

Comments Invited

Although this action is in the form of a final rule and was not preceded by notice and opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 97-NM-31-AD." The postcard will be date stamped and returned to the commenter.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities

under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

97-11-08 Bombardier, Inc. (Formerly Canadair): Amendment 39-10037. Docket 97-NM-31-AD.

Applicability: All Model CL-415 series airplanes, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent loss of airplane controllability, or engine overspeed and consequent loss of engine power caused by the power levers being positioned below the flight idle stop while the airplane is in flight, accomplish the following:

(a) Within 30 days after the effective date of this AD, revise the Limitations Section of the FAA-approved Airplane Flight Manual (AFM) to include the following statements. This action may be accomplished by inserting a copy of this AD into the AFM.

"Positioning of power levers below the flight idle stop while the airplane is in flight is prohibited. Such positioning may lead to loss of airplane control or may result in an overspeed condition and consequent loss of engine power."

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, New York Aircraft Certification Office (ACO), FAA, Engine and Propeller Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, New York ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the New York ACO.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) This amendment becomes effective on June 6, 1997.

Issued in Renton, Washington, on May 16, 1997.

Darrell M. Pederson,

Acting Manager, Transport Airplane

Directorate, Aircraft Certification Service.

[FR Doc. 97-13465 Filed 5-21-97; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 530**

[Docket No. 97N-0172]

Extralabel Animal Drug Use; Fluoroquinolones and Glycopeptides; Order of Prohibition

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; order of prohibition.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order prohibiting the extralabel use of fluoroquinolones and glycopeptides. The agency is issuing this order because it believes that some extralabel uses of fluoroquinolones and glycopeptides in food-producing animals are capable of increasing the level of drug resistant zoonotic pathogens (pathogens that are infective to humans) in treated animals at the time of slaughter. FDA finds that some extralabel uses of fluoroquinolone and glycopeptide drugs in food-producing animals likely will cause an adverse event, which constitutes a finding under the Animal Medicinal

Drug Use Clarification Act of 1994 (the AMDUCA) that extralabel use of these drugs in food animals presents a risk to the public health. Therefore, the agency is issuing this order of prohibition.

DATES: The order of prohibition is effective August 20, 1997. Submit written comments by July 21, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Richard L. Arkin, Center for Veterinary Medicine (HFV-238), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. 301-594-1737.
SUPPLEMENTARY INFORMATION:

I. Background

On October 22, 1994, the President signed the AMDUCA into law (Pub. L. 103-396). The AMDUCA which amended the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*) to allow licensed veterinarians to prescribe extralabel uses of approved animal drugs and human drugs in animals. Section 2(a)(4)(D) of the AMDUCA (21 U.S.C. 360b(a)(4)(D)) provides that the agency may prohibit an extralabel drug use in animals if, after affording an opportunity for public comment, the agency finds that such use presents a risk to the public health.

In the **Federal Register** of November 7, 1996 (61 FR 57732), FDA published the implementing regulations for the AMDUCA. The regulations will be codified in part 530 (21 CFR part 530). Sections 530.21 and 530.25 describe the basis for issuing an order prohibiting an extralabel drug use in food-producing animals. The procedure to be followed in issuing an order of prohibition is set out in § 530.25. The list of drugs prohibited from extralabel use is set forth in § 530.41.

The AMDUCA requires that opportunity be given for public comment before a prohibition becomes effective. The regulation provides, at § 530.25, for a public comment period of not less than 60 days. It also provides that the order of prohibition will become effective 90 days after the date of publication, unless FDA revokes the order, modifies it or extends the period of public comment. The regulation also states that reasons for the prohibition will be specified.

In the November 7, 1996 final rule, FDA responded to comments from the public on the proposed rule to implement the AMDUCA (61 FR 25106, May 17, 1996) that expressed concerns about the implications of extralabel use

for the development and transfer of antimicrobial resistance. FDA's response to these comments noted that the agency believes that the selection of resistant human pathogens could be a basis for restricting extralabel drug use provided that the statutory standards for restriction can be met for particular drugs or classes of drugs (61 FR 57732 at 57736 and 57737). The agency is aware that an association between use of antimicrobial drugs and antimicrobial resistance has been documented (Refs. 1, 2, 3, 4, and 5). Antimicrobial resistant zoonotic enteric microorganisms can be transmitted to humans through consumption of animal products, and certain resistant microorganisms can be transmitted through contact with farm animals and through the environment.

In response to comments suggesting that the agency prohibit extralabel use of approved fluoroquinolones and glycopeptides in food-producing animals, the agency stated that it had decided to initiate the process specified by the AMDUCA to implement such prohibition (61 FR 57732 at 57737). The agency's Center for Veterinary Medicine (CVM) has, since the time it first approved a fluoroquinolone for use in food animals (August 1995), informally asked veterinarians to voluntarily refrain from extralabel use of these drugs in food animals. Veterinarians' professional associations have actively encouraged their members to refrain from indiscriminate extralabel use of fluoroquinolones.

FDA intends to prohibit by order the extralabel use of fluoroquinolones and glycopeptides in food-producing animals because, as discussed in sections II and III of this document, the agency has determined that use of these drugs other than for the approved label indications in food-producing animals meets the criteria for prohibition in the AMDUCA. These drugs are added to the list of drugs prohibited for extralabel use at § 530.41.

Sixty days from the date of this publication are provided for comment. The order will become effective 90 days from the date of this publication, unless the agency before that time revokes or modifies the order, or extends the period for public comment.

In passing the AMDUCA, Congress granted FDA broad authority to protect the public health by allowing the agency to restrict or prohibit extralabel uses. A prohibition may be based on a finding that an extralabel use "presents a risk to the public health," which FDA has defined in § 530.3(e) as "likely will cause an adverse event." The statutory scheme clearly establishes that prohibiting an extralabel use does not

jeopardize an underlying approval or the future approvability of the same active ingredient or class of drug. A total prohibition against extralabel use is an action by the agency which restricts use of the drug to conditions of use established through approval of a new animal drug application. A finding of "likely will cause an adverse event" is not a determination regarding the safety of the drug for its approved uses. That determination is made in the approval process, i.e., an approved drug has been determined to be safe for use under labeled conditions.

II. Fluoroquinolones

FDA has approved sarafloxacin and enrofloxacin, both of which are fluoroquinolones, for therapeutic use in poultry. The approvals, the first of which was granted in August 1995, are for sarafloxacin hydrochloride for use in drinking water and sarafloxacin and enrofloxacin injectable products. The agency had previously approved enrofloxacin for use in nonfood animals.

All of these approvals are conditioned on use under a veterinarian's supervision. This restriction for the food-producing animal approvals was established, among other reasons, to reduce the rate of emergence of sarafloxacin-resistant organisms. Public health concerns associated with potential increases in antimicrobial resistance were satisfactorily addressed in the poultry approvals by establishing conditions of use intended to minimize inappropriate use of the products and to minimize excretion of the drug and drug-resistant zoonotic pathogens into the environment. Essentially, the agency was assured that under the conditions of use stated in the approval, any increase in the level of resistant zoonotic pathogens present in the animals at time of slaughter would be insignificant. The sponsors agreed to provide baseline susceptibility information on target animal pathogens and to conduct ongoing monitoring of the target animal pathogens as a postmarketing surveillance program. Also, FDA implemented with the Centers for Disease Control and Prevention and the U.S. Department of Agriculture a national antibiotic resistance monitoring program in zoonotic enteric pathogens in order to detect emerging resistance to these pathogens and contain their development. Thus, the agency concluded that resistance development under the conditions of approval could be monitored and adequately contained.

Before granting the food animal approvals for fluoroquinolones, CVM

sought advice from its Veterinary Medicine Advisory Committee, and the Center for Drug Evaluation and Research's Anti-Infective Drugs Advisory Committee (the joint committee), in a joint meeting held May 11 and 12, 1994. The joint committee agreed that there is a need for fluoroquinolones in food animal medicine and did not object to the approval of fluoroquinolones for such use. However, the joint committee members generally supported restrictions on the use of the drugs in order to maximize benefits and minimize risks related to the development of resistant organisms. Use restrictions that were suggested included prohibiting extralabel use, as well as requiring a veterinarian's supervision and monitoring resistance levels.

The data and information presented to the joint committee, and otherwise available to the agency, support the agency's conclusion that some extralabel uses of fluoroquinolones in food animals meet the AMDUCA regulation's standard of "likely will cause an adverse event" (Ref. 6). Recent reports from the United Kingdom (U.K.) of the occurrence of human cases and epizootic spread of a multiple-drug resistant strain of *Salmonella typhimurium*, Definitive Type 104 (DT 104) are also of concern, (Refs. 7, 8, and 9). Epidemiological surveys have found an increase in the percentage of DT 104 isolates in the U.K. to be resistant to ciprofloxacin, a fluoroquinolone which is used for the treatment of invasive salmonellosis in humans including salmonellosis caused by DT 104. The spread of DT 104 in the U.K. from animals to man has been associated with exposure via food and direct contact is supported by data from the U.K. An association between veterinary use of enrofloxacin and the development of fluoroquinolone resistance in DT 104 has been suggested by several scientists (Ref. 7). Additionally, studies in the U.K. and Europe document the development of *Campylobacter* and *Salmonella* resistant to fluoroquinolones following introduction of fluoroquinolone use in both humans and food animals (Refs. 10, 11, 12, 13, 14, and 15).

Expert opinion expressed during the joint committee meeting and opinions in comments to the proposed AMDUCA implementing regulations support the view that increased selective pressure on bacteria resulting from some of the many potential extralabel uses of fluoroquinolones likely will lead to resistance development and to the maintenance of the resistance levels

until slaughter, thereby increasing the risk of transfer of resistant organisms to humans and the compromise of human therapy. The data and information necessary to determine, in particular situations, whether the resistance level at time of slaughter would be increased above normal as a result of extralabel use is not generally available to practicing veterinarians, who must make the extralabel use decisions. Thus, while the agency cannot know the effect of each and every potential extralabel use on the development of resistant pathogens and on their presence on or in animals at the time of slaughter, it can reasonably conclude, based on available information, that such development likely will occur, and that such resistant pathogens likely will be present at slaughter as a result of some extralabel uses. Because some extralabel uses likely would cause an adverse public health event, the agency is acting in the interest of the public health by prohibiting extralabel use of fluoroquinolones in food-producing animals. The agency is thereby restricting such drugs to conditions of use that are established through the new animal drug approval process.

As explained previously, this conclusion does not undermine the new animal drug approvals that have been granted for fluoroquinolones because the necessary assurances of safety to the public were provided for the approved conditions of use during the approval process.

The AMDUCA does not require the agency to prohibit an extralabel use when the use meets the statutory standard for prohibition. The act states that the agency "may" do so. The agency believes that this is an appropriate case for the use of the prohibition authority Congress provided. In addition to the reasons previously stated, the agency notes that fluoroquinolones are used extensively in human medicine to treat many infectious diseases, and they are the only antimicrobial agents that are effective for treatment of certain diseases. Also, extralabel use of fluoroquinolones in food-producing animals would interfere with CVM's ability to interpret the monitoring and surveillance data that will be obtained through the National Antimicrobial Susceptibility Monitoring Program (see 61 FR 57732 at 57736 and 57737) and the postapproval monitoring program for the approved fluoroquinolones. These data are critical because early detection of emerging resistance, identified through the monitoring program, will allow the agency to

contain any resistance that does occur, thereby limiting its spread.

III. Glycopeptides

One glycopeptide, vancomycin, is approved for use in human medicine. No glycopeptides are approved for animal use. Thus, as a practical matter, the agency's prohibition against extralabel use in animals of glycopeptides applies only to this one human drug product. However, the prohibition will apply to any future animal drug approvals of glycopeptides unless the circumstances at the time of such approval cause the agency to reevaluate any part of the prohibition.

A number of scientific organizations and individual experts who commented on the proposed AMDUCA regulations recommended that the agency prohibit extralabel use of glycopeptides (Ref. 16). Those comments are supported by the following data and information. Glycopeptide-resistant *Enterococci* have become a very serious concern in human medicine, because a lack of effective alternative drugs for treatment have resulted in increased morbidity and mortality (Ref. 4). Vancomycin is a major agent used for treating serious methicillin-resistant *Staphylococcus aureus* infections.

One study in the U.K. has shown that vancomycin resistant bacteria may be acquired from animals (Ref. 17). Another study, done in Denmark, has established a connection between feed use of avoparcin, a glycopeptide, and vancomycin-resistant *Enterococcus faecium* (*E. Faecium*) (Ref. 18). The resistant organisms were found in food products from both poultry and swine that had been fed avoparcin. Further, vancomycin-resistant *E. faecium* of the same type were found in both pigs and humans, leading the authors to conclude that vancomycin resistant *E. faecium* can be transmitted to humans through food.

The "adverse event" associated with extralabel use of glycopeptides in food-producing animals is therefore the same as that discussed earlier with regard to extralabel use of fluoroquinolones. The agency's basis for prohibiting extralabel uses in food-producing animals of glycopeptides is also the same as that for fluoroquinolones. That is, the extralabel use of glycopeptides in food-producing animals likely will lead to increased risk of transfer of resistant organisms to humans and compromise human therapy. Therefore, the agency is acting in the interest of the public health and prohibiting the extralabel use of glycopeptides in food-producing animals.

IV. References

The following information has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. *Report of the ASM Task Force on Antibiotic Resistance*, The American Society for Microbiology Public and Scientific Affairs Board, Washington, March 16, 1995.

2. Lederberg, J., R. E. Shope, and S. C. Oaks, eds., *Emerging Infections; Microbial Threats to Health in the United States*, Institute of Medicine Committee on Emerging Microbial Threats to Health, pp. 159–160, National Academy Press, 15, Washington, 1992.

3. Letter from Kenneth I. Berns and Gail Cassell, American Society of Microbiology, p. 1, to Dockets Management Branch (HFA–305), Food and Drug Administration, dated July 31, 1996.

4. U.S. Congress, Office of Technology Assessment, *Impacts of Antibiotic-Resistant Bacteria*, OTA–H–629 p. 72, U.S. Government Printing Office, Washington, DC, September 1995.

5. Piddock, L. J. V., “Does the Use of Antimicrobial Agents in 16 Veterinary Medicine and Animal Husbandry Select Antibiotic-Resistant Bacteria That Infect Man and Compromise Antimicrobial Chemotherapy?” *Journal of Antimicrobial Chemotherapy*, Vol. 38, pp. 1–3, 1996.

6. Joint Meeting of the Veterinary Medicine Advisory Committee and Anti-Infective Drugs Advisory Committee, Food and Drug Administration, Gaithersburg, MD, Associated Reporters of Washington, pp. 144–195 (transcript), Washington, May 12, 1994.

7. Threlfall, E. J., et al., “Increasing Spectrum of Resistance in Multiresistant *Salmonella typhimurium*,” *Lancet*, Vol. 327, pp. 1053–1054, 1996.

8. Threlfall, E. J., et al., “Epidemic in Cattle of *Salmonella Typhimurium* DT104 with Chromosomally Integrated Multiple Drug Resistance,” *Veterinary Record*, Vol. 134, p. 577, 1994.

9. Wall, P. G., et al., “A Case Control Study of Infection with an Epidemic Strain of Multi-resistant *Salmonella Typhimurium* DT104 in England and Wales,” *Communicable Disease Report*, Vol. 4, pp. R130–135, 1995.

10. Endtz, et al., “Quinolone Resistance in *Campylobacter* Isolated from Man and Poultry Following the Introduction of Fluoroquinolones in Veterinary Medicine,” *Journal of Antimicrobial Chemotherapy*, Vol. 27, pp. 199–208, 1991.

11. Endtz, H. P., et al., “Fluoroquinolone Resistance in *Campylobacter* Spp. Isolated from Human Stools and Poultry Products,” *Lancet*, Vol. 335, p. 787, 1990.

12. Piddock, L. J. V., et al., “Quinolone Resistance in *Salmonella* Spp: Veterinary Pointers,” *Lancet*, Vol. 336, p. 125, 1990.

13. Piddock, L. J. V., “Quinolone Resistance and *Campylobacter* Spp.” (review), *Journal of Antimicrobial Chemotherapy*, Vol. 36, pp. 891–898, 1995.

14. Griggs, D. J., et al., “Quinolone Resistance in Veterinary Isolates of

Salmonella,” *Journal of Antimicrobial Chemotherapy*, Vol. 33, pp. 1173–1189, 1994.

15. Velazquez, J. B., et al., “Incidence and Transmission of Antibiotic Resistance in *Campylobacter Jejuni* and *Campylobacter Coli*,” *Journal of Antimicrobial Chemotherapy*, Vol. 35, pp. 173–178, 1995.

16. Letter from William A. Craig, Professor of Medicine and Pharmaceutics, University of Wisconsin, to Dockets Management Branch (HFA–305), Food and Drug Administration, July 31, 1996.

17. Bates, J., J. Z. Jordens, and D. T. Griffiths, “Farm Animals as a Putative Reservoir for Vancomycin-resistant Enterococcal Infection in Man,” *Journal of Antimicrobial Chemotherapy*, Vol. 34, pp. 507–516, 1994.

18. “Report from the Danish Veterinary Laboratory: The Effect of Avoparcin Used as a Feed Additive on the Occurrence of Vancomycin Resistant *Enterococcus Faecium* in Pig and Poultry Production,” Danish Veterinary Laboratory, Copenhagen, July 1995.

V. Request for Comments

Interested persons may, on or before July 21, 1997, submit to the Dockets Management Branch (address above) written comments regarding this document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office between 9 a.m. and 4 p.m., Monday through Friday.

VI. Order of Prohibition

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under the authority delegated to the Commissioner of Food and Drugs, I hereby issue the following order under section 2(a)(4)(D) of the AMDUCA, Pub. L. 1–3–396 (21 U.S.C. 360b(a)(4)(D)) and §§ 530.21 and 530.25. FDA finds that some extralabel uses of fluoroquinolone and glycopeptide drugs in food-producing animals likely will cause an adverse event, which constitutes a finding under the AMDUCA that extralabel use of these drugs in food animals presents a risk to the public health. Therefore, fluoroquinolone and glycopeptide drugs are prohibited for extralabel use in food-producing animals.

List of Subjects in 21 CFR Part 530

Administrative practice and procedure, Advertising, Animal drugs, Animal feeds, Drugs, Labeling, Prescription drugs, Reporting and recordkeeping requirements.

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 530 is amended to read as follows:

PART 530—EXTRALABEL DRUG USE IN ANIMALS

1. The authority citation for 21 CFR part 530 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 501, 502, 503, 505, 507, 512, 701, and 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 357, 360b, 371, 379e).

2. Section 530.41 is revised to read as follows:

§ 530.41 Drugs prohibited for extralabel use in animals.

(a) The following drugs, families of drugs, and substances are prohibited for extralabel animal and human drug uses in food-producing animals.

- (1) Chloramphenicol;
- (2) Clenbuterol;
- (3) Diethylstilbestrol (DES);
- (4) Dimetridazole;
- (5) Iprnidazole;
- (6) Other nitroimidazoles;
- (7) Furazolidone (except for approved topical use);
- (8) Nitrofurazone (except for approved topical use);
- (9) Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxypridazine);
- (10) Fluoroquinolones; and
- (1) Glycopeptides.

(b) The following drugs, families of drugs, and substances are prohibited for extralabel animal and human drug uses in nonfood-producing animals: [Reserved.]

Dated: May 19, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–13677 Filed 5–20–97; 2:50 pm]

BILLING CODE 4160–01–F

ARMS CONTROL AND DISARMAMENT AGENCY

22 CFR Part 606

Standards of Ethical Conduct for Employees of the United States Arms Control and Disarmament Agency

AGENCY: Arms Control and Disarmament Agency.

ACTION: Final rule.

SUMMARY: The United States Arms Control and Disarmament Agency