

DEPARTMENT OF COMMERCE**Bureau of Industry and Security****15 CFR Parts 742, 744, 748 and 774**

[Docket No. 070105004-7809-02]

RIN 0694 AD95

December 2006 Wassenaar Arrangement Plenary Agreement Implementation: Categories 1, 3, 6, and 7 of the Commerce Control List; Wassenaar Reporting Requirements**AGENCY:** Bureau of Industry and Security, Commerce.**ACTION:** Final rule; correction.

SUMMARY: On November 5, 2007, the Bureau of Industry and Security published a final rule that amended the Export Administration Regulations (EAR) to implement the agreement reached at the December 2006 plenary meeting of the Wassenaar Arrangement on Export Controls for Conventional Arms and Dual-Use Goods and Technologies. The November 5 final rule contained errors in Parts 742 and 744, and Categories 1, 3, 6 and 7 on the Commerce Control List. This rule corrects those errors.

In addition, the November 5th rule indirectly affected an item of the list of eligible items for Authorized Validated End-User (VEU) Applied Materials China, Ltd. This rule corrects that item listing to harmonize with revisions of the November 5th rule.

DATES: Effective Date: This rule is effective February 5, 2008.

FOR FURTHER INFORMATION CONTACT: For questions of a general nature contact Sharron Cook, Office of Exporter Services, Bureau of Industry and Security, U.S. Department of Commerce at (202) 482-2440 or E-mail: scook@bis.doc.gov.

For questions of a technical nature contact:

Category 1: Bob Teer 202-482-4749

Category 3: Brian Baker 202-482-5534

Category 6: Chris Costanzo 202-482-0718 and Mark Jaso 202-482-0987

Comments regarding the collections of information associated with this rule, including suggestions for reducing the burden, should be sent to OMB Desk Officer, New Executive Office Building, Washington, DC 20503, Attention: David Rostker; and to the Office of Administration, Bureau of Industry and Security, Department of Commerce, 14th and Pennsylvania Avenue, NW., Room 6883, Washington, DC 20230.

SUPPLEMENTARY INFORMATION**Background**

This document corrects errors contained in the Bureau of Industry and Security (BIS) final rule published in the **Federal Register** on November 5, 2007 (72 FR 62524). Specifically, this rule corrects sections of the EAR as set forth below.

Part 742

- Section 742.6 is amended by adding the phrase “(except 6A002.a.3.d.a.2 and 6A002.a.3.e for lead selenide focal plane arrays)” after 6A002.a.3 in paragraph (a)(1) to reflect the change in RS controls in Export Control Classification Number (ECCN) 6A002 that was published on November 5, 2007.

Part 744

- Section 744.17 is amended by revising the reference in the first sentence to “Part 42” to read “Part 742” to fix the typographical error.

Category 1

- ECCN 1A002 is amended to fix a typographical error by revising the phrase “structures of laminates” to read “structures or laminates” in the last note in the items paragraph of the List of Items Controlled section.

Category 3

- ECCN 3A001 is amended by revising the abbreviation “TWAS” to read “TWTAs” in the GBS paragraph of the License Exception section to fix that typographical error.

Category 6

- ECCN 6A004 is amended by replacing the double quotes with single quotes around the term ‘aspheric optical element’ in the Related Definitions paragraph of the List of Items Controlled section of ECCN 6A004, because single quotes signify a local definition found in the ECCN as opposed to a definition that is located in Part 772.

- ECCN 6A005 is amended by:
 - Removing the reference to a.4 in the NP control paragraph of the License Requirements section, because the equipment in this paragraph is not controlled for nuclear non-proliferation;
 - Revising the phrase “6A005.c.1.b and 6A005.c.2.b” to read “6A005.c.1.b or 6A005.c.2.b” in paragraphs h and i of the License Requirement Note; and
 - Revising the GBS and CIV paragraphs in the License Exception section of ECCN 6A005 (lasers);

Rationale: The license exception language under the recently revised ECCN 6A005 does not represent the intent of the agencies involved in the revisions for ECCN 6A005. The intent was for the items described under the

revised license exception language to match the descriptions under the earlier version. The license exception language for License Exceptions GBS and CIV under the previous ECCN 6A005 allowed only certain dye, liquid, CO and CO2, and neodymium lasers to be eligible for these exceptions. The license exception language under the recently revised ECCN 6A005 allows all lasers and components, with the exception of NP controlled items, to be eligible for GBS and CIV exceptions. Implementing controls for fiber lasers was a significant part of the 2006 Wassenaar revisions to 6A005. An unintended consequence of the language published on November 5, 2007 permitted these lasers to be eligible for License Exceptions GBS and CIV.

- ECCN 6A995 is amended by:
 - Revising the numbering of the paragraphs in 6A995.d.1, because these paragraphs were mis-numbered; and
 - Revising the average output power from “500 W” to “50 W” in 6A995.e.1.b to maintain the anti-terrorism controls on lasers that were controlled in 6A005.c.2.c.3.b.2 prior to the November 2007 rule.

- ECCN 6E201 is amended by revising the heading to:
 - Remove the phrase “not controlled by 6E001 or 6E002”, because 6E001 controls development technology and 6E002 controls production technology, and therefore, the phrase is not necessary in 6E201, which controls use technology; and
 - Remove the reference to 6A005.a.4, because it is not controlled for nuclear non-proliferation reasons.

Category 7

- ECCN 7A101 is amended by replacing the word “therefore” with “therefor” in the heading.

- ECCNs 7D001 and 7D003 are amended by revising the MT paragraph in the License Requirements section to replace the text “MT applies to entire entry except 7A008” with “MT applies to “software” for equipment controlled for MT reasons. MT does not apply to “software” for equipment controlled by 7A008”. This amendment clarifies that the MT controls for these ECCNs only apply to equipment controlled for MT reasons and do not apply to software for equipment controlled by 7A008.

- ECCNs 7E001 and 7E002 are amended by revising the MT paragraph in the License Requirements section to replace the text “MT applies to entire entry except 7A008” with “MT applies to “technology” for equipment controlled for MT reasons. MT does not apply to “technology” for equipment controlled by 7A008”. This amendment clarifies that the MT controls for these

ECCNs only apply to equipment controlled for MT reasons and do not apply to technology for equipment controlled by 7A008.

**Supplement No. 7 to Part 748
“Authorization Validated End-User (VEU): List of Validated End-Users, Respective Items Eligible for Export, Reexport and Transfer, and Eligible Destinations”**

The November 5th Wassenaar implementation rule redesignated 3B001.f.2 as 3B001.f.3. Therefore, this rule replaces the listing of “3B001.f.2” with “3B001.f.3” for Applied Materials China, Ltd in Supplement No 7 to Part 748.

Saving Clause

Shipments of items removed from license exception eligibility or eligibility for export without a license as a result of this regulatory action that were on dock for loading, on lighter, laden aboard an exporting carrier, or en route aboard a carrier to a port of export, on February 5, 2008, pursuant to actual orders for export to a foreign destination, may proceed to that destination under the previous license exception eligibility or without a license so long as they have been exported from the United States before April 7, 2008. Any such items not actually exported before midnight, on April 7, 2008, require a license in accordance with this regulation.

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as extended by the Notice of August 15, 2007, 72 FR 46137 (August 16, 2007), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act.

Rulemaking Requirements

1. This final rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule involves two collections of information subject to the PRA. One of the collections has been approved by OMB under control number 0694 0088, “Multi Purpose Application,” and

carries a burden hour estimate of 58 minutes for a manual or electronic submission. The other of the collections has been approved by OMB under control number 0694 0106, “Reporting and Recordkeeping Requirements under the Wassenaar Arrangement,” and carries a burden hour estimate of 21 minutes for a manual or electronic submission. Send comments regarding these burden estimates or any other aspect of these collections of information, including suggestions for reducing the burden, to OMB Desk Officer, New Executive Office Building, Washington, DC 20503; and to the Office of Administration, Bureau of Industry and Security, Department of Commerce, 14th and Pennsylvania Avenue, NW., Room 6622, Washington, DC 20230.

3. This rule does not contain policies with Federalism implications as that term is defined under Executive Order 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military and foreign affairs function of the United States (5 U.S.C. 553(a)(1)). Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under the Administrative Procedure Act or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*) are not applicable. Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Sharron Cook, Office of Exporter Services, Bureau of Industry and Security, Department of Commerce, 14th & Pennsylvania Ave., NW., Room 2705, Washington, DC 20230.

List of Subjects

15 CFR Part 742

Exports, Terrorism.

15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

15 CFR Part 748

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

15 CFR Part 774

Exports, Reporting and recordkeeping requirements.

■ Accordingly, Parts 742, 744, 748 and 774 of the Export Administration Regulations (15 CFR Parts 730–774) are amended as follows:

PART 742—[AMENDED]

■ 1. The authority citation for part 742 continues to read as follows:

Authority: 50 U.S.C. app. 2401, *et seq.*; 50 U.S.C. 1701, *et seq.*; 22 U.S.C. 3201, *et seq.*; 42 U.S.C. 2139a; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; Sec 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23 of May 7, 2003, 68 FR 26459, May 16, 2003; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of October 27, 2006, 71 FR 64109 (October 31, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

■ 2. Section 742.6 is amended by revising paragraph (a)(1) to read as follows:

§ 742.6 Regional stability.

(a) * * *

(1) As indicated in the CCL and in RS Column 1 of the Country Chart (see Supplement No. 1 to part 738 of the EAR), a license is required to all destinations, except Canada, for items described on the CCL under ECCNs 6A002.a.1, a.2, a.3, .c, or .e; 6A003.b.3 and b.4; 6A008.j.1; 6A998.b; 6D001 (only “software” for the “development” or “production” of items in 6A002.a.1, a.2, a.3 (except 6A002.a.3.d.a.2 and 6A002.a.3.e for lead selenide focal plane arrays), .c; 6A003.b.3 and .b.4; or 6A008.j.1); 6D002 (only “software” for the “use” of items in 6A002.a.1, a.2, a.3, .c; 6A003.b.3 and .b.4; or 6A008.j.1); 6D991 (only “software” for the “development,” “production,” or “use” of equipment controlled by 6A002.e or 6A998.b); 6E001 (only “technology” for “development” of items in 6A002.a.1, a.2, a.3, and .c or .e, 6A003.b.3 and b.4, or 6A008.j.1); 6E002 (only “technology” for “production” of items in 6A002.a.1, a.2, a.3, .c, or .e, 6A003.b.3 or b.4, or 6A008.j.1); 6E991 (only “technology” for the “development,” “production,” or “use” of equipment controlled by 6A998.b); 7D001 (only “software” for “development” or “production” of items in 7A001, 7A002, or 7A003); 7E001 (only “technology” for the “development” of inertial navigation systems, inertial equipment, and specially designed components therefor

for civil aircraft); 7E002 (only “technology” for the “production” of inertial navigation systems, inertial equipment, and specially designed components therefor for civil aircraft); 7E101 (only “technology” for the “use” of inertial navigation systems, inertial equipment, and specially designed components for civil aircraft).

* * * * *

PART 744—[AMENDED]

■ 3. The authority citation for part 744 continues to read as follows:

Authority: 50 U.S.C. app. 2401, *et seq.*; 50 U.S.C. 1701, *et seq.*; 22 U.S.C. 3201, *et seq.*; 42 U.S.C. 2139a; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of October 27, 2006, 71 FR 64109 (October 31, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

■ 4. Section 744.17 is amended by revising the reference “Part 42” to read “Part 742” in paragraph (a).

PART 748—[AMENDED]

■ 5. The authority citation for part 748 continues to read as follows:

Authority: 50 U.S.C. app. 2401, *et seq.*; 50 U.S.C. 1701, *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

■ 6. Supplement No. 7 to part 748 is amended by removing the reference to “3B001.f.2” and adding in its place “3B001.f.3” in the Eligible Items (By ECCN) column for Applied Materials China, Ltd.

PART 774—[AMENDED]

■ 7. The authority citation for part 774 continues to read as follows:

Authority: 50 U.S.C. app. 2401, *et seq.*; 50 U.S.C. 1701, *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201, *et seq.*; 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 46 U.S.C. app. 466c; 50 U.S.C. app. 5; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

Supplement No. 1 to part 774—Commerce Control List [AMENDED]

■ 8. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1 Materials, Chemicals, Microorganisms, and Toxins, Export Control Classification Number (ECCN) 1A002 is amended by revising the phrase “structures of laminates” to read “structures or laminates” in the last Note appearing in the “items” paragraph in the List of Items Controlled section.

■ 9. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 3 Electronics, Export Control Classification Number (ECCN) 3A001 is amended by removing the abbreviation “TWAS” and adding in its place “TWTAs” in the GBS paragraph of the License Exceptions section.

■ 10. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 6 Sensors, Export Control Classification Number (ECCN) 6A004 is amended by removing the double quotes and adding in their place single quotes around the term “aspheric optical element” in the Related Controls paragraph and the Related Definitions paragraph of the List of Items Controlled section.

■ 11. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 6 Sensors, Export Control Classification Number (ECCN) 6A005 is amended by:

- a. Removing “a.4” from the list of references in the NP paragraph of the License Requirements section;
- b. Revising the phrase “6A005.c.1.b and 6A005.c.2.b” to read “6A005.c.1.b or 6A005.c.2.b” in paragraphs (h) and (i) of the License Requirement Note; and
- c. Revising the GBS and CIV paragraphs in the License Exception section, to read as follows:

6A005 “Lasers” (other than those described in 0B001.g.5 or .h.6), components and optical equipment, as follows (see List of Items Controlled).

* * * * *

License Exceptions

* * * * *

GBS: Neodymium-doped (other than glass) “lasers” controlled by 6A005.b.6.c.2 (except 6A005.b.6.c.2.b) that have an output wavelength exceeding 1,000 nm, but not exceeding 1,100 nm, and an average or CW output power not exceeding 2kW, and operate in a pulse-excited, non-“Q-switched” multiple-transverse mode, or in a continuously excited, multiple-transverse mode; Dye and Liquid Lasers controlled by 6A005.c.1 and c.2, except for a pulsed single longitudinal mode oscillator having an average output power exceeding 1 W and a repetition rate exceeding 1 kHz if the “pulse duration” is less than 100 ns; CO “lasers” controlled by 6A005.d.2 having a CW maximum rated single or multimode output

power not exceeding 10 kW; CO₂ or CO/CO₂ “lasers” controlled by 6A005.d.3 having an output wavelength in the range from 9,000 to 11,000 nm and having a pulsed output not exceeding 2 J per pulse and a maximum rated average single or multimode output power not exceeding 5 kW; CO₂ “lasers” controlled by 6A005.d.3 that operate in CW multiple-transverse mode, and having a CW output power not exceeding 15kW; and 6A005.f.1.

CIV: Neodymium-doped (other than glass) “lasers” controlled by 6A005.b.6.c.2 (except 6A005.b.6.c.2.b) that have an output wavelength exceeding 1,000 nm, but not exceeding 1,100 nm, and an average or CW output power not exceeding 2kW, and operate in a pulse-excited, non-“Q-switched” multiple-transverse mode, or in a continuously excited, multiple-transverse mode; Dye and Liquid Lasers controlled by 6A005.c.1 and c.2, except for a pulsed single longitudinal mode oscillator having an average output power exceeding 1 W and a repetition rate exceeding 1 kHz if the “pulse duration” is less than 100 ns; CO “lasers” controlled by 6A005.d.2 having a CW maximum rated single or multimode output power not exceeding 10 kW; CO₂ or CO/CO₂ “lasers” controlled by 6A005.d.3 having an output wavelength in the range from 9,000 to 11,000 nm and having a pulsed output not exceeding 2 J per pulse and a maximum rated average single or multimode output power not exceeding 5 kW; CO₂ “lasers” controlled by 6A005.d.3 that operate in CW multiple-transverse mode, and having a CW output power not exceeding 15kW; and 6A005.f.1.

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■ 12. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 6 Sensors, Export Control Classification Number (ECCN) 6A995 is amended by:

- a. Revising paragraph d.1.a in the items paragraph of the List of Items Controlled section, to read as set forth below; and
- b. Revising the average output power from “500 W” to read “50 W” in 6A995.e.1.b.

6A995 “Lasers”, not controlled by 0B001.g.5, 0B001.h.6, 6A005 or 6A205.

* * * * *

List of Items Controlled

* * * * *

Items:

* * * * *

- d. * * *
- d.1. * * *
- d.1.a. A single transverse mode output and having any of the following:
 - d.1.a.1. A ‘wall-plug efficiency’ exceeding 12% and an “average output power” exceeding 10W and capable of operating at a pulse repetition frequency greater than 1kHz; or
 - d.1.a.2. An “average output power” exceeding 20W; or

* * * * *

■ 13. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 6 Sensors, Export Control Classification

Number (ECCN) 6E201 is amended by revising the heading to read as follows:

note to 6A005); 6A202, 6A203, 6A205, 6A225 or 6A226.

Navigation and Avionics, Export Control Classification Number (ECCN) 7D001 is amended by revising the MT paragraph of the License Requirements section, to read as follows:

6E201 "Technology" according to the General Technology Note for the "use" of equipment controlled by 6A003.a.2, 6A003.a.3, 6A003.a.4; 6A005.a.2, 6A005.b.2.b, 6A005.b.3.a, 6A005.b.4.b, 6A005.b.6.b, 6A005.c.1.b, 6A005.c.2.b, 6A005.d.3.c, or 6A005.d.4.c (as described in the license requirement

- * * * * *
- 14. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 7 Navigation and Avionics, Export Control Classification Number (ECCN) 7A101 is amended by removing the word "therefore" and adding in its place "therefor" in the heading.
- 15. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 7

7D001 "Software" specially designed or modified for the "development" or "production" of equipment controlled by 7A (except 7A994) or 7B (except 7B994). License Requirements

* * * * *

<i>Control(s)</i>					<i>Country Chart</i>
*	*	*	*	*	*
MT applies to "software" for equipment controlled for MT reasons. MT does not apply to "software" for equipment controlled by 7A008.					MT Column 1.
*	*	*	*	*	*

■ 16. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 7 Navigation and Avionics, Export Control Classification Number (ECCN)

7D003 is amended by revising the MT paragraph of the License Requirements section, to read as follows:

7D003 Other "software", as follows (see List of Items Controlled). License Requirements

* * * * *

<i>Control(s)</i>					<i>Country chart</i>
*	*	*	*	*	*
MT applies to "software" for equipment controlled for MT reasons. MT does not apply to "software" for equipment controlled by 7A008.					MT Column 1.
*	*	*	*	*	*

■ 17. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 7 Navigation and Avionics, Export Control Classification Number (ECCN) 7E001 is amended by revising the MT

paragraph in the License Requirements section to read as follows:

"software" controlled by 7A (except 7A994), 7B (except 7B994) or 7D (except 7D994). License Requirements

7E001 "Technology" according to the General Technology Note for the "development" of equipment or

* * * * *

<i>Control(s)</i>					<i>Country chart</i>
*	*	*	*	*	*
MT applies to "technology" for equipment controlled for MT reasons. MT does not apply to "technology" for equipment controlled by 7A008.					MT Column 1.
*	*	*	*	*	*

■ 18. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 7 Navigation and Avionics, Export Control Classification Number (ECCN) 7E002 is amended by revising the MT

paragraph in the License Requirements section, to read as follows:

"production" of equipment controlled by 7A (except 7A994) or 7B (except 7B994). License Requirements

7E002 "Technology" according to the General Technology Note for the

* * * * *

<i>Control(s)</i>					<i>Country chart</i>
*	*	*	*	*	*
MT applies to "technology" for equipment controlled for MT reasons. MT does not apply to "technology" for equipment controlled by 7A008.					MT Column 1.
*	*	*	*	*	*

Eileen M. Albanese,
Director for Office of Exporter Services.
[FR Doc. 08-480 Filed 2-4-08; 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; Spectinomycin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to correct an error in the indications for use for spectinomycin oral solution in swine. FDA is also amending the regulations for other oral dosage forms of spectinomycin to reflect a current format. These actions are being taken to improve the accuracy and readability of the animal drug regulations.

DATES: This rule is effective February 5, 2008.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9019, e-mail: george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA has noticed that the animal drug regulations do not reflect the approved indications for use for spectinomycin oral solution in swine. At this time, FDA is amending the animal drug regulations in § 520.2123c (21 CFR 520.2123c) to correct this error. FDA is also amending the regulations in § 520.2123a for spectinomycin tablets and in § 520.2123b for spectinomycin powder to reflect a current format. These actions are being taken to improve the accuracy and readability of the animal drug 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 520

Animal drugs.

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

■ 2. Revise § 520.2123 to read as follows:

§ 520.2123 Spectinomycin oral dosage forms.

■ 3. Revise § 520.2123a to read as follows:

§ 520.2123a Spectinomycin tablets.

(a) *Specifications.* Each tablet contains spectinomycin dihydrochloride pentahydrate equivalent to 100 milligrams (mg) spectinomycin.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Administer orally to provide 10 mg per pound (lb) of body weight twice daily. Dosage may be continued for 4 consecutive days.

(2) *Indications for use.* For the treatment of infectious diarrhea and gastroenteritis caused by organisms susceptible to spectinomycin.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 4. Revise § 520.2123b to read as follows:

§ 520.2123b Spectinomycin powder.

(a) *Specifications.* Each gram (g) of powder contains spectinomycin dihydrochloride pentahydrate equivalent to 0.5 g spectinomycin.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.600 of this chapter.

(d) *Conditions of use in chickens.* It is administered in the drinking water of growing chickens as follows:

(1) *Indications for use and amounts—*(i) For increased rate of weight gain and improved feed efficiency in broiler chickens, administer 0.5 g per gallon of water as the only source of drinking water for the first 3 days of life and for 1 day following each vaccination.

(ii) As an aid in controlling infectious synovitis due to *Mycoplasma synoviae* in broiler chickens, administer 1 g per gallon of water as the only source of drinking water for the first 3 to 5 days of life.

(iii) As an aid in the prevention or control of losses due to CRD associated with *M. gallisepticum* (PPLO) in growing chickens, administer 2 g per gallon of water as the only source of drinking water for the first 3 days of life

and for 1 day following each vaccination.

(2) *Limitations.* Do not administer to laying chickens. Do not administer within 5 days of slaughter.

■ 5. Revise § 520.2123c to read as follows:

§ 520.2123c Spectinomycin solution.

(a) *Specifications.* Each milliliter of solution contains spectinomycin dihydrochloride pentahydrate equivalent to 50 milligrams (mg) spectinomycin.

(b) *Sponsors.* See Nos. 000856, 059130, and 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.600 of this chapter.

(d) *Conditions of use in swine—(1) Amount.* Administer 5 mg per pound (lb) of body weight orally twice daily for 3 to 5 days.

(2) *Indications for use.* For the treatment and control of porcine enteric colibacillosis (scours) caused by *E. coli* susceptible to spectinomycin in pigs under 4 weeks of age.

(3) *Limitations.* Do not administer to pigs over 15 lb body weight or over 4 weeks of age. Do not administer within 21 days of slaughter.

Dated: January 24, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 110

[Docket No. USCG-2007-0036, formerly CGD07-122]

RIN 1625-AA01

Anchorage Regulation; Port Everglades, FL

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard amends the anchorage regulations for Port Everglades, Florida. The amendment modifies the current anchorage area by eliminating that portion of the anchorage closest to sensitive coral reef areas, expands that portion of the anchorage area that poses less risk to these areas, and limits the amount of time a vessel may remain in the anchorage area. These changes ensure