TABLE 1.—FOLLOW-ON ACTIONS—Continued

If the P/N is—	And the Amend Block is marked with an "A"—	And the serial number is—	Then—
764711	Yes	0868–0889 ...	Prior to further flight, remove the RAT actuator and replace it with one which has been cleaned, tested and re- identified by its manufacturer.
764711	Yes	Other than 0868–0889.	Prior to further flight, reidentify the RAT actuator, in accordance with paragraph 2.G. of the Accomplishment Instructions of Hamilton Sundstrand/Arkwin Industries Service Bulletin ERPS08A–29–2, dated February 22, 2001.

Parts Installation

(d) *As of the effective date of this AD:* No person may install an Arkwin Industries RAT actuator having P/N 764711 on any Airbus Model A319, A320, or A321 airplane, unless it is in compliance with this AD.

Incorporation by Reference

(e) The actions shall be done in accordance with Airbus Service Bulletin A320–29–1098, Revision 02, dated February 20, 2003; and Hamilton Sundstrand/Arkwin Industries Service Bulletin ERPS08A–29–2, dated February 22, 2001; as applicable. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 1: The subject of this AD is addressed in French airworthiness directive 2001–236(B) R1, dated December 24, 2002.

Effective Date

(f) This amendment becomes effective on April 22, 2004.

Issued in Renton, Washington, on March 9, 2004.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–5848 Filed 3–17–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 745 and 774

[Docket No. 040220063–4063–01]

RIN 0694–AC96

Amendments to the Export Administration Regulations (EAR) Implementing the Understandings Reached at the June 2003 Australia Group (AG) Plenary Meeting and a Subsequent AG Intersessional Decision on Certain Animal Pathogens

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 2003 plenary meeting of the Australia Group (AG) and to amend the Export Administration Regulations (EAR), as needed, to implement these AG understandings. Specifically, this final rule amends the EAR by adding twelve new viruses and two new bacteria to the list of AG-controlled human and zoonotic pathogens and toxins described on the Commerce Control List (CCL).

This rule also amends the EAR to implement an AG intersessional decision, which was adopted after the June 2003 AG plenary meeting, by adding two viruses to the list of AG-controlled animal pathogens described on the CCL.

Finally, this rule updates the list of countries that are currently States Parties to the Chemical Weapons Convention (CWC) by adding nine countries that recently became States Parties: Afghanistan, Belize, Cape Verde, Kyrgyzstan, Libya, Sao Tome and Principe, Timor Leste, Tonga, and Tuvalu.

DATES: This rule is effective March 18, 2004.

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 Nonproliferation 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 2003 Plenary Meeting of the Australia Group

The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) to implement the understandings reached at the annual plenary meeting of the Australia Group (AG) that was held in Paris on June 2–5, 2003. 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.

The understandings reached at the June 2003 plenary meeting resulted in multiple additions to the list of biological agents controlled by the AG. This final rule implements these changes by amending the EAR to add twelve new viruses and two new bacteria to the list of AG-controlled human and zoonotic pathogens and toxins described in Export Control Classification Number (ECCN) 1C351 on the Commerce Control List (CCL) (Supplement No. 1 to Part 774 of the EAR).

Specifically, this rule adds the following twelve viruses to the list of AG-controlled viruses described in ECCN 1C351.a on the CCL: Kyasanur Forest virus, Louping ill virus, Murray Valley encephalitis virus, Omsk haemorrhagic fever virus, Oropouche

virus, Powassan virus, Rocio virus, St. Louis encephalitis virus, Hendra virus (Equine morbillivirus), South American haemorrhagic fever (Sabia, Flexal, Guanarito), Pulmonary and renal syndrome-haemorrhagic fever viruses (Seoul, Dobrava, Puumala, Sin Nombre), and Nipah virus. These AG-listed viruses, along with all other items controlled by ECCN 1C351, require a license for export or reexport to all destinations, worldwide.

In addition, this rule adds the following two bacteria to the list of AG-controlled bacteria in ECCN 1C351.c on the CCL: Clostridium perfringens, epsilon toxin producing types and Enterohaemorrhagic Escherichia coli, serotype O157 and other verotoxin producing serotypes. ECCN 1C351.c, as revised by this rule, does not control Clostridium perfringens strains other than epsilon toxin producing types, since the other strains can be used as positive control cultures for food testing and quality control.

In conjunction with the additions to the list of AG-controlled bacteria in ECCN 1C351.c, this rule amends the Technical Note following ECCN 1C353.a to clarify that ECCN 1C353 does not control nucleic acid sequences associated with the pathogenicity of enterohaemorrhagic Escherichia coli, serotype O157 and other verotoxin producing strains, except those nucleic acid sequences that contain coding for the verotoxin or its sub-units.

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

BIS also is amending the EAR to implement an AG intersessional decision on animal pathogens that was adopted after the June 2003 AG plenary meeting. Specifically, this rule adds the following two viruses to the list of AG-controlled animal pathogens described in ECCN 1C352 on the CCL: Lumpy skin disease virus and African horse sickness virus.

C. Revisions 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 nine countries that have recently become States Parties to the CWC (*i.e.*, Afghanistan, Belize, Cape Verde, Kyrgyzstan, Libya, Sao Tome and Principe, Timor Leste, Tonga, and Tuvalu).

Savings 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 March 18, 2004, 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 19, 2004. Any such items not actually exported before midnight, on April 19, 2004, 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 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 contains a collection of information subject to the requirements of the PRA. This collection has been approved by OMB under Control Number 0694–0088 (Multi-Purpose Application), which carries a burden hour estimate of 58 minutes to prepare and submit form BIS–748. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to David Rostker, Office of Management and Budget (OMB), by e-mail to *David_Rostker@omb.eop.gov*, or by fax to (202) 395–7285; and to the Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, PO Box 273, Washington, DC 20044.

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

PART 745—[AMENDED]

■ 1. 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.

■ 2. Supplement No. 2 to part 745 is amended by revising the undesignated center heading ''List of States Parties as of April 1, 2003'' to read ''List of States Parties as of March 1, 2004'' and by adding, in alphabetical order, the countries ''Afghanistan'', ''Belize'', ''Cape Verde'', ''Kyrgyzstan'', ''Libya'', ''Sao Tome and Principe'', ''Timor Leste (East Timor)'', ''Tonga'', and ''Tuvalu'.

PART 774—[AMENDED]

■ 3. 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 7, 2003, 68 FR 47833, August 11, 2003.

■ 4. In Supplement No. 1 to part 774 (the Commerce Control List), Category 1—Materials, Chemicals, ''Microorganisms'' & ''Toxins,'' ECCN 1C351 is amended by revising 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. Clostridium perfringens strains, other than the epsilon toxin-producing strains of Clostridium perfringens described in c.14, are excluded from the scope of this entry, since they may be used as positive control cultures for food testing and quality control.

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;

a.20. Yellow fever virus;

a.21. Kyasanur Forest virus;

a.22. Louping ill virus;

a.23. Murray Valley encephalitis virus;

a.24. Omsk haemorrhagic fever virus;

a.25. Oropouche virus;

a.26. Powassan virus;

a.27. Rocio virus;

a.28. St. Louis encephalitis virus;

a.29. Hendra virus (Equine morbillivirus);

a.30. South American haemorrhagic fever (Sabia, Flexal, Guanarito);

a.31. Pulmonary and renal syndrome-haemorrhagic fever viruses (Seoul, Dobrava, Puumala, Sin Nombre); or

a.32. Nipah 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;

c.13. Yersinia pestis;

c.14. Clostridium perfringens, epsilon toxin producing types; or

c.15. Enterohaemorrhagic Escherichia coli, serotype O157 and other verotoxin producing serotypes.

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).

5. In Supplement No. 1 to part 774 (the Commerce Control List), Category 1—Materials, Chemicals, ''Microorganisms'' & ''Toxins,'' ECCN 1C352 is amended by revising the List of Items Controlled to read as follows:

1C352 Animal pathogens, as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

Unit: $ value.

Related Controls: All vaccines are excluded from the scope of this entry. *See* ECCN 1C991.

Related Definitions: N/A.

Items:

a. *Viruses, as follows:*

a.1. African swine fever virus;

a.2. Avian influenza viruses that are:

a.2.a. Defined in EC Directive 92/40/EC (O.J. L.16 23.1.92 p. 19) as having high pathogenicity, as follows:

a.2.a.1. Type A viruses with an IVPI (intravenous pathogenicity index) in 6 week old chickens of greater than 1.2; or

a.2.a.2. Type A viruses H5 or H7 subtype for which nucleotide sequencing has demonstrated multiple basic amino acids at the cleavage site of haemagglutinin;

a.3. Bluetongue virus;

a.4. Foot and mouth disease virus;

a.5. Goat pox virus;

a.6. Porcine herpes virus (Aujeszky's disease);

a.7. Swine fever virus (Hog cholera virus);

a.8. Lyssa virus;

a.9. Newcastle disease virus;

a.10. Peste des petits ruminants virus;

a.11. Porcine enterovirus type 9 (swine vesicular disease virus);

a.12. Rinderpest virus;

a.13. Sheep pox virus;

a.14. Teschen disease virus;

a.15. Vesicular stomatitis virus;

a.16. Lumpy skin disease virus;

a.17. African horse sickness virus.

b. Bacteria, as follows:

b.1. Mycoplasma mycoides;

b.2. Reserved.

6. In Supplement No. 1 to part 774 (the Commerce Control List), Category 1—Materials, Chemicals, ''Microorganisms'' & ''Toxins,'' ECCN 1C353 is amended by revising 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: 1. Genetic elements include, inter alia, chromosomes, genomes, plasmids, transposons, and vectors, whether genetically modified or unmodified.

2. This ECCN does not control nucleic acid sequences associated with the pathogenicity of enterohaemorrhagic Escherichia coli, serotype O157 and other verotoxin producing strains, except those nucleic acid sequences that contain coding for the verotoxin or its sub-units.

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.

Dated: March 5, 2004.

Peter Lichtenbaum,

Assistant Secretary for Export Administration.

[FR Doc. 04–6111 Filed 3–17–04; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 203

[Docket No. 1992N–0297]

RIN 0905–AC81

Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of1992; Policies, Requirements, and Administrative Procedures; Delay of Effective Date; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of effective date; correction.

SUMMARY: On February 23, 2004 (69 FR 8105), FDA published a delay of the effective date of certain requirements in a final rule published in the **Federal Register** of December 3, 1999 (64 FR 67720). FDA is correcting typographical errors in the **SUMMARY** and **SUPPLEMENTARY INFORMATION** sections of the February 23, 2004, document.

FOR FURTHER INFORMATION CONTACT: Aileen H. Ciampa, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The **SUMMARY** and **SUPPLEMENTARY INFORMATION** sections of the document published on February 23, 2004 (69 FR 8105), are corrected as follows:

1. In the second paragraph of the **SUMMARY**, in the second from last sentence, the words ''Therefore, it is necessary to delay the effective date of §§ 203.3(u) and 203.50 (21 CFR 203.3(u) and 203.50) until December 1, 2007 * * *'' is corrected to read ''Therefore, it is necessary to delay the effective date of §§ 203.3(u) and 203.50 (21 CFR 203.3(u) and 203.50) until December 1, 2006 * * *''.

2. In the **SUPPLEMENTARY INFORMATION** section in the ninth paragraph, the last sentence is corrected to read as follows: ''The agency's decision to delay the effective date of §§ 203.3(u) and 203.50 was based, in part, on comments received on FDA's Counterfeit Drug Task Force's Interim Report (Docket 03N–0361).''

3. In the **SUPPLEMENTARY INFORMATION** section, in the tenth paragraph, the second from last sentence is corrected to read as follows: ''One comment suggested an interim solution of a ''one forward, one back'' pedigree for those drugs most likely to be counterfeited.''

4. In the **SUPPLEMENTARY INFORMATION** section, in the thirteenth paragraph, the first two sentences are corrected to read as follows: ''Although FDA is further delaying the effective date of §§ 203.3(u) and 203.50, the agency encourages wholesalers to provide pedigree information that documents the prior history of the product, particularly for those drugs most likely to be counterfeited, even when such a pedigree is not required by the act. The suggestion from the comments that there be a one-forward, one-back pedigree for those drugs most likely to be counterfeited until an electronic pedigree is uniformly adopted may have some merit.''

Dated: March 12, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

For the convenience of the reader, the text of the February 23, 2004, document as corrected, is reprinted as follows:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 203

[Docket No. 1992N–0297]

RIN 0905–AC81

Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Delay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of effective date.

SUMMARY: The Food and Drug Administration (FDA) is further delaying until December 1, 2006, the effective date of certain requirements of a final rule published in the **Federal Register** of December 3, 1999 (64 FR 67720). In the **Federal Register** of May 3, 2000 (65 FR 25639), the agency delayed until October 1, 2001, the effective date of certain requirements in the final rule relating to wholesale distribution of prescription drugs by distributors that are not authorized distributors of record, and distribution of blood derivatives by entities that meet the definition of a ''health care entity'' in the final rule. The agency further delayed the effective date of these requirements in three subsequent **Federal Register** notices. Most recently, in the **Federal Register** of January 31, 2003 (68 FR 4912), FDA delayed the effective date until April 1, 2004. This action further delays the effective date of these requirements until December 1, 2006. The final rule implements the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992 (PDA), and the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). The agency is taking this action to address concerns about the requirements in the final rule raised by affected parties.

As explained in the **SUPPLEMENTARY INFORMATION**section, FDA is working with stakeholders through its counterfeit drug initiative to facilitate widespread, voluntary adoption of track and trace technologies that