$100,000 to stay in business. ARSA maintains that measuring the impact on small businesses based on annual revenues is not appropriate. ARSA asserts that the FAA should measure economic impact based on profits. The FAA has reviewed ARSA’s suggestion and determined that it is not appropriate for this analysis. Use of annual revenues is consistent with the SBA’s measure of the impact on small businesses. See 13 CFR 121.106; 121.201. Thus, based on the projected costs for the smallest of entities that could be affected by this final rule, the FAA concludes no firm would incur a significant economic impact.

Accordingly, although a substantial number of small businesses are impacted by this rule, because the economic impact is not significant, under 5 U.S.C. 605(b), I certify, as the FAA Administrator, that this rule will not have a significant economic impact on a substantial number of small entities.

Issued in Washington, DC, on July 7, 2011.

J. Randolph Babbitt,
Administrator, Federal Aviation Administration.

[FR Doc. 2011–17472 Filed 7–7–11; 4:15 pm]

BILLING CODE P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 748

[Docket No. 110413240–1255–02]

RIN 0694–AF23

Technical Amendment to the Authorization Validated End-User Regulations of the Export Administration Regulations

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: In this rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR), 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—to add a column that lists Federal Register citations for the respective entries. This rule does not make any substantive changes to Supplement No. 7 or elsewhere in the EAR.

DATES: This rule is effective July 12, 2011.

FOR FURTHER INFORMATION CONTACT: Karen Nies-Vogel, Chair, End-User Review Committee, Bureau of Industry and Security, U.S. Department of Commerce, 14th Street & Pennsylvania Avenue, NW., Washington, DC 20230; by telephone: (202) 482–5991, fax: (202) 482–3911, or e-mail: ERC@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

Background

Authorization Validated End-User (VEU)

BIS amended the EAR in a final rule on June 19, 2007 (72 FR 33646), creating a new authorization for “valified end-users” (VEUs) located in eligible destinations to which eligible items may be exported, reexported, or transferred (in-country) under a general authorization instead of a license, in conformance with section 748.15 of the EAR.

VEUs may obtain eligible items that are on the Commerce Control List, set forth in Supplement No. 1 to Part 774 of the EAR, without having to wait for their suppliers to obtain export licenses from BIS. Eligible items may include commodities, software, and technology, except those controlled for missile technology or crime control reasons.

The VEUs listed in Supplement No. 7 to Part 748 of the EAR were reviewed and approved by the U.S. Government in accordance with the provisions of section 748.15 and Supplement Nos. 8 and 9 to Part 748 of the EAR. The End-User Review Committee (ERC), composed of representatives from the Departments of State, Defense, Energy and Commerce, and other agencies, as appropriate, is responsible for administering the VEU program. A unanimous vote by the ERC is required to authorize VEU status for a candidate or to add eligible items to an existing authorization. Majority vote of the ERC is required to remove VEU authorization or to remove eligible items from an existing authorization.

In addition to U.S. exporters, Authorization VEU may be used in accordance with the provisions of the EAR by foreign reexporters and by persons transferring in-country, and it does not have an expiration date. VEUs are subject to regular reviews, based on information available to the United States government, to ensure that items shipped under Authorization VEU are used for civilian purposes. In addition, VEUs are subject to on-site reviews as warranted.

As of the date of this rule, pursuant to section 748.15(h) of the EAR, VEUs are only located in the PRC and India.

Amendment to Supplement No.7 to Part 748 of the EAR

In this final rule, BIS amends the EAR, 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 to add a column that lists Federal Register citations for the respective entries. This rule does not make any substantive changes to Supplement No.7 or elsewhere in the EAR.

The Federal Register citation that appears first for each VEU in the new column added to Supplement No. 7 indicates the initial date on which the authorization for that listed VEU and its respective list of approved “Eligible Items” and “Eligible Destinations” were published in the Federal Register and became effective. Subsequent citations indicate the dates on which amendments to a VEU’s authorization were published in the Federal Register and became effective.

Since August 21, 2001, the Export Administration Act has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp. p. 783 (2002)), as extended most recently by the Notice of August 16, 2010 (75 FR 50681, August 16, 2010), has continued the EAR in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provisions of law, no person is required to respond to nor 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 does not involve a collection of information, and, therefore, does not implicate requirements of the PRA.

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

4. The Department finds that there is good cause under 5 U.S.C. 553(b)(A) and (B) to waive the provisions of the Administrative Procedure Act (APA) requiring prior notice and the opportunity for public comment because they are unnecessary. This rule is procedural, which is exempted from the notice and comment requirements of the APA. This rule only adds a column to the existing Supplement No. 7 to Part 748 of the EAR for purposes of providing Federal Register citations for entries in the Supplement to the public. Because these revisions are not substantive changes, it is unnecessary to provide notice and opportunity for public comment. In addition, the 30-day delay in effectiveness required by 5 U.S.C. 553(d) is not applicable because this rule is not a substantive rule. 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 APA 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.

List of Subjects in 15 CFR Part 748

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

Accordingly, part 748 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

PART 748—[AMENDED]

1. The authority citation for 15 CFR part 748 continues to read as follows:


2. Supplement No. 7 to Part 748 is revised to read as follows:

<table>
<thead>
<tr>
<th>Country</th>
<th>Validated end-user</th>
<th>Eligible items (by ECCN)</th>
<th>Eligible destination</th>
<th>Federal Register citation</th>
</tr>
</thead>
<tbody>
<tr>
<td>China (People’s Republic of)</td>
<td>Advanced Micro Devices China, Inc.</td>
<td>3D002, 3D003, 3E001 (limited to “technology” for items classified under 3C002 and 3C004 and “technology” for use during the International Technology Roadmap for Semiconductors (ITRS) process for items classified under ECCNs 3B001 and 3B002), 3E002 (limited to “technology” for use during the ITRS process for items classified under ECCNs 3B001 and 3B002), 3E003.e (limited to the “development” and “production” of integrated circuits for commercial applications), 4D001, 4D002, 4D003 and 4E001 (limited to the “development” of products under ECCN 4A003), 2B006.b, 2B230, 2B350.g.3, 2B350.i, 3B001.b, 3B001.c, 3B001.d, 3B001.e, 3B001.f, 3C001, 3C002, 3D002 (limited to “software” specially designed for the “use” of stored program controlled items classified under ECCN 3B001), 3B001.b, 3B001.c, 3B001.d, 3B001.e, 3B001.f, 3C001, 3C002, 3D002 (limited to “software” specially designed for the “use” of stored program controlled items classified under ECCN 3B001), and 3E001 (limited to “technology” according to the General Technology Note for the “development” or “production” of items controlled by ECCN 3B001).</td>
<td>AMD Technologies (China) Co., Ltd., No. 88, Su Tong Road, Suzhou, China 215021. Advanced Micro Devices (Shanghai) Co., Ltd., Buildings 46, 47, 48 &amp; 49, River Front Harbor, Zhangjiang Hi-Tech Park, 1387 Zhangdong Rd., Pudong, Shanghai, 201203. AMD Technology Development (Beijing) Co., Ltd., 18F, North Building, Raycom Infotech, Park Tower C, No. 2 Science Institute South Rd., Zhong Guan Cun, Haidian District, Beijing, China 100190.</td>
<td>75 FR 25763, 5/10/10. 76 FR 2802, 1/18/11.</td>
</tr>
<tr>
<td></td>
<td>Applied Materials (China), Inc.</td>
<td>2B230, 2B350.g.3, 2B350.i, 3B001.b, 3B001.c, 3B001.d, 3B001.e, 3B001.f, 3C001, 3C002, 3D002 (limited to “software” specially designed for the “use” of stored program controlled items classified under ECCN 3B001), and 3E001 (limited to “technology” according to the General Technology Note for the “development” or “production” of items controlled by ECCN 3B001).</td>
<td>Applied Materials South East Asia Pte. Ltd.—Shanghai Depot c/o Shanghai Applied Materials Technical Service Center No. 2667 Zuchongzhi Road, Shanghai, China 201203. Applied Materials South Asia Pte. Ltd.—Beijing Depot c/o Beijing Applied Materials Technical Service Center No. 1 North Di Sheng Street, BDA Beijing, China 100176. Applied Materials South East Asia Pte. Ltd.—Wuxi Depot c/o Wuxi Optics Fuchang Logistics Co., Ltd. 1 Xi Qin Road, Wuxi Export Processing Zone Wuxi, Jiangsu, China 214028. Applied Materials (China), Inc.—Beijing Depot No. 2667, Zuchongzhi Road Shanghai, China 201203. Applied Materials South Asia Pte. Ltd.—Wuhan Depot c/o Wuhan Optics Valley Import &amp; Export Co., Ltd. No. 101 Guanggu Road East Lake High-Tech Development Zone Wuhan, Hubei, China 430074. Applied Materials (China), Inc.—Beijing Depot No. 1 North Di Sheng Street, BDA Beijing, China 100176. Applied Materials (Xi’an) Ltd. No. 28 Xin Xi Ave., Xi’an High Tech Park Export Processing Zone Xi’an, Shaanxi, China 710075.</td>
<td>72 FR 59164, 10/19/07. 74 FR 19382, 4/29/09. 75 FR 27185, 5/14/10.</td>
</tr>
</tbody>
</table>

AUTHORIZATION VALIDATED END-USER (VEU): LIST OF VALIDATED END-USERS, RESPECTIVE ITEMS ELIGIBLE FOR EXPORT, REEXPORT AND TRANSFER, AND ELIGIBLE DESTINATIONS
<table>
<thead>
<tr>
<th>Country</th>
<th>Validated end-user</th>
<th>Eligible items (by ECCN)</th>
<th>Eligible destination</th>
<th>Federal Register citation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boeing Tianjin Composites Co. Ltd.</td>
<td>1A002.a, 1B001.f, 1C010.b, 1C010.e, 1D001 (limited to “software” specially designed or modified for the “development”, “production” or “use” of equipment controlled by 1B001.f), 1E001 (limited to “technology” according to the General Technology Note for the “development” or “production” of items controlled by 1A002.a, 1B001.f, 1C010.b &amp; .e, and 2B001.a); 2B001.b.2 (limited to machine tools with accuracies no better than (i.e., less than) 13 microns); 2B001.e; 2D001 (limited to “software,” other than that controlled by 2D002, specially designed or modified for the “development”, “production” or “use” of equipment controlled by 2B001.b.2 and 2B001.e); 2D002 (limited to “software” for electronic devices, even when residing in an electronic device or system, enabling such devices or systems to function as a “numerical control” unit, capable of coordinating simultaneously more than 4 axes for “contouring control” controlled by 2B001.b.2 and 2B001.e).</td>
<td>Boeing Tianjin Composites Co. Ltd., No. 4–388 Heibei Road, Tanggu Tianjin, China.</td>
<td>72 FR 59164, 10/19/07, 74 FR 19382, 4/29/09.</td>
<td></td>
</tr>
<tr>
<td>CSMC Technologies Corporation.</td>
<td>1C350.c.3, 1C350.d.7, 2B230, 2B350.c, 2B350.d, 2B350.g, 3B001.a.1, 3B001.c.1, 3B001.e, 3B001.h (except for multilayer masks with a phase shift layer designed to produce “space qualified” semiconductor devices), 3C002.a, and 3C004.</td>
<td>CSMC Technologies Fab 1 Co., Ltd., 14 Liangxi Road, Wuxi, Jiangsu 214061, China. CSMC, Technologies Fab 2 Co., Ltd., Block 86, 87, Wuxi National Hi-New Tech Industrial Development Zone, Wuxi, Jiangsu 214061, China. Wuxi CR Semiconductor Wafers and Chips Co., Ltd., 14 Liangxi Road, Wuxi, Jiangsu 214061, China.</td>
<td>75 FR 2435, 1/15/10, 76 FR 2802, 1/18/11, 76 FR 37634, 6/28/11.</td>
<td></td>
</tr>
<tr>
<td>Grace Semiconductor Manufacturing Corporation.</td>
<td>1C350.c.3, 1C350.d.7, 2B230, 2B350.d, 2B350.g, 3B001.a.1, 3B001.c.1, 3B001.e, 3B001.h (limited to production technology for integrated circuits controlled by ECCNs 5A002 or 5A992 that have been successfully reviewed under the encryption review process specified in sections 740.17(b)(2) or 740.17(b)(3) and 742.15 of the EAR; Note also the guidance on cryptographic interfaces (OCI) in section 740.17(b) of the EAR).</td>
<td>1399 Zuchongzhi Road Zhangjiang Hi-Tech Park Shanghai, PR China 201203.</td>
<td>75 FR 2435, 1/15/10.</td>
<td></td>
</tr>
<tr>
<td>Hynix Semiconductor China Ltd.</td>
<td>3B001.a, 3B001.b, 3B001.c, 3B001.d, 3B001.e, and 3B001.f.</td>
<td>Hynix Semiconductor China Ltd. Lot K7/K7–1, Export Processing Zone Wuxi, Jiangsu, PR China. Hynix Semiconductor (Wuxi) Ltd., Lot K7/K7–1, Export Processing Zone, Wuxi, Jiangsu, PR, China.</td>
<td>75 FR 62462, 10/12/10.</td>
<td></td>
</tr>
<tr>
<td>Hynix Semiconductor (Wuxi) Ltd.</td>
<td>3B001.a, 3B001.b, 3B001.c, 3B001.d, 3B001.e, and 3B001.f.</td>
<td>Lam Research Shanghai Co., Ltd. (Shanghai WGQ Bonded Warehouse), No. 55, West Shang Feng Road, Tangzhen, Pudong New Area, Shanghai, China 201203. Lam Research Shanghai Co., Ltd., No. 1 Jilong Rd., Room 424–2, Waigaoqiao Free Trade Zone, Shanghai, China 200131. Lam Research International Sarl (Shanghai TSS), c/o HMG Logistic (Shanghai), Co., Ltd., No. 55, West Shang Feng Road, Tangzhen, Pudong New Area, Shanghai, China 201203. Lam Research Shanghai Co., Ltd., (Shanghai) Service Co., 1st Floor, Area C, Hua Hong Science &amp; Technology Park, 177 Bi Bo Road Zhangjiang Hi-Tech Park, Pudong, Shanghai, China 201203. Lam Research Shanghai Co., Ltd., No. 4–388 Heibei Road, Tanggu Tianjin, China.</td>
<td>75 FR 62462, 10/12/10, 75 FR 62462, 10/12/10.</td>
<td></td>
</tr>
<tr>
<td>Lam Research Corporation.</td>
<td>2B230, 2B350.c, 2B350.d, 2B350.g, 2B350.h, 3B001.c, 3B001.e (items controlled under 3B001.c and 3B001.e are limited to parts and components), 3D001, 3D002 (limited to “software” specially designed for the “use” of stored program controlled items classified under ECCN 3B001), and 3E001 (limited to “technology” according to the General Technology Note for the “development” of equipment controlled by ECCN 3B001).</td>
<td>Lam Research Shanghai Co., Ltd. (Beijing Branch), Room 322 Dadi Mansion, No. 18 Hongda Beilu Beijing Economic &amp; Technological Development Area, Beijing, China 100176. Lam Research (Shanghai) Service Co., 1st Floor, Area C, Hua Hong Science &amp; Technology Park, 177 Bi Bo Road Zhangjiang Hi-Tech Park, Pudong, Shanghai, China 201203. Lam Research Shanghai Co., Ltd., No. 1 Jilong Rd., Room 424–2, Waigaoqiao Free Trade Zone, Shanghai, China 200131. Lam Research International Sarl (Shanghai TSS), c/o HMG Logistic (Shanghai), Co., Ltd., No. 55, West Shang Feng Road, Tangzhen, Pudong New Area, Shanghai, China 201203. Lam Research Shanghai Co., Ltd., (Shanghai) Service Co., 1st Floor, Area C, Hua Hong Science &amp; Technology Park, 177 Bi Bo Road Zhangjiang Hi-Tech Park, Pudong, Shanghai, China 201203. Lam Research Shanghai Co., Ltd., (Shanghai) Service Co., 1st Floor, Area C, Hua Hong Science &amp; Technology Park, 177 Bi Bo Road Zhangjiang Hi-Tech Park, Pudong, Shanghai, China 201203.</td>
<td>75 FR 62462, 10/12/10.</td>
<td></td>
</tr>
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</table>
**Authorization Validated End-User (VEU): List of Validated End-Users, Respective Items Eligible for Export, Reexport and Transfer, and Eligible Destinations—Continued**

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</thead>
<tbody>
<tr>
<td></td>
<td>National Semiconductor Corporation.</td>
<td>3A001.a.5.a.1; 3A001.a.5.a.2; 3A001.a.5.a.3; 3A001.a.5.a.4; 3A001.a.5.a.5; 3A001.a.5.b.</td>
<td>Lam Research Co., Ltd. (Wuxi Representative Office), 5E, Bldg. C International Science &amp; Technology Park, #2 Taishan Road, WND, Wuxi, Jiangsu, China 214028. Lam Research International Sarl (Wuxi EPZ Bonded Warehouse) c/o HMG WHL Logistic (Wuxi) Co., Ltd., F1, Area 4, No. 1, Plot J3, No. 5 Gaolang East Road, Export Processing Zone, Wuxi, China 214028. Lam Research Co., Ltd. (Wuhan Representative Office), Room 1810, Guanggu International Building B, 456 Luoyu Road, East-Lake Hi-Tech Development Zone, Wuhan City, Hubei Province, China 430074. Lam Research International Sarl (Wuhan TSS), c/o HMG Wuhan Logistic Co., Ltd., 1st—2nd Floor, No. 5 Building, Hua Shi Yuan Er Road, Optical Valley Industry Park, East-Lake Hi-Tech Development Zone, Wuhan City, Hubei Province, China 430223. National Semiconductor Corporation. 3A001.a.5.a.1; 3A001.a.5.a.2; 3A001.a.5.a.3; 3A001.a.5.a.4; 3A001.a.5.a.5; 3A001.a.5.b.</td>
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<tr>
<td></td>
<td>Semiconductor Manufacturing International Corporation.</td>
<td>1C350.c.3; 1C350.d.7; 2B006.b.1; 2B230; 2B350.d.2; 2B350.g.3; 2B350.i.4; 3B001.a; 3B001.b; 3B001.c; 3B001.d; 3B001.e; 3B001.f; 3C001; 3C002; 3C004; 3B002; 5E002 (limited to “technology” according to the General Technology Note for the “production” of integrated circuits controlled by ECCN 5A002 that has been successfully reviewed under the encryption review process specified in §§740.17.b.2 or 740.17.b.3 and 742.15 of the EAR).</td>
<td>National Semiconductor Hong Kong Limited, Beijing Representative Office, Room 604, CN Resources Building, No. 8 Jianggumenbei A, Beijing, China 100005. National Semiconductor Hong Kong Limited, Shanghai Representative Office, Room 903–905 Central Plaza, No. 227 Huangpi Road North, Shanghai, China 200003. National Semiconductor Hong Kong Limited, Shenzhen Representative Office, Room 1709 Di Wang Commercial Centre, Shung Hing Square, 5002 Shenna Road East, Shenzhen, China 518008. Semiconductor Manufacturing International (Shanghai) Corporation, 18 Zhang Jiang Rd., Pudong New Area, Shanghai, China 201203. Semiconductor Manufacturing International (Tianjin) Corporation, 19 Xing Hua Avenue, Xi Qing Economic Development Area, Tianjin, China 100176. Semiconductor Manufacturing International (Beijing) Corporation, No. 18 Wen Chang Road, Beijing Economic-Technological Development Area, Beijing, China 100176. Semiconductor Manufacturing International (Chengdu) Corporation, Assembly and Testing (AT2) Facility, 8–8 Ke Xin Road, Export Processing Zone (West Area), Chengdu, China 611731. Headquarters and Fab. 1 of HHNEC, No. 1188 Chuan Qiao Rd., Pu Dong, Shanghai, China 201206. Fab. 2 of HHNEC, No. 668 Guo Shou Jing Rd., Zhang Jiang High Tech Park, Pu Dong, Shanghai, China 201203.</td>
</tr>
<tr>
<td>India</td>
<td>GE India</td>
<td>AIFACS Bldg., 1 Rafi Marg, New Delhi 110 001 India.</td>
<td>For GEITC: 1C002.a.1, 1C002.a.2, 1C002.b.1.a and 1C002.b.1.b, 1E001, 2E983, 9E003.a.1, 9E003.a.4, 9E003.a.5, 9E003.a.6, 9E003.a.8, and 9E003.c. For BEC: 1C002.a.1, 1C002.a.2, 1C002.b.1.a, 1C002.b.1.b, 1E001, 9E003.a.1, 9E003.a.2, 9E003.a.4, 9E003.a.5, 9E003.a.6, 9E003.a.8, and 9E003.c.</td>
</tr>
</tbody>
</table>
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520


Oral Dosage Form New Animal Drugs: Amprolium

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 an original abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group Ltd. The original ANADA provides for the use of amprolium soluble powder for the treatment of coccidiosis in chickens and turkeys.

DATES: This rule is effective July 12, 2011.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HV–170), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8197, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200–488 for the use of AMPROMED–P (amprolium) for poultry, a water-soluble powder used for the treatment of coccidiosis in chickens and turkeys. Cross Vetpharm Group Ltd.’s AMPROMED–P for Poultry is approved as a generic copy of Huvepharma AD’s AMPROL 128 (amprolium) 20% Soluble Powder, approved under NADA 33–165. The ANADA is approved as of May 23, 2011, and the regulations in 21 CFR 520.100 are amended to reflect the approval.

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.

FDA has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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:


2. In § 520.100, paragraph (b)(4) is revised to read as follows:

§ 520.100 Amprolium.

* * * * *

(b) * * *

(4) No. 061623 for use of product described in paragraph (a)(2) of this section as in paragraphs (d)(1) and (d)(2) of this section.

* * * * *

Dated: June 30, 2011.

Bernadette Dunham, Director, Center for Veterinary Medicine.

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2011–0507]

RIN 1625–AA00

Safety Zones; Fireworks Within the Sector Boston Captain of the Port Zone

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary safety zones within the Sector Boston Captain of the Port (COTP) Zone for various fireworks displays. These safety zones are necessary to provide for the safety of life on navigable waters during these fireworks events. Entering into, transiting through, mooring or anchoring within these zones is prohibited unless authorized by the COTP or the designated on-scene representative.

DATES: This rule is effective in the CFR on July 12, 2011 through 11:59 p.m. September 9, 2011. This rule is effective with actual notice for purposes of enforcement beginning at 8:30 p.m. June 27, 2011.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2011–0507 and are available online by going to http://www.regulations.gov, inserting USCG–2011–0507 in the “Keyword” box, and then clicking “Search.” They are 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 temporary rule, call or e-mail MST1 David Labadie of the Waterways Management Division, U.S. Coast Guard Sector Boston, telephone 617–223–3010, e-mail david.j.labadie@uscg.mil. If you have questions on viewing material related to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule. The safety zones listed in this rule are associated with annual fireworks events. The Coast Guard intends to make these safety zones permanent regulations and has submitted a NPRM for submission to the Federal Register requesting public