant Secretary for Export Administration.

[FR Doc. 03–23888 Filed 9–17–03; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Change of Sponsor

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 two approved new animal drug applications (NADAs) from Teva Pharmaceuticals USA to Delmarva Laboratories, Inc.

DATES: This rule is effective September 18, 2003.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967, e-mail: *dnewkirk@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Teva Pharmaceuticals USA, 650 Cathill Rd., Sellersville, PA 18960, has informed FDA that it has transferred ownership of, and all rights and interest in, the following two approved NADAs to Delmarva Laboratories, Inc., 1500 Huguenot Rd., suite 106, Midlothian, VA 23113:

NADA No.	Trade Name
65–492	ROBAMOX V (amoxicillin trihydrate) Tablets
65–495	ROBAMOX V (amoxicillin trihydrate)

Accordingly, the agency is amending the regulations in 21 CFR 520.88b and 520.88f to reflect the transfer of ownership.

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.

§ 520.88b [Amended]

■ 2. Section 520.88b *Amoxicillin trihydrate for oral suspension* is amended in paragraph (c) by removing ''*Sponsor*. See Nos. 000093 and 000856'' and by adding in its place ''*Sponsors*. See Nos. 000856 and 059079''.

§ 520.88f [Amended]

■ 3. Section 520.88f *Amoxicillin trihydrate tablets* is amended in paragraph (b) by removing ''*Sponsor*. See Nos. 000093 and 000856'' and by adding in its place ''*Sponsors*. See Nos. 000856 and 059079''.

Dated: August 28, 2003.

Steven D. Vaughn,

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

[FR Doc. 03–23779 Filed 9–17–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

New Animal Drugs; Ractopamine

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Elanco Animal Health. The NADA provides for use of ractopamine hydrochloride Type A medicated articles to make Type B and Type C medicated feeds used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter.

DATES: This rule is effective September 18, 2003.

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary

Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0232, e-mail: *edubbin@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 141–221 that provides for use of OPTAFLEXX 45 (ractopamine hydrochloride) Type A medicated article to make dry and liquid Type B and dry Type C medicated feeds used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 28 to 42 days on feed. The NADA is approved as of June 13, 2003, and the regulations in 21 CFR 556.570 and 558.500 are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application 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.

The agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning June 13, 2003 .

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

21 CFR Part 556

Animal drugs, Foods.

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 parts 556 and 558 are amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 2. Section 556.570 is revised to read as follows:

§ 556.570 Ractopamine.

(a) *Acceptable Daily Intake (ADI).* The ADI for total residues of ractopamine hydrochloride is 1.25 micrograms per kilogram of body weight per day.

(b) *Tolerances* —(1) *Cattle*—(i) *Liver (the target tissue).* The tolerance for ractopamine hydrochloride (the marker residue) is 0.09 parts per million (ppm).

(ii) *Muscle.* The tolerance for ractopamine hydrochloride (the marker residue) is 0.03 ppm.

(2) *Swine*—(i) *Liver (the target tissue).* The tolerance for ractopamine hydrochloride (the marker residue) is 0.15 ppm.

(ii) *Muscle.* The tolerance for ractopamine hydrochloride (the marker residue) is 0.05 ppm.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 4. Section 558.500 is amended by adding paragraphs (d)(3) and (e)(2) to read as follows:

§ 558.500 Ractopamine.

* * * * *

(d) * * *

(3) Ractopamine liquid Type B cattle feeds may be manufactured from dry ractopamine Type A articles. The liquid Type B feeds must be maintained at a pH of 4.5 to 7.5. Mixing directions for liquid Type B feeds requiring recirculation or agitation: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(e) * * *

(2) *Cattle*—

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 8.2 to 24.6		Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency during the last 28 to 42 days on feed.	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding.	000986
(ii) 9.8 to 24.6		Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness during the last 28 to 42 days on feed.	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding.	000986

Dated: September 9, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03–23892 Filed 9–17–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 602

[TD 9061]

RIN 1545–BB55

Automatic Extension of Time To File Certain Information Returns and Exempt Organization Returns; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final and temporary regulations.

SUMMARY: This document contains corrections to final and temporary regulations that were published in the **Federal Register** on June 11, 2003 (68 FR 34797), regarding an automatic extension of time to file certain information returns and exempt organization returns under section 6081 of the Internal Revenue Code.

DATES: This correction is effective June 11, 2003.

FOR FURTHER INFORMATION CONTACT: Charles A. Hall (202) 622–4940 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations that are the subject of these corrections are under section 6081 of the Internal Revenue Code.

Need for Correction

As published, these final and temporary regulations (TD 9061) contain errors that may prove to be misleading and are in need of clarification.

Correction of Publication

■ Accordingly, the publication of the final and temporary regulations (TD 9061), which were the subject of FR Doc. 03–14603, is corrected to read as follows:

■ On page 34799, column 3, § 602.101(b), the entries in the table are corrected to read as follows:

§ 602.101 OMB Control numbers

* * * * *

(b)* * *

CFR part or section where identified and described	Current OMB control No.
* * * *	*
1.6081–8T	1545–1840
1.6081–9T	1545–1840
* * * *	*

Cynthia E. Grigsby,

Acting Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedures and Administration).

[FR Doc. 03–23876 Filed 9–17–03; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[CGD05–03–129]

RIN 1625–AA08

Special Local Regulations for Marine Events; James River, Jamestown Beach to First Colony Beach, VA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary special local regulations during the ''James River Cancer Swim'', a marine event to be held September 21, 2003 on the waters of the James River, between Jamestown Beach and First Colony Beach, Virginia. These special local regulations are necessary to provide for the safety of life on navigable waters during the event. This action is intended to temporarily restrict vessel traffic in a portion of the James River between Jamestown Beach and First Colony Beach, Virginia during the event.

DATES: This rule is effective from 12:45 p.m. to 3:45 p.m. on September 21, 2003.

ADDRESSES: Documents indicated in this preamble as being available in the docket, are part of docket CGD05–03–129 and are available for inspection or copying at Commander (oax), Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704–5004, between 9 a.m. and 2 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: S. L. Phillips, Project Manager, Auxiliary and Recreational Boating Safety Branch, at (757) 398–6204.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B) the Coast Guard finds that good cause exists for not publishing an NPRM. The event will take place on September 21, 2003. There is not sufficient time to allow for a notice and comment period, prior to the event. Because of the danger posed to the swimmers competing within a confined area, special local regulations are necessary to provide for the safety of event participants, support craft and other vessels transiting the event area.

For the same reasons, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date would be contrary to the public interest, since immediate action is needed to ensure the safety of participants, support craft, spectator craft and other vessels transiting the event area. For the safety concerns noted, it is in the public interest to have these regulations in effect during the event. However, advance notifications will be made to affected users of the waterway via marine information broadcasts and area newspapers.

Background and Purpose

On September 21, 2003, the College of William and Mary will sponsor the ''James River Cancer Swim''. The event will consist of approximately 60 swimmers competing across a portion of the James River between Jamestown Beach and First Colony Beach, Virginia. The competition will begin at the southern shoreline. The participants will swim across to the northern shore, and then return to the finish line on the southern shore. Approximately 10 support vessels will accompany the swimmers. Due to the need for vessel control during the swimming event, the Coast Guard will temporarily restrict vessel traffic in the event area to provide for the safety of participants, support craft and other transiting vessels.

Discussion of Rule

The Coast Guard is establishing temporary special local regulations on specified waters of the James River between Jamestown Beach and First Colony Beach, Virginia. The temporary special local regulations will be in effect from 12:45 p.m. to 3:45 p.m. on September 21, 2003. The effect will be to restrict general navigation in the regulated area during the event. Except for persons or vessels authorized by the