[FR Doc. 03–14586 Filed 6–9–03; 8:45 am]
BILLING CODE 4910–13–M

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 742, 745, and 774

[Docket No. 030523133–3133–01]

RIN 0694–AC70

Implementation of the Understandings Reached at the June 2002 Australia Group (AG) Plenary Meeting and the AG Intersessional Decision on Cross Flow Filtration Equipment—Chemical and Biological Weapons Controls in the Export Administration Regulations

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Industry and Security (BIS) is publishing this final rule to describe the understandings reached at the June 2002 plenary meeting of the Australia Group (AG) and to amend the Export Administration Regulations (EAR), as needed, to implement these AG understandings. This final rule amends the licensing policy provisions in the EAR that apply to exports and reexports of items on the AG control list by clarifying several factors that are among those used to evaluate license applications for these AG-listed items and by identifying additional factors not previously listed in the EAR. In addition, this rule clarifies the circumstances under which BIS would deny license applications to export or reexport these AG-listed items. All of these changes are intended to ensure that the EAR provisions that apply to AG-listed items are consistent with the ''Guidelines for Transfers of Sensitive Chemical or Biological Items,'' which were adopted at the June 2002 AG plenary meeting.

This rule also implements understandings reached at the June 2002 plenary meeting concerning AG controls on fermenters and toxins. The control threshold for AG-listed fermenters described on the Commerce Control List (CCL) is lowered from a capacity of 100 liters or greater to a capacity of 20 liters or greater. In addition, this rule adds eight new toxins to the list of AG-listed human and zoonotic pathogens and toxins described on the CCL.

In addition to the AG plenary meeting changes described above, this rule implements an AG intersessional decision concerning cross (tangential) flow filtration equipment.

The rule makes corrections in four CCL entries that contain AG-listed items. One entry, containing AG-listed genetic elements and genetically modified organisms, is amended to correct errors in the use of the terms ''organism'' and ''microorganism.'' Another entry, containing AG-listed chemical manufacturing facilities and equipment, is amended to clarify the scope of that entry's controls on certain valves containing nickel and nickel alloys and on agitators for use in reaction vessels or reactors. Two other CCL entries are amended to clarify the license requirements that apply to technology for the ''development'' or ''production'' of AG-listed valves containing nickel and nickel alloys. In addition, the rule amends the AG-based licensing provisions in the EAR to identify certain CCL entries that were inadvertently omitted when BIS amended these provisions on previous occasions.

Finally, this rule updates the list of countries that are currently States Parties to the Chemical Weapons Convention (CWC) by adding six countries that recently became States Parties: Andorra, Guatemala, Palau, Saint Vincent and the Grenadines, Samoa, and Thailand.

DATES: This rule is effective June 10, 2003.

ADDRESSES: Written comments should be sent to Willard Fisher, Regulatory Policy Division, Office of Exporter Services, Bureau of Industry and Security, Room 2705, 14th Street and Pennsylvania Avenue, NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Douglas Brown, Office of Chemical and Biological Controls and Treaty Compliance, Bureau of Industry and Security, Telephone: (202) 482–7900.

SUPPLEMENTARY INFORMATION:

Background

A. Revisions to the EAR Based on the June 2002 Plenary Meeting of the Australia Group

The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) to implement understandings reached at the annual plenary meeting of the Australia Group (AG) that was held in Paris on June 3–6, 2002. The Australia Group is a multilateral forum, consisting of 33 participating countries, that maintains export controls on a list of chemicals, biological agents, and related equipment and technology that could be used in a chemical or biological weapons program. The AG periodically reviews items on its control list to enhance the effectiveness of participating governments' national controls and to achieve greater harmonization among these controls.

This rule implements two understandings reached at the June 2002 plenary meeting concerning AG controls on fermenters and toxins. The control threshold for AG-listed fermenters, described in ECCN 2B352.b on the Commerce Control List (CCL), is lowered from a capacity (*i.e.*, volume) of 100 liters or greater to a capacity of 20 liters or greater. In addition, this rule adds the following eight toxins to the list of AG-listed toxins described in ECCN 1C351.d on the CCL: (1) abrin, (2) cholera toxin, (3) diacetoxyscirpenol toxin, (4) T–2 toxin, (5) HT–2 toxin, (6) modeccin toxin, (7) volkensin toxin, and (8) viscum album lectin 1 (viscumin). These AG-listed toxins, along with all other items controlled by ECCN 1C351, require a license for export or reexport to all destinations, worldwide.

This rule makes conforming changes to the List of Items Controlled in ECCN 1C991 by revising ECCN 1C991.d to include medical products containing any of the eight toxins that were added to ECCN 1C351.d by this rule. In addition, this rule revises the Related Definitions paragraph in the List of Items Controlled by ECCN 1C991 by adding the AG definition of ''vaccine,'' which was adopted at the June 2002 AG plenary meeting. For the purpose of ECCN 1C991, ''vaccine'' is defined as a medicinal (or veterinary) product in a pharmaceutical formulation, approved by the U.S. Food and Drug Administration or the U.S. Department of Agriculture to be marketed as a medical (or veterinary) product or for use in clinical trials, that is intended to stimulate a protective immunological response in humans or animals in order to prevent disease in those to whom or to which it is administered. ECCN 1C991.a is revised to conform with the AG definition of ''vaccine'' by clarifying the control language to indicate that 1C991.a controls vaccines against items controlled by ECCN 1C351, 1C352, 1C353, or 1C354.

This final rule also amends the EAR to ensure that the licensing policy provisions in the EAR that apply to AG-listed items are consistent with the ''Guidelines for Transfers of Sensitive Chemical or Biological Items,'' which were adopted by the AG at the June 2002 plenary meeting. Specifically, this rule amends section 742.2(b)(2) of the EAR by clarifying several factors that are among those used to evaluate license applications to export or reexport these AG-listed items and by identifying

additional factors not previously listed in the EAR. The additional licensing factors that are now identified in the EAR include: (1) The reliability of the parties to the transaction (including previous licensing history, information on any clandestine or illegal procurement activities, and the end-user's ability to securely handle and store the items to be exported); (2) relevant information about proliferation and terrorism activities (including those involving any parties to the transaction); (3) the risk of diversion of the items; and (4) the applicability of other multilateral export control or nonproliferation agreements (*e.g.*, the Chemical Weapons Convention and the Biological and Toxin Weapons Convention) to the transaction.

In addition, this rule clarifies the circumstances under which BIS would deny license applications to export or reexport AG-listed chemical and biological items. Specifically, this rule amends section 742.2(b)(1) of the EAR to show that where an export is intended to be used in a chemical weapons or biological weapons program, or for chemical or biological weapons terrorism purposes, it is deemed to make a material contribution to the design, development production, stockpiling, or use of chemical or biological weapons. Note that certain AG-listed chemicals also are controlled for Chemical Weapons Convention (CW) reasons and, therefore, are subject to the licensing requirements and policies described in section 742.18 of the EAR, as well as those in section 742.2 of the EAR.

B. Additional Understandings Reached at the June 2002 Plenary Meeting of the Australia Group That Conform With Existing Provisions in the EAR

Certain understandings reached at the June 2002 plenary meeting of the Australia Group (AG) do not require any regulatory action by the BIS, because they are adequately addressed by existing provisions in the EAR. These understandings are important because they represent a significant step by AG participating countries to further harmonize controls on AG-listed items and related technology.

Participating countries in the AG reached an understanding, at the June 2002 plenary meeting, to control transfers of technology for the ''development'' or ''production'' of AG-listed dual-use biological equipment. Since this technology currently is controlled by the EAR under ECCNs 2E001 and 2E002, this rule makes no changes in existing EAR controls on such technology.

The AG participating countries also agreed, for the first time, to establish AG controls on the intangible transfer of information and knowledge that could be used for chemical or biological weapons purposes. The transfer of such information and knowledge currently is defined in the EAR as ''technical assistance,'' which may take such forms as instruction, skills, training, working knowledge, and consulting services and may involve the transfer of ''technical data'' (''technical assistance'' is described in the note that follows the definition of ''technology'' in section 772.1 of the EAR). Since the EAR currently define ''technology'' (*e.g.*, technology for AG-listed items) to include ''technical data'' or ''technical assistance,'' this rule makes no changes in existing EAR controls that apply to the provision of ''technical assistance.''

Finally, the AG participating countries agreed to expand the license requirement for exports of AG-listed biological agents to apply to all destinations, with an exception for intra-European Union (EU) trade. In accordance with section 742.2(a)(1) of the EAR, these AG-listed biological agents currently are controlled under ECCNs 1C351, 1C352, 1C353, and 1C354 on the CCL and require a license, for CB (chemical/biological) reasons, to all of the destinations indicated under CB Column 1 in the Commerce Country Chart (Supplement No. 1 to part 738 of the EAR), *i.e.*, all destinations, worldwide. Since the EAR currently have a worldwide licensing requirement for these biological agents, this rule makes no changes in the existing EAR licensing provisions for these agents. In addition, please note that the EAR continue to require a license for reexports of U.S.-origin AG-listed biological agents to all destinations, including reexports among EU member countries.

C. Revisions to the EAR Based on an Intersessional Decision by the Australia Group

BIS is amending the EAR to implement an intersessional decision by the AG that was made prior to the June 2002 plenary meeting. Specifically, this rule revises AG controls on cross (tangential) flow filtration equipment by amending ECCN 2B352.d to lower the control threshold for such equipment from a total filtration area equal to or greater than 5 square meters (5 m^2) to a total filtration area equal to or greater than 1 square meter (1 m^2). In addition, this rule revises 2B352.d to indicate that the ECCN controls not only cross (tangential) flow filtration equipment capable of in-situ sterilization, but also such equipment capable of being disinfected in-situ. A technical note is added to 2B352.d to define the terms ''sterilized'' and ''disinfected'' and to demonstrate how the processes of ''disinfection'' and ''sterilization'' are distinct from the process of ''sanitization.'' This rule also adds a *nota bene* (*i.e.*, N.B.) to 2B352.d that excludes reverse osmosis equipment, as specified by the manufacturer, from control under this ECCN.

In addition, this rule amends 2B352.d to control cross (tangential) flow filtration components that: (1) have a filtration area equal to or greater than 0.2 square meters (0.2 m^2) for each component and (2) are designed for use with the cross (tangential) flow filtration equipment described in 2B352.d.

D. Corrections to ECCN 1C353 (Genetic Elements and Genetically Modified Organisms) and ECCN 2B350 (Chemical Manufacturing Facilities and Equipment).

This rule amends the heading and the List of Items Controlled in ECCN 1C353 to correct errors in the use of the terms ''organism'' and ''microorganism.'' The revisions to this ECCN that were made in a final rule published by BIS on May 31, 2002 (67 FR 37977) incorrectly used the term ''organisms'' in 1C353.a.1 and .b.1 when referring to ''microorganisms'' controlled by 1C351.a. to .c. In addition, that rule did not revise the heading of the ECCN to include the term genetically modified ''organisms.'' This rule corrects these errors.

In addition, this rule amends the heading in ECCN 2B350 to indicate that this entry does not control valves described in ECCN 2A292. BIS published a rule, on August 29, 2002 (67 FR 55594), that revised the heading of ECCN 2B350 to exclude valves controlled by ECCN 2A226; however, an exclusion for valves controlled by ECCN 2A292 was unintentionally omitted. This rule corrects that omission. Valves controlled by ECCN 2A226 or ECCN 2A292, which also meet or exceed the technical parameters described in ECCN 2B350.g, continue to be subject to CB controls (as well as NP and AT controls) even though they are not controlled under ECCN 2B350.

This rule also amends the List of Items Controlled in ECCN 2B350 to clarify that 2B350.b controls only those agitators that are for use in reaction vessels or reactors described in 2B350.a.

E. Corrections to § 742.2 (Proliferation of Chemical and Biological Weapons) and ECCNs 2E001 and 2E002

This rule revises § 742.2(a)(3) of the EAR, which identifies ECCNs

containing items that require a license to Country Group D:3 destinations for CB reasons, to include a reference to medical products controlled by ECCN 1C991.d. A reference to these medical products was inadvertently omitted in previous rulemakings. ECCN 1C991.d controls medical products containing biological toxins controlled by ECCN 1C351.d.2 through .d.19, except biological toxins controlled for CW reasons under 1C351.d.5 or .d.6.

This rule also revises § 742.2(a)(3) of the EAR and ECCNs 2E001 and 2E002 to clarify the control status of technology for valves described in ECCN 2A226 or 2A292 that also possess the characteristics of valves described in ECCN 2B350.g. The control status of the valves, themselves, was first clarified in a final rule published by BIS on August 29, 2002 (67 FR 55594) and is further clarified in this rule (*see* the changes to the heading of ECCN 2B350, as described in part D, Background, in the **SUPPLEMENTARY INFORMATION** section of this rule). First, this rule revises § 742.2(a)(3) to clarify that ''development'' and ''production'' technology for valves controlled by ECCN 2A226 or 2A292 for CB reasons (*i.e.*, valves in 2A226 or 2A292 that also possess the characteristics of valves described in ECCN 2B350.g) is controlled under ECCNs 2E001 (''development'' technology) and 2E002 (''production'' technology) and requires a license to Country Group D:3 destinations for CB reasons—note that this technology also requires a license to certain destinations for NP and AT reasons. *Second,* this rule revises § 742.2(a)(3) to indicate that ''use'' technology for valves controlled by ECCN 2A226 or 2A292 for CB reasons is controlled under ECCNs 2E201 and 2E290, respectively, and requires a license to Country Group D:3 destinations for CB reasons—note that this technology also requires a license to certain destinations for NP and AT reasons. *Third,* this rule revises the License Requirements sections of ECCNs 2E001 and 2E002 on the CCL to indicate that CB controls apply to technology in these ECCNs for the ''development'' or ''production,'' respectively, of valves controlled for CB reasons under ECCN 2A226 or 2A292.

F. Clarifications to ECCNs 1C351 and 1C991

This rule revises the heading of ECCN 1C351 to clarify that this entry controls certain zoonotic pathogens and toxins that are the causative organisms for a number of zoonoses (*i.e.*, diseases of animals that may be transmitted to humans under natural conditions). In addition, this rule revises ECCN 1C991.d to clarify that it does not control medical products containing botulinum toxins described in ECCN 1C351.d.1. Medical products containing 1C351.d.1 toxins are controlled by 1C991.c for anti-terrorism (AT) reasons only, while the medical products in 1C991.d are controlled for both CB and AT reasons.

G. Changes to the EAR Based on the Addition of New States Parties to the Chemical Weapons Convention (CWC)

This rule revises Supplement No. 2 to part 745 of the EAR (titled ''States Parties to the Convention on the Prohibition of the Development, Production, Stockpiling, and Use of Chemical Weapons and on Their Destruction'') by adding the names of six countries that have recently become States Parties to the CWC (*i.e.*, Andorra, Guatemala, Palau, Saint Vincent and the Grenadines, Samoa, and Thailand).

Savings Clause

Shipments of items removed from license exception eligibility or NLR authorization 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 June 10, 2003, pursuant to actual orders for export to a foreign destination, may proceed to that destination under the previous license exception eligibility or NLR authorization provisions so long as they have been exported from the United States before July 10, 2003. Any such items not actually exported before midnight, on July 10, 2003, require a license in accordance with this regulation.

Rulemaking Requirements

1. This 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, unless that collection of information displays a currently valid OMB Control Number. This rule contains collections of information subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). These collections have been approved by the Office of Management and Budget under Control Numbers 0694–0088 and 0694–0117.

3. This rule does not contain policies with Federalism implications as that term is defined in 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 (Sec. 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 5 U.S.C. 553 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 Willard Fisher, Regulatory Policy Division, Bureau of Industry and Security, U.S. Department of Commerce, Room 2705, 14th Street and Pennsylvania Avenue, NW., Washington, DC 20230.

List of Subjects

15 CFR Part 742

Exports, Foreign trade.

15 CFR Part 745

Administrative practice and procedure, Chemicals, Exports, Foreign trade, Reporting and recordkeeping requirements.

15 CFR Part 774

Exports, Foreign trade, Reporting and recordkeeping requirements.

■ Accordingly, parts 742, 745, and 774 of the Export Administration Regulations (15 CFR parts 730–799) are amended as follows:

PART 742—[AMENDED]

■ 1. The authority citation for 15 CFR part 742 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 18 U.S.C. 2510 *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. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; notice of November 9, 2001, 66 FR 56965, 3 CFR, 2001 Comp., p. 917; notice of August 14, 2002, 67 FR 53721, August 16, 2002.

■ 2. Section 742.2 is amended by revising paragraphs (a)(3) and (b) to read as follows:

§ 742.2 Proliferation of chemical and biological weapons.

(a) * * *

(3) If CB Column 3 of the Country Chart (Supplement No. 1 to part 738 of the EAR) is indicated in the appropriate ECCN, a license is required to Country Group D:3 (*see* Supplement No. 1 to part 740 of the EAR) for the following:

(i) Equipment and materials identified in ECCN 2B350 or 2B351 on the CCL, and valves controlled by ECCN 2A226 or ECCN 2A292 having the characteristics of those described in 2B350.g, which can be used in the production of chemical weapons precursors or chemical warfare agents;

(ii) Equipment and materials identified in ECCN 2B352, which can be used in the production of biological agents;

(iii) Medical products identified in ECCN 1C991.d;

(iv) Technology identified in ECCN 2E001, 2E002, or 2E301 for:

(A) The development, production, or use of items controlled by ECCN 2B350, 2B351, or 2B352; or

(B) The development or production of valves controlled by ECCN 2A226 or 2A292 having the characteristics of those described in ECCN 2B350.g; and

(v) Technology identified in ECCN 2E201 or 2E290 for the use of valves controlled by ECCN 2A226 or 2A292 having the characteristics of those described in 2B350.g.

* * * * *

(b) *Licensing policy.* (1) License applications for the items described in paragraph (a) of this section will be considered on a case-by-case basis to determine whether the export or reexport would make a material contribution to the design, development, production, stockpiling or use of chemical of biological weapons. When an export or reexport is deemed to make such a material contribution, the license will be denied. When an export or reexport is intended to be used in a chemical weapons or biological weapons program, or for chemical or biological weapons terrorism purposes, it is deemed to make a material contribution. The factors listed in paragraph (b)(2) of this section are among those that will be considered to determine what action should be taken on license applications for these items.

(2) The following factors are among those that will be considered to determine what action should be taken on license applications for the items described in paragraph (a) of this section:

(i) The specific nature of the end-use, including the appropriateness of the stated end-use;

(ii) The significance of the export and reexport in terms of its potential contribution to the design, development, production, stockpiling, or use of chemical or biological weapons;

(iii) The nonproliferation credentials of the importing country, including the importing country's chemical and biological capabilities and objectives;

(iv) The risk that the items will be diverted for use in a chemical weapons or biological weapons program, or for chemical weapons or biological weapons terrorism purposes;

(v) The reliability of the parties to the transaction, including whether:

(A) An export or reexport license application involving any such parties has previously been denied;

(B) Any such parties have been engaged in clandestine or illegal procurement activities;

(C) The end-user is capable of securely handling and storing the items to be exported or reexported;

(vi) Relevant information about proliferation and terrorism activities, including activities involving the design, development, production, stockpiling, or use of chemical or biological weapons by any parties to the transaction;

(vii) The types of assurances or guarantees against the design, development, production, stockpiling, or use of chemical or biological weapons that are given in a particular case, including any relevant assurances provided by the importing country or the end-user;

(viii) The applicability of other multilateral export control or nonproliferation agreements (*e.g.*, the Chemical Weapons Convention and the Biological and Toxin Weapons Convention) to the transaction; and

(ix) The existence of a pre-existing contract.

(3) BIS will review license applications in accordance with the licensing policy described in paragraph (b)(1) of this section for items not described in paragraph (a) of this section that:

(i) Require a license for reasons other than short supply; *and*

(ii) Could be destined for the design, development, production, stockpiling, or use of chemical or biological weapons, or for a facility engaged in such activities.

* * * * *

PART 745—[AMENDED]

■ 4. The authority citation for 15 CFR part 745 continues to read as follows:

Authority: 50 U.S.C. 1701 *et seq.*; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; notice of November 9, 2000, 65 FR 68063, 3 CFR, 2000 Comp., p. 408.

■ 5. Supplement No. 2 to part 745 is amended by revising the undesignated center heading ''List of States Parties as of May 1, 2002'' to read ''List of States Parties as of April 1, 2003'' and by adding, in alphabetical order, the countries ''Andorra'', ''Guatemala'', ''Palau'', ''Saint Vincent and the Grenadines'', ''Samoa'' and ''Thailand'.

PART 774—[AMENDED]

■ 6. The authority citation for 15 CFR 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); 18 U.S.C. 2510 *et seq.*; 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 14, 2002, 67 FR 53721, August 16, 2002.

■ 7. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1—Materials, Chemicals, ''Microorganisms'' & ''Toxins,'' ECCN 1C351 is amended by revising the heading of the ECCN and the List of Items Controlled to read as follows:

1C351 Human and zoonotic pathogens and ''toxins'', as follows (*see* **List of Items Controlled).**

* * * * *

List of Items Controlled

Unit: Value.

Related Controls: Certain forms of ricin and saxitoxin in 1C351.d.5. and d.6 are CWC Schedule 1 chemicals (*see* § 742.18 of the EAR). The U.S. Government must provide advance notification and annual reports to the OPCW of all exports of Schedule 1 chemicals. *see* § 745.1 of the EAR for notification procedures. *see* 22 CFR part 121, Category XIV and § 121.7 for additional CWC Schedule 1 chemicals controlled by the Department of State. All vaccines and ''immunotoxins'' are excluded from the scope of this entry. Certain medical products and diagnostic and food testing kits that contain biological toxins controlled under paragraph (d) of this entry, with the exception of toxins controlled for CW reasons under d.5 and d.6, are excluded

from the scope of this entry. Vaccines, ''immunotoxins'', certain medical products, and diagnostic and food testing kits excluded from the scope of this entry are controlled under ECCN 1C991. For the purposes of this entry, only saxitoxin is controlled under paragraph d.6; other members of the paralytic shellfish poison family (*e.g.* neosaxitoxin) are classified as EAR99.

Related Definitions: 1. For the purposes of this entry ''immunotoxin'' is defined as an antibody-toxin conjugate intended to destroy specific target cells (*e.g.*, tumor cells) that bear antigens homologous to the antibody. 2. For the purposes of this entry ''subunit'' is defined as a portion of the ''toxin''.

Items:

a. Viruses, as follows:
- a.1. Chikungunya virus;
- a.2. Congo-Crimean haemorrhagic fever virus;
- a.3. Dengue fever virus;
- a.4. Eastern equine encephalitis virus;
- a.5. Ebola virus;
- a.6. Hantaan virus;
- a.7. Japanese encephalitis virus;
- a.8. Junin virus;
- a.9. Lassa fever virus
- a.10. Lymphocytic choriomeningitis virus;
- a.11. Machupo virus;
- a.12. Marburg virus;
- a.13. Monkey pox virus;
- a.14. Rift Valley fever virus;
- a.15. Tick-borne encephalitis virus (Russian Spring-Summer encephalitis virus);
- a.16. Variola virus;
- a.17. Venezuelan equine encephalitis virus;
- a.18. Western equine encephalitis virus;
- a.19. White pox; or
- a.20. Yellow fever virus.

b. Rickettsiae, as follows:
- b.1. Bartonella quintana (Rochalimea quintana, Rickettsia quintana);
- b.2. Coxiella burnetii;
- b.3. Rickettsia prowasecki; or
- b.4. Rickettsia rickettsii.

c. Bacteria, as follows:
- c.1. Bacillus anthracis;
- c.2. Brucella abortus;
- c.3. Brucella melitensis;
- c.4. Brucella suis;
- c.5. Burkholderia mallei (Pseudomonas mallei);
- c.6. Burkholderia pseudomallei (Pseudomonas pseudomallei);
- c.7. Chlamydia psittaci;
- c.8. Clostridium botulinum;
- c.9. Francisella tularensis;
- c.10. Salmonella typhi;
- c.11. Shigella dysenteriae;
- c.12. Vibrio cholerae; or
- c.13. Yersinia pestis.

d. ''Toxins'', as follows, and ''subunits'' thereof:
- d.1. Botulinum toxins;
- d.2. Clostridium perfringens toxins;
- d.3. Conotoxin;
- d.4. Microcystin (Cyanginosin);
- d.5. Ricin;
- d.6. Saxitoxin;
- d.7. Shiga toxin;
- d.8. Staphylococcus aureus toxins;
- d.9. Tetrodotoxin;
- d.10. Verotoxin;
- d.11. Aflatoxins;
- d.12. Abrin;
- d.13. Cholera toxin;
- d.14. Diacetoxyscirpenol toxin;
- d.15. T–2 toxin;
- d.16. HT–2 toxin;
- d.17. Modeccin toxin;
- d.18. Volkensin toxin; or
- d.19. Viscum Album Lectin 1 (Viscumin).

8. In Supplement No. 1 to part 774 (the Commerce Control List), Category 1—Materials, Chemicals, ''Microorganisms'' & ''Toxins,'' ECCN 1C353 is amended by revising the ECCN heading and the List of Items Controlled to read as follows:

1C353 Genetic elements and genetically modified organisms, as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

Unit: $ value.

Related Controls: Vaccines that contain genetic elements or genetically modified organisms identified in this entry are controlled by ECCN 1C991.

Related Definitions: N/A.

Items:

a. Genetic elements, as follows:
- a.1. Genetic elements that contain nucleic acid sequences associated with the pathogenicity of microorganisms controlled by 1C351.a. to .c, 1C352, or 1C354;
- a.2. Genetic elements that contain nucleic acid sequences coding for any of the ''toxins'' controlled by 1C351.d or ''subunits of toxins'' thereof.

Technical Note: Genetic elements include, *inter alia*, chromosomes, genomes, plasmids, transposons, and vectors, whether genetically modified or unmodified.

b. Genetically modified organisms, as follows:
- b.1. Genetically modified organisms that contain nucleic acid sequences associated with the pathogenicity of microorganisms controlled by 1C351.a. to .c, 1C352, or 1C354;
- b.2. Genetically modified organisms that contain nucleic acid sequences coding for any of the ''toxins'' controlled by 1C351.d or ''subunits of toxins'' thereof.

■ 9. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1—Materials, Chemicals, ''Microorganisms'' & ''Toxins,'' ECCN 1C991 is amended by revising the List of Items Controlled to read as follows:

1C991 Vaccines, immunotoxins, medical products, diagnostic and food testing kits, as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

Unit: $ value.

Related Controls: Medical products containing ricin or saxitoxin, as follows, are controlled for CW reasons under ECCN 1C351:

(1) Ricinus Communis $Agglutinin_{II}$ (RCA_{II}), also known as ricin D, or Ricinus Communis $Lectin_{III}$ (RCL_{III});

(2) Ricinus Communis $Lectin_{IV}$ (RCL_{IV}), also known as ricin E; or

(3) Saxitoxin identified by C.A.S. #35523–89–8.

Related Definitions: For the purpose of this entry, ''*immunotoxin*'' is defined as an antibody-toxin conjugate intended to destroy specific target cells (*e.g.*, tumor cells) that bear antigens homologous to the antibody. For the purpose of this entry, ''*medical products*'' are: (1) pharmaceutical formulations designed for human administration in the treatment of medical conditions, (2) prepackaged for distribution as medical products, and (3) approved by the U.S. Food and Drug Administration to be marketed as medical products. For the purpose of this entry, ''*diagnostic and food testing kits*'' are specifically developed, packaged and marketed for diagnostic or public health purposes. Biological toxins in any other configuration, including bulk shipments, or for any other end-uses are controlled by ECCN 1C351. For the purpose of this entry, ''*vaccine*'' is defined as a medicinal (or veterinary) product in a pharmaceutical formulation, approved by the U.S. Food and Drug Administration or the U.S. Department of Agriculture to be marketed as a medical (or veterinary) product or for use in clinical trials, that is intended to stimulate a protective immunological response in humans or animals in order to prevent disease in those to whom or to which it is administered.

Items:

a. Vaccines against items controlled by ECCN 1C351, 1C352, 1C353, or 1C354;

b. Immunotoxins containing items controlled by 1C351.d;

c. Medical products containing botulinum toxins controlled by ECCN 1C351.d.1;

d. Medical products containing items controlled by ECCN 1C351.d, except

botulinum toxins controlled by ECCN 1C351.d.1 and items controlled for CW reasons under 1C351.d.5 or .d.6; *and*

e. Diagnostic and food testing kits containing items controlled by ECCN 1C351.d, except items controlled for CW reasons under ECCN 1C351.d.5 or .d.6.

10. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2—Materials Processing, ECCN 2B350 is amended by revising the ECCN heading and the List of Items Controlled to read as follows:

2B350 Chemical manufacturing facilities and equipment, except valves controlled by 2A226 or 2A292, as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

Unit: Equipment in number.

Related Controls: The controls in this entry do not apply to equipment that is: (a) Specially designed for use in civil applications (*e.g.*, food processing, pulp and paper processing, or water purification); AND (b) inappropriate, by the nature of its design, for use in storing, processing, producing or conducting and controlling the flow of chemical weapons precursors controlled by 1C350.

Related Definitions: For purposes of this entry the term ''chemical warfare agents'' are those agents subject to the export licensing authority of the U.S. Department of State, Office of Defense Trade Controls. (*See* 22 CFR part 121)

Items:

a. Reaction vessels or reactors, with or without agitators, with total internal (geometric) volume greater than 0.1 m^3 (100 liters) and less than 20 m^3 (20,000 liters), where all surfaces that come in direct contact with the chemical(s) being processed or contained are made from any of the following materials:
  a.1. Alloys with more than 25% nickel and 20% chromium by weight;
  a.2. Fluoropolymers;
  a.3. Glass (including vitrified or enameled coating or glass lining);
  a.4. Nickel or alloys with more than 40% nickel by weight;
  a.5. Tantalum or tantalum alloys;
  a.6. Titanium or titanium alloys; *or*
  a.7. Zirconium or zirconium alloys.

b. Agitators for use in reaction vessels or reactors described in 2B350.a, and impellers, blades or shafts designed for such agitators, where all surfaces that come in direct contact with the chemical(s) being processed or contained are made from any of the following materials:
  b.1. Alloys with more than 25% nickel and 20% chromium by weight;
  b.2. Fluoropolymers;
  b.3. Glass (including vitrified or enameled coatings or glass lining);
  b.4. Nickel or alloys with more than 40% nickel by weight;
  b.5. Tantalum or tantalum alloys;
  b.6. Titanium or titanium alloys; *or*
  b.7. Zirconium or zirconium alloys.

c. Storage tanks, containers or receivers with a total internal (geometric) volume greater than 0.1 m3 (100 liters) where all surfaces that come in direct contact with the chemical(s) being processed or contained are made from any of the following materials:
  c.1. Alloys with more than 25% nickel and 20% chromium by weight;
  c.2. Fluoropolymers;
  c.3. Glass (including vitrified or enameled coatings or glass lining);
  c.4. Nickel or alloys with more than 40% nickel by weight;
  c.5. Tantalum or tantalum alloys;
  c.6. Titanium or titanium alloys; *or*
  c.7. Zirconium or zirconium alloys.

d. Heat exchangers or condensers with a heat transfer surface area of less than 20 m^2, but greater than 0.15 m^2, and tubes, plates, coils or blocks (cores) designed for such heat exchangers or condensers, where all surfaces that come in direct contact with the chemical(s) being processed are made from any of the following materials:
  d.1. Alloys with more than 25% nickel and 20% chromium by weight;
  d.2. Fluoropolymers;
  d.3. Glass (including vitrified or enameled coatings or glass lining);
  d.4. Graphite or carbon-graphite;
  d.5. Nickel or alloys with more than 40% nickel by weight;
  d.6. Silicon carbide;
  d.7. Tantalum or tantalum alloys;
  d.8. Titanium or titanium alloys;
  d.9. Titanium carbide; *or*
  d.10. Zirconium or zirconium alloys.

e. Distillation or absorption columns of internal diameter greater than 0.1 m, and liquid distributors, vapor distributors or liquid collectors designed for such distillation or absorption columns, where all surfaces that come in direct contact with the chemical(s) being processed are made from any of the following materials:
  e.1. Alloys with more than 25% nickel and 20% chromium by weight;
  e.2. Fluoropolymers;
  e.3. Glass (including vitrified or enameled coatings or glass lining);
  e.4. Graphite or carbon-graphite;
  e.5. Nickel or alloys with more than 40% nickel by weight;
  e.6. Tantalum or tantalum alloys;
  e.7. Titanium or titanium alloys; *or*
  e.8. Zirconium or zirconium alloys.

f. Remotely operated filling equipment in which all surfaces that come in direct contact with the chemical(s) being processed are made from any of the following materials:
  f.1. Alloys with more than 25% nickel and 20% chromium by weight; *or*
  f.2. Nickel or alloys with more than 40% nickel by weight.

g. Valves with nominal sizes greater than 1.0 cm (3/8 in.), and casings (valve bodies) or preformed casing liners designed for such valves, in which all surfaces that come in direct contact with the chemical(s) being processed or contained are made from any of the following materials:
  g.1. Nickel or alloys with more than 40% nickel by weight;
  g.2. Alloys with more than 25% nickel and 20% chromium by weight;
  g.3. Fluoropolymers;
  g.4. Glass or glass lined (including vitrified or enameled coatings);
  g.5. Tantalum or tantalum alloys;
  g.6. Titanium or titanium alloys; *or*
  g.7. Zirconium or zirconium alloys.

h. Multi-walled piping incorporating a leak detection port, in which all surfaces that come in direct contact with the chemical(s) being processed or contained are made from any of the following materials:
  h.1. Alloys with more than 25% nickel and 20% chromium by weight;
  h.2. Fluoropolymers;
  h.3. Glass (including vitrified or enameled coatings or glass lining);
  h.4. Graphite or carbon-graphite;
  h.5. Nickel or alloys with more than 40% nickel by weight;
  h.6. Tantalum or tantalum alloys;
  h.7. Titanium or titanium alloys; *or*
  h.8. Zirconium or zirconium alloys.

i. Multiple-seal, canned drive, magnetic drive, bellows or diaphragm pumps, with manufacturer's specified maximum flow-rate greater than 0.6 m^3/hour, or vacuum pumps with manufacturer's specified maximum flow-rate greater than 5 m^3/hour (under standard temperature (273 K (0° C)) and pressure (101.3 kPa) conditions), and casings (pump bodies), preformed casing liners, impellers, rotors or jet pump nozzles designed for such pumps, in which all surfaces that come into direct contact with the chemical(s) being processed are made from any of the of the following materials:

i.1. Alloys with more than 25% nickel and 20% chromium by weight;
i.2. Ceramics;
i.3. Ferrosilicon;
i.4. Fluoropolymers;
i.5. Glass (including vitrified or enameled coatings or glass lining);
i.6. Graphite or carbon-graphite;
i.7. Nickel or alloys with more than 40% nickel by weight;
i.8. Tantalum or tantalum alloys;
i.9. Titanium or titanium alloys, *or*
i.10. Zirconium or zirconium alloys.

j. Incinerators designed to destroy chemical warfare agents, chemical weapons precursors controlled by 1C350, or chemical munitions having specially designed waste supply systems, special handling facilities and an average combustion chamber temperature greater than 1000° C in which all surfaces in the waste supply system that come into direct contact with the waste products are made from or lined with any of the following materials:
j.1. Alloys with more than 25% nickel and 20% chromium by weight;
j.2. Ceramics; *or*
j.3. Nickel or alloys with more than 40% nickel by weight.

Technical Note: Carbon-graphite is a composition consisting primarily of graphite and amorphous carbon, in which the graphite is 8 percent or more by weight of the composition.

■ 11. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2—Materials Processing, ECCN 2B352 is amended by revising the List of Items Controlled to read as follows:

2B352 Equipment capable of use in handling biological materials, as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

Unit: Equipment in number
Related Controls: N/A
Related Definitions: For purposes of this entry, isolators include flexible isolators, dry boxes, anaerobic chambers and glove boxes.
Items:

a. Complete containment facilities at P3 or P4 containment level.

Technical Note: P3 or P4 (BL3, BL4, L3, L4) containment levels are as specified in the WHO Laboratory Biosafety Manual (Geneva, 1983).

b. Fermenters capable of cultivation of pathogenic microorganisms, viruses, or for toxin production, without the propagation of aerosols, having a capacity equal to or greater than 20 liters.

Technical Note: Fermenters include bioreactors, chemostats, and continuous-flow systems.

c. Centrifugal separators capable of the continuous separation of pathogenic microorganisms, without the propagation of aerosols, and having all of the following characteristics:
c.1. One or more sealing joints within the steam containment area;
c.2. A flow rate greater than 100 liters per hour;
c.3. Components of polished stainless steel or titanium; *and*
c.4. Capable of in-situ steam sterilization in a closed state.

Technical Note: Centrifugal separators include decanters.

d. Cross (tangential) flow filtration equipment and accessories, as follows:
d.1. Cross (tangential) flow filtration equipment capable of separation of pathogenic microorganisms, viruses, toxins or cell cultures, without the propagation of aerosols, having all of the following characteristics:
d.1.a. A total filtration area equal to or greater than 1 square meter (1 m^2); *and*
d.1.b. Capable of being sterilized or disinfected in-situ.

N.B.: 2B352.d.1 does not control reverse osmosis equipment, as specified by the manufacturer.

d.2. Cross (tangential) flow filtration components (*e.g.*, modules, elements, cassettes, cartridges, units or plates) with filtration area equal to or greater than 0.2 square meters (0.2 m^2) for each component and designed for use in cross (tangential) flow filtration equipment controlled by 2B352.d.1.

Technical Note: In this ECCN, ''sterilized'' denotes the elimination of all viable microbes from the equipment through the use of either physical (*e.g.*, steam) or chemical agents. ''Disinfected'' denotes the destruction of potential microbial infectivity in the equipment through the use of chemical agents with a germicidal effect. ''Disinfection'' and ''sterilization'' are distinct from ''sanitization'', the latter referring to cleaning procedures designed to lower the microbial content of equipment without necessarily achieving elimination of all microbial infectivity or viability.

e. Steam sterilizable freeze-drying equipment with a condenser capacity of 10 kgs of ice or greater in 24 hours, but less than 1,000 kgs of ice in 24 hours.

f. Protective and containment equipment, as follows:
f.1. Protective full or half suits, or hoods dependant upon a tethered external air supply and operating under positive pressure;

Technical Note: This entry does not control suits designed to be worn with self-contained breathing apparatus.

f.2. Class III biological safety cabinets or isolators with similar performance standards, *e.g.*, flexible isolators, dry boxes, anaerobic chambers, glove boxes or laminar flow hoods (closed with vertical flow).

g. Chambers designed for aerosol challenge testing with microorganisms, viruses, or toxins and having a capacity of 1 m^3 or greater.

■ 12. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2—Materials Processing, ECCN 2E001 is amended by revising the License Requirements section to read as follows:

2E001 ''Technology according to the General Technology Note for the ''development'' of equipment or ''software'' controlled by 2A (except 2A991, 2A993, or 2A994), 2B (except 2B991, 2B993, 2B996, 2B997 or 2B998), or 2D (except 2D991, 2D992, or 2D994).

License Requirements

Reason for Control: NS, MT, NP, CB, AT

Control(s)	Country chart
NS applies to ''technology'' for items controlled by 2A001, 2B001 to 2B009, 2D001 or 2D002.	NS Column 1
MT applies to ''technology'' for items controlled by 2B004, 2B009, 2B018, 2B104, 2B105, 2B109, 2B116, 2B117, 2D001 or 2D101 for MT reasons.	MT Column 1
NP applies to ''technology'' for items controlled by 2A225, 2A226, 2B001, 2B004, 2B006, 2B007, 2B009, 2B104, 2B109, 2B116, 2B201, 2B204, 2B206, 2B207, 2B209, 2B225 to 2B232, 2D001, 2D002, 2D101, 2D201 or 2D202 for NP reasons.	NP Column 1
NP applies to ''technology'' for items controlled by 2A290 to 2A293, 2B290, or 2D290 for NP reasons.	NP Column 2
CB applies to ''technology'' for equipment controlled by 2B350 to 2B352 and for valves controlled by 2A226 or 2A292 having the characteristics of those controlled by 2B350.g.	CB Column 3

Control(s)	Country chart
AT applies to entire entry	AT Column 1

License Requirement Notes: *See* § 743.1 of the EAR for reporting requirements for exports under License Exceptions.

* * * * *

■ 13. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2—Materials Processing, ECCN 2E002 is amended by revising the License Requirements section to read as follows:

2E002 ''Technology'' according to the General Technology Note for the ''production'' of equipment controlled by 2A, (except 2A991, 2A993, or 2A994) or 2B (except 2B991, 2B993, 2B996, 2B997, or 2B998).

License Requirements

Reason for Control: NS, MT, NP, CB, AT

Control(s)	Country chart
NS applies to ''technology'' for equipment controlled by 2A001, 2B001 to 2B009.	NS Column 1
MT applies to ''technology'' for equipment controlled by 2B004, 2B009, 2B018, 2B104, 2B105, 2B109, 2B116 or 2B117 for MT reasons.	MT Column 1
NP applies to ''technology'' for equipment controlled by 2A225, 2A226, 2B001, 2B004, 2B006, 2B007, 2B009, 2B104, 2B109, 2B116, 2B201, 2B204, 2B206, 2B207, 2B209, 2B225 to 2B232 for NP reasons.	NP Column 1
NP applies to ''technology'' for equipment controlled by 2A290 to 2A293, 2B290 for NP reasons.	NP Column 2
CB applies to ''technology'' for equipment controlled by 2B350 to 2B352 and for valves controlled by 2A226 or 2A292 having the characteristics of those controlled by 2B350.g.	CB Column 3
AT applies to entire entry	AT Column 1

License Requirement Notes: *See* § 743.1 of the EAR for reporting requirements for exports under License Exceptions.

* * * * *

Dated: May 29, 2003.

James J. Jochum,

Assistant Secretary for Export Administration.

[FR Doc. 03–14602 Filed 6–9–03; 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; Pyrantel Pamoate Paste

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 abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group, Ltd. The ANADA provides for the oral use of pyrantel pamoate paste for the removal and control of certain internal parasites in horses and ponies.

DATES: This rule is effective June 10, 2003.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group, Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200–350 that provides for the use of EXODUS (pyrantel pamoate) Paste for the removal and control of certain internal parasites in horses and ponies. Cross Vetpharm Group Ltd.'s EXODUS Paste is approved as a generic copy of Pfizer, Inc.'s STRONGID (pyrantel pamoate) Paste approved under NADA 129–831. The ANADA is approved as of March 25, 2003, and the regulations are amended in 21 CFR 520.2044 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 Dockets Management Branch (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 determined under 21 CFR 25.33(a)(1) 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:

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

■ 2. Section 520.2044 is amended by adding paragraphs (a)(3) and (b)(3) to read as follows:

§ 520.2044 Pyrantel pamoate paste.

(a) * * *

(3) Each mL contains 171 mg pyrantel base (as pyrantel pamoate).

(b) * * *

(3) No. 061623 for use of product described in paragraph (a)(3) of this section.

* * * * *

Dated: May 27, 2003.

Steven F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03–14546 Filed 6–9–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable 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