## PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 178.3295 is amended in the table by revising the entry for ''Sodium 2,2′-methylenebis (4,6-di-*tert*-butylphenyl) phosphate'' to read as follows:

**§ 178.3295 Clarifying agents for polymers.**

* * * * *

| Substances | Limitations |
|---|---|
| * * * | * * * * |
| Sodium 2,2′-methylenebis (4,6-di-*tert*-butylphenyl) phosphate (CAS Reg. No. 85209–91–2). | For use only:<br>1. As a clarifying agent at a level not exceeding 0.30 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 3.1, or 3.2 (where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight percent of polymer units derived from polypropylene). The finished polymers contact foods only of types I, II, IV-B, VI-B, VII-B, and VIII as identified in Table 1 of § 176.170(c) of this chapter and limited to conditions of use B through H, described in Table 2 of § 176.170(c), or foods of all types, limited to conditions of use C through H described in Table 2 of § 176.170(c).<br>2. As a clarifying agent at a level not exceeding 0.10 percent by weight of polypropylene complying with § 177.1520(c) of this chapter, item 1.1. The finished polypropylene may be used in contact with foods of all types under conditions of use A through H described in Table 2 of § 176.170(c) of this chapter. |

Dated: September 26, 1996.

William K. Hubbard,

*Associate Commissioner for Policy Coordination.*

[FR Doc. 96–25258 Filed 10–2–96; 8:45 am]

**BILLING CODE 4160–01–F**

## 21 CFR Part 558

## New Animal Drugs for Use in Animal Feeds; Oxytetracycline Type A Medicated Articles

**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 a supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides revised labeling for Pfizer's pioneer, Type A, oxytetracycline-containing, medicated articles which brings the products into compliance with the findings of the National Academy of Sciences/National Research Council (NAS/NRC), Drug Efficacy Study Group's (DESI) effectiveness evaluation and subsequent FDA conclusions. In addition, the regulations are further amended to reflect approval, based on FDA's DESI ''me-too'' policy, of one original NADA each filed by Pfizer and PennField Oil Co. for Type A medicated articles that are copies of the Pfizer pioneer products.

**EFFECTIVE DATE:** October 3, 1996.

**FOR FURTHER INFORMATION CONTACT:** Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1623.

**SUPPLEMENTARY INFORMATION:** Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to its approved NADA 8–804 which covers the Type A medicated articles bearing the Terramycin® (oxytetracycline (OTC)) trade name on their labels. The articles contain OTC quaternary salt expressed in terms of an equivalent amount of OTC hydrochloride (HCl) (i.e., Terramycin® 10, 20, 50, 50D, 100, 100D, 100SS, and 200). Pfizer also filed original NADA 95–143 which covers the Type A medicated articles OXTC® 10, 30, 50, 50–S, 100, 100–S, 100MR, and 200. These articles contain OTC dihydrate base expressed in terms of an equivalent amount of OTC HCl. PennField Oil Co., 14040 Industrial Rd., Omaha, NE 68137, filed original NADA 138–938 which covers the Type A medicated articles Oxytetracycline 50, 100, and 100 MR (formulated for use in calf milk replacers or starter feeds). These articles also contain OTC quaternary salt expressed in terms of an equivalent amount of OTC HCl.

Pfizer Type A medicated articles covered by NADA 8–804 were the subject of a NAS/NRC DESI evaluation of effectiveness (DESI 8622V). The findings were published in the Federal Register of May 5, 1970 (35 FR 7089). NAS/NRC evaluated the articles as probably effective when used for the control and treatment of specific diseases of livestock (swine, cattle, sheep, rabbits, and mink) and poultry (broiler chickens, laying chickens, and turkeys), and concluded that use may result in faster gains and improved feed efficiency under appropriate conditions. NAS/NRC stated that:

1. Labels and package inserts require extensive revision. There is inadequate documentation of claims, excessive claims are made, and bold conclusions are reached in the absence of sufficient controlled experimental evidence.

2. Claims for growth promotion or stimulation are not allowed and claims for faster gains and/or feed efficiency should be stated as ''may result in faster gains and/or improved feed efficiency under appropriate conditions.''

3. Each disease claim should be properly qualified as ''appropriate for use in (name of disease) caused by pathogens sensitive to (name of drug) and if the disease cannot be so qualified the claim must be dropped.''

4. The label claims ''for prevention of'' or ''to prevent'' should be replaced with ''as an aid in the control of'' or ''to aid in the control of.''

5. The label claim pertaining to egg production and hatchability should be modified to read, ''May aid in maintaining egg production and

hatchability, under appropriate conditions, by controlling pathogenic organisms.''

6. The labels should carry a warning that treated animals under the conditions that prevail must actually consume sufficient medicated water, or medicated feed, to constitute a therapeutic dose. As a precaution, the labels should state what the desired oral dose is in terms of animal weight per day for each species to serve as a guide to effective use of the preparations in drinking water or feed.

7. The labels should declare the dosage for the treatment of individual animals in terms of the amount of drug which should be given per unit of animal weight.

The ''probably effective'' finding of NAS/NRC was subsequently reviewed by FDA, resulting in an upgrade to ''effective'' status for the control and treatment of bacterial diseases susceptible to OTC in poultry, cattle, swine, sheep, and bees. FDA also made the following conclusions:

1. The claims for hexamitiasis should be included under the susceptible host.

2. Appropriate claims regarding faster weight gains and improved feed efficiency should be stated as ''For increased rate of weight gain and improved feed efficiency (under appropriate conditions of use).''

Pfizer filed a supplement to NADA 8–804 that revised the labeling of its products to comply with the findings of the NAS/NRC review and FDA's conclusions concerning those findings. Pfizer's supplement to NADA 8–804 also provides for transfer to 8–804 of its proprietary claims previously approved, under NADA 38–439, for use of OTC in lobster, catfish, Pacific salmon, and salmonids. The supplemental NADA is approved as of March 14, 1996.

The Type A medicated articles covered by Pfizer's NADA 95–143 (containing OTC dihydrate base) and those covered by PennField's NADA 138–938 (containing OTC quaternary salt) have demonstrated comparability to Pfizer's pioneer products (NADA 8–804, Terramycin® Premixes containing OTC quaternary salt equivalent in activity to a concentration of OTC HCl declared in grams per pound of premix) which were subject to the NAS/NRC evaluation of May 5, 1970. Based on that comparability, original NADA's 95–143 and 138–938 are approved as of May 30, 1996, and March 15, 1996, respectively, under FDA's DESI ''me-too'' policy.

FDA has now completed the NAS/NRC DESI evaluation for OTC Type A articles. Accordingly, FDA is revising § 558.450 *Oxytetracycline* (21 CFR 558.450) to set out the NAS/NRC and FDA-approved conditions of use for OTC articles. FDA also has replaced the claims for OTC articles listed in § 558.15(g)(1) (21 CFR 558.15(g)(1)) with a cross-reference to § 558.450. This change makes the § 558.15(g)(1) reference to OTC Type A articles the same as that for chlortetracycline (CTC) which cross-refers to § 558.128 (21 CFR 558.128), the DESI-finalized claims for that product (see the Federal Register of July 9, 1996, 61 FR 35949).

The NAS/NRC DESI evaluation is concerned only with the drugs' effectiveness and safety to the treated animals. Nothing herein will constitute a bar to further proceedings with respect to questions of safety of the drugs or their metabolites in food products derived from treated animals.

Products that comply with the NAS/NRC findings and FDA's conclusions regarding those findings are eligible for copying under the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) (see the eighth in a series of policy letters issued to facilitate implementation of GADPTRA that published in the Federal Register of August 21, 1991 (56 FR 41561)). Accordingly, sponsors may now obtain approval of abbreviated new animal drug applications (ANADA's) for these OTC Type A medicated articles.

Also, the agency is revising § 558.515(d)(2) (21 CFR 558.515(d)(2)) to make the claim language for the robenidine/OTC combination consistent with the NAS/NRC DESI findings.

In the Federal Register of October 21, 1977 (42 FR 56264), the then Bureau of Veterinary Medicine issued a notice of opportunity for a hearing (NOOH) on a proposal to withdraw approval of certain NADA's listed in § 558.15, for most subtherapeutic uses of tetracycline (CTC and OTC) in animal feed. The NOOH was issued in response to scientific research suggesting that subtherapeutic use of such drugs has contributed to the pool of antibiotic-resistant pathogenic microorganisms in food animals. Furthermore, research indicated that the drug resistance could be transferred to pathogenic organisms in humans. The NOOH is still pending and approval of these supplements to finalize the DESI review process for OTC Type A medicated articles does not constitute a bar to subsequent action to withdraw approval on the grounds cited in the outstanding NOOH.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of these applications may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) and (c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii) and (c)(2)(F)(iii)), these approvals for food-producing animals do not qualify for marketing exclusivity because the original and supplemental applications do not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) and new human food safety studies (other than bioequivalence or residue studies) essential to the approvals and conducted or sponsored by the applicants.

The agency has carefully considered the potential environmental effects of approving supplemental NADA 8–804. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) that approval of original NADA's 95–143 and 138–938 is the type of action that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither environmental assessments nor environmental impact statements are required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

### § 558.15 [Amended]

2. Section 558.15 *Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals* is amended in the

table, in paragraph (g)(1) to read as follows:

a. In the entry for ''Pfizer, Inc., PennField Oil Co., VPO, Inc., and Purina Mills, Inc.'', by removing '', VPO, Inc., and Purina Mills, Inc.'';

b. Under the ''Species'' column of this entry, by removing ''Chickens and turkeys.'' and adding in its place ''Sec. 558.450.'';

c. All of the subentries for Pfizer, Inc., PennField Oil Co., represented by ''Do.'' are removed;

d. The ''Pfizer, Inc.'' entry for oxytetracycline for sheep, including the three subentries represented by ''Do.'' are removed;

e. The ''Pfizer, Inc.'' entry for oxytetracycline for chickens, including the first subentry represented by ''Do.'' is removed.

3. Section 558.450 is revised to read as follows:

**§ 558.450 Oxytetracycline.**

(a) *Approvals.* Type A medicated articles:

(1) 10, 20, 30, 50, 100, and 200 grams per pound to 000069 in § 510.600(c) of this chapter.

(2) 50 and 100 grams per pound to 053389 in § 510.600(c) of this chapter.

(b) *Special considerations.* (1) In accordance with § 558.5 labeling shall bear the statement: ''FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS.''

(2) The articles in paragraph (a)(1) of this section contain an amount of mono-alkyl ($C_8$–$C_{18}$) trimethylammonium oxytetracycline expressed in terms of an equivalent amount of oxytetracycline hydrochloride or an amount of oxytetracycline dihydrate base expressed in terms of an equivalent amount of oxytetracycline hydrochloride.

(3) The articles in paragraph (a)(2) of this section contain an amount of mono-alkyl ($C_8$–$C_{18}$) trimethylammonium oxytetracycline expressed in terms of an equivalent amount of oxytetracycline hydrochloride.

(c) *Related tolerances.* See § 556.500 of this chapter.

(d)(1) *Conditions of use.* It is used in feed as follows:

TABLE 1

| Oxytetracycline amount | Combination | Indications for use | Limitations | Sponsor |
|---|---|---|---|---|
| (i) 10 to 20 grams per ton (g/ton) | | Sheep; increased rate of weight gain and improved feed efficiency. | | 000069, 053389 |
| (ii) 10 to 50 g/ton | | 1. Chickens; increased rate of weight gain and improved feed efficiency. | Do not feed to chickens producing eggs for human consumption. | do |
| | | 2. Growing turkeys; increased rate of weight and improved feed efficiency. | Do not feed to turkeys producing eggs for human consumption. | do |
| | | 3. Swine; increased rate of weight and improved feed efficiency. | | do |
| (iii) 100 g/ton | | Turkeys; control of hexamitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline. | Feed continuously for 7 to 14 days (d); do not feed to turkeys producing eggs for human consumption. | do |
| (iv) 100 to 200 g/ton | | Chickens; control of infectious synovitis caused by *Mycoplasma synoviae*; control of fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline. | Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption; in low calcium feed, withdraw 3 d before slaughter. | do |
| | Nequinate 18.16 g/ton (0.002%) | Chickens; control of infectious synovitis caused by *M. synoviae*; control of fowl cholera caused by *P. multocida* susceptible to oxytetracycline; as an aid in the control of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti*, and *E. mivati.* | do | 000069 |
| (v) 200 g/ton | | Turkeys; control of infectious synovitis caused by *M. synoviae* susceptible to oxytetracycline. | Feed continuously for 7 to 14 d; withdraw 5 d before slaughter; do not feed to turkeys producing eggs for human consumption. | 000069, 053389 |
| (vi) 400 g/ton | | Chickens; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to oxytetracycline. | Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption; in low calcium feeds, withdraw 3 d before slaughter. | do |

TABLE 1—Continued

| Oxytetracycline amount | Combination | Indications for use | Limitations | Sponsor |
|---|---|---|---|---|
| | Monensin 90 to 110 g/ton | Chickens; control of CRD and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to oxytetracycline; and as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati*, and *E. maxima*. | do | 000069 |
| | Nequinate 18.16 g/ton (0.002%) | Chickens; control of CRD and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to oxytetracycline; as an aid in prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti*, and *E. mivati*. | do | do |
| (vii) 500 g/ton | | Chickens; reduction of mortality due to air sacculitis (air-sac-infection) caused by *E. coli* susceptible to oxytetracycline. | Feed continuously for 5 d; do not feed to chickens producing eggs for human consumption; withdraw 24 hours before slaughter; in low calcium feeds withdraw 3 d before slaughter. | 000069, 053389 |
| | Monensin 90 to 110 g/ton | Chickens; reduction of mortality due to air sacculitis (air-sac-infection) caused by *E. coli* susceptible to oxytetracycline; as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*. | do | 000069 |
| | Salinomycin 40 to 60 g/ton | Chickens; reduction of mortality due to air sacculitis (air-sac-infection) caused by *E. coli* susceptible to oxytetracycline; prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*. | do | 000069, 012799 |
| (viii) 0.05 to 0.1 milligram/pound (mg/lb) of body weight daily. | | Calves (up to 250 lb); for increased rate of weight gain and improved feed efficiency. | Feed continuously; in milk replacers or starter feed. | 000069, 053389 |
| (ix) 10 mg/lb of body weight daily. | | 1.Calves and beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida* susceptible to oxytetracycline. | Feed continuously for 7 to 14 d; in feed or milk replacers; withdraw 5 d before slaughter. | do |
| | | 2. Calves (up to 250 lb); treatment of bacterial enteritis caused by *E. coli* susceptible to oxytetracycline. | Feed continuously for 7 to 14 d; in milk replacers or starter feed; withdraw 5 d before slaughter. | do |
| | | 3. Sheep; treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline. | Feed continuously for 7 to 14 d; withdraw 5 d before slaughter. | do |

TABLE 1—Continued

| Oxytetracycline amount | Combination | Indications for use | Limitations | Sponsor |
|---|---|---|---|---|
| | | 4. Swine; treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* susceptible to oxytetracycline and treatment of bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline. | Feed continuously for 7 to 14 d; withdraw 5 d before slaughter. | do |
| | | 5. Breeding swine; control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline. | Feed continuously for not more than 14 d; withdraw 5 d before slaughter. | do |
| (x) 25 mg/lb of body weight | | Turkeys; control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to oxytetracycline. | Feed continuously for 7 to 14 d; withdraw 5 d before slaughter; do not feed to turkeys producing eggs for human consumption. | do |
| (xi) 25 mg/head/day | | Calves (250 to 400 lb); increased rate of weight gain and improved feed efficiency. | | do |
| (xii) 75 mg/head/day | | Growing cattle (over 400 lb); increased rate of weight gain; improved feed efficiency, and reduction of liver condemnation due to liver abscesses. | | do |
| (xiii) 0.5 to 2.0 g/head/day | | Cattle; prevention and treatment of the early stages of shipping fever complex. | Feed 3 to 5 d before and after arrival in feedlots. | do |
| (xiv) 200 mg/colony | | Honey bees; control of American foulbrood caused by *Bacillus larvae* and European foulbrood caused by *Streptococcus pluton* susceptible to oxytetracycline. | Remove at least 6 weeks prior to main honey flow. | do |

(2) It is used in fish feed as follows:

TABLE 2

| Oxytetracycline amount | Combination | Indications for use | Limitations | Sponsor |
|---|---|---|---|---|
| (i) 250 mg/kilogram of fish/d (11.35 g/100 lb of fish/d). | | Pacific salmon for marking of skeletal tissue. | For salmon not over 30 g body weight; administer as sole ration for 4 consecutive days in feed containing oxytetracycline hydrochloride or mono-alkyl ($C_8$–$C_{18}$) trimethyl ammonium oxytetracycline; fish not to be liberated for at least 7 d following the last administration of medicated feed. | 000069 |
| (ii) 2.5 to 3.75 g/100 lb of fish/d. | | 1. Salmonids; control of ulcer disease caused by *Hemophilus piscium*, furunculosis caused by *Aeromonas salmonicida*, bacterial hemorrhagic septicemia caused by *A. liquefaciens*, and pseudomonas disease. | Administer as mono-alkyl ($C_8$–$C_{18}$) trimethyl ammonium oxytetracycline in mixed ration for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of medicated feed; do not administer when water temperature is below 9 °C (48.2 °F). | 000069 |

TABLE 2—Continued

| Oxytetracycline amount | Combination | Indications for use | Limitations | Sponsor |
|---|---|---|---|---|
| | | 2. Catfish; control of bacterial hemorrhagic septicemia caused by *A. liquefaciens* and pseudomonas disease. | Administer as mono-alkyl ($C_8$–$C_{18}$) trimethyl ammonium oxytetracycline in mixed ration for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of medicated feed; do not administer when water temperature is below 16.7 °C (62 °F) | 000069 |
| (iii) 1 g/lb of medicated feed. | | Lobsters; control of gaffkemia caused by *Aerococcus viridans*. | Administer as sole ration for 5 consecutive days in feed containing monoalkyl ($C_8$–$C_{18}$) trimethyl ammonium oxytetracycline; withdraw medicated feed 30 d before harvesting lobsters. | 000069 |

(3) Oxytetracycline may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Robenidine hydrochloride in accordance with § 558.515.

(ii) Lasalocid as in § 558.311.

4. Section 558.515 is amended by revising paragraph (d)(2) to read as follows:

**§ 558.515 Robenidine hydrochloride.**

* * * * *

(d) * * *

(2) *For broiler chickens*—(i) *Amount per ton*. Robenidine hydrochloride, 30 grams (0.0033 percent) plus oxytetracycline, 400 grams.

(ii) *Indications for use*. As an aid in the prevention of coccidiosis caused by *Eimeria mivati, E. brunetti, E. tenella, E. acervulina, E. maxima, and E. necatrix*; control of CRD and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to oxytetracycline.

(iii) *Limitations*. Feed continuously for 7 to 14 days; do not feed to chickens producing eggs for human consumption; withdraw 5 days before slaughter; do not use in feeds containing bentonite; feed must be used within 50 days of manufacture; oxytetracycline as provided by No. 000069 of this chapter.

Dated: September 16, 1996.

Stephen F. Sundlof,

*Director, Center for Veterinary Medicine.*

[FR Doc. 96–25257 Filed 10–2–96; 8:45 am]

BILLING CODE 4160–01–F

## ARMS CONTROL AND DISARMAMENT AGENCY

### 22 CFR Part 603

### Privacy Act Policy and Procedures

**AGENCY:** Arms Control and Disarmament Agency.

**ACTION:** Final rule.

**SUMMARY:** The United States Arms Control and Disarmament Agency (ACDA) is revising and restating in their entirety its rules that govern the means by which individuals can examine and request correction of ACDA records containing personal information. Clarifying these rules will help the public interact better with ACDA and is part of ACDA's effort to update and streamline its regulations.

**EFFECTIVE DATE:** October 3, 1996.

**FOR FURTHER INFORMATION CONTACT:**

Frederick Smith, Jr., United States Arms Control and Disarmament Agency, Room 5635, 320 21st Street, NW., Washington, DC 20451, telephone (202) 647–3596.

**SUPPLEMENTARY INFORMATION:** On June 13, 1996, ACDA published a notice of proposed rulemaking (61 FR 30009–30012) with a 36-day comment period. No comments were received during the comment period. Accordingly, the rule is adopted as proposed.

List of Subjects in 22 CFR Part 603

Privacy Act.

Chapter VI of Title 22 of the Code of Federal Regulations is amended by revising part 603 to read as follows:

## PART 603—PRIVACY ACT POLICY AND PROCEDURES



Authority: 5 U.S.C. 552a; 22 U.S.C. 2581; and 31 U.S.C. 9701.

### § 603.1 Purpose and scope.

This part 603 contains the regulations of the U.S. Arms Control and Disarmament Agency implementing the provisions of the Privacy Act of 1974, 5 U.S.C. 552a. In addition to containing internal policies and procedures, these regulations set forth procedures whereby an individual can determine if a system of records maintained by the Agency contains records pertaining to the individual and can request disclosure and amendment of such records. These regulations also set forth the bases for denying amendment requests and the procedures for appealing such denials.

### § 603.2 Definitions.

As used in this part:

(a) *Act* means the Privacy Act of 1974, 5 U.S.C. 552a.

(b) *ACDA* and *Agency* mean the U.S. Arms Control and Disarmament Agency.

(c) *Privacy Act Officer* means the Agency official who receives and acts