On August 7, 1998, Congress passed WIA. Under WIA, which superseded the JTPA, Congress required the Secretary of Labor to develop and publish interim final regulations (IFR) to implement this transition no later than 180 days after WIA’s enactment date. See 20 U.S.C. 9276(c)(1). The Department published the WIA IFR on April 15, 1999. See 64 FR 18662. In that IFR, the Department explicitly provided for the phased transition of the JTPA programs to WIA, to be fully completed by July 1, 2000. See 64 FR 18662, 18663 (Apr. 15, 1999). The final rule implementing WIA was published on August 11, 2000. See 65 FR 49293 (Aug. 11, 2000).

Initially, although the JTPA authorizing legislation was repealed, the Department retained the JTPA regulations in the Code of Federal Regulations for grant closeout and auditing purposes. However, now that the JTPA programs have been transitioned to WIA for over a decade, the Department finds no reason to retain the JTPA regulations. Furthermore, the Department has previously removed several other JTPA regulatory provisions. Parts 629 and 630 were removed at 57 FR 62004 (Dec. 29, 1992). Part 635 was re-designated as 20 CFR part 1005 at 54 FR 39352 (Sept. 26, 1989), and the Department later removed part 1005 at 59 FR 26601 (May 1989). Those JTPA regulatory provisions that remain by removing Parts 626, 627, 628, 631, 632, 633, 634, 636, 637, and 638 as follows:

**PART 626—[REMOVED AND RESERVED]**

1. Remove and reserve part 626, consisting of §§ 626.1 through 626.5.

**PART 627—[REMOVED AND RESERVED]**

2. Remove and reserve part 627, consisting of §§ 627.100 through 627.906.

**PART 628—[REMOVED AND RESERVED]**

3. Remove and reserve part 628, consisting of §§ 628.100 through 628.804.

**PART 631—[REMOVED AND RESERVED]**

4. Remove and reserve part 631, consisting of §§ 631.1 through 631.87.

**PART 632—[REMOVED AND RESERVED]**

5. Remove and reserve part 632, consisting of §§ 632.1 through 632.263.

**PART 633—[REMOVED AND RESERVED]**

6. Remove and reserve part 633, consisting of §§ 633.102 through 633.322.

**PART 634—[REMOVED AND RESERVED]**

7. Remove and reserve part 634, consisting of §§ 634.1 through 634.5.

**PART 635—[REMOVED AND RESERVED]**

8. Remove and reserve part 635, consisting of §§ 635.1 through 635.11.
review of safety or effectiveness data, summaries of the basis of approval (FOI
Summaries) under the Freedom of
Information Act (FOIA). These public
documents may be seen in the Division
of Dockets Management (HFA–305),
Food and Drug Administration, 5630
Fishers Lane, Rm. 1061, Rockville, MD
20852, between 9 a.m. and 4 p.m.,
Monday through Friday. Persons with
access to the Internet may obtain these
documents at the Center for Veterinary
Medicine FOIA Electronic Reading
Room: http://www.fda.gov/AboutFDA/
CentersOffices/OfficeofFoods/CVM/
CVMFOIAElectronicReadingRoom/
default.htm.
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

<table>
<thead>
<tr>
<th>NADA/ ANADA</th>
<th>Sponsor</th>
<th>New animal drug product name</th>
<th>Action</th>
<th>21 CFR Section</th>
<th>FOIA summary</th>
<th>NEPA review</th>
</tr>
</thead>
<tbody>
<tr>
<td>141–344……..</td>
<td>Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201.</td>
<td>VERAFLOX (pradofloxacin) Oral Suspension for Cats.</td>
<td>Original approval for the treatment of skin infections (wounds and abscesses) in cats caused by susceptible strains of Pasteurella multocida, Staphylococcus canis, S. aureus, S. felis, and S. pseudintermedius.</td>
<td>520.1850</td>
<td>Yes</td>
<td>CE 1</td>
</tr>
<tr>
<td>141–346……..</td>
<td>Abbott Laboratories, Inc., North Chicago, IL 60064.</td>
<td>OROCAM (meloxicam) Transmucosal Oral Spray.</td>
<td>Original approval for the control of pain and inflammation associated with osteoarthritis in dogs.</td>
<td>529.1350</td>
<td>Yes</td>
<td>CE 1</td>
</tr>
<tr>
<td>141–068……..</td>
<td>Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201.</td>
<td>TYLOVET 100 (tylosin phosphate) and RUMENSIN (monensin) and MGA (melengestrone acetate) liquid and dry combination drug Type C medicated.</td>
<td>Original approval as a generic copy of NADA 138–870.</td>
<td>558.342</td>
<td>Yes</td>
<td>CE 1</td>
</tr>
<tr>
<td>200–534……..</td>
<td>Huvepharma AD, 5th Floor, 3A Nikolay Hailov St., 1113 Sofia, Bulgaria.</td>
<td>Yes CE 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 The Agency has determined under 21 CFR 25.33 that this action is categorically excluded (CE) from the requirement to submit an environmental assessment or an environmental impact statement because it is of a type that does not individually or cumulatively have a significant effect on the human environment.

List of Subjects

21 CFR Parts 520, 522, and 529
Animal drugs.

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 delegated to the Center for Veterinary Medicine, 21 CFR parts 520, 522, 529, and 558 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:


2. Add § 520.1860 to read as follows:

§ 520.1860 Pradofloxacin.

(a) Specifications. Each milliliter of suspension contains 25 milligrams (mg) pradofloxacin.
(b) Sponsor. See No. 000859 in § 510.600(c) of this chapter.

(c) Special considerations. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

(d) Conditions of use in cats—(1) Amount. Administer 3.4 mg/lb (7.5 mg/kg) body weight once daily for 7 consecutive days.

(2) Indications for use. For the treatment of skin infections (wounds and abscesses) in cats caused by susceptible strains of Pasteurella multocida, Streptococcus canis, Staphylococcus aureus, Staphylococcus felis, and Staphylococcus pseudintermedius.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 522 continues to read as follows:


4. In § 522.812, revise paragraph (e)(3)(ii) to read as follows:

§ 522.812 Enrofloxacin.

* * * * * * * *  
(e) No. 529.1350 to read as follows:

5. The authority citation for 21 CFR part 529 continues to read as follows:


6. Add § 529.1350 to read as follows:

§ 529.1350 Meloxicam.

(a) Specifications. Each milliliter of solution contains 5 milligrams (mg) meloxicam.
(b) Sponsor. See No. 000074 in § 510.600(c) of this chapter.
PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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


§558.342 [Amended]
8. In §558.342, in the table, in paragraph (e)(1)(xi), in the “Limitations” column, revise the last sentence to read “Monensin provided by No. 000986 and tylosin provided by Nos. 000986 and 016592 in §510.600(c) of this chapter.”; and in the “Sponsor” column, add “016592”.


Bernadette Dunham,
Director, Center for Veterinary Medicine.

[FR Doc. 2012–31397 Filed 12–28–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF STATE

22 CFR Parts 120 and 126

[Public Notice 8135]

RIN 1400–AD26

Amendment to the International Traffic in Arms Regulations: Afghanistan and Change to Policy on Prohibited Exports

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is amending the International Traffic in Arms Regulations (ITAR) to list Afghanistan as a major non-NATO ally, and to make available the use of two additional defense export license exemptions for proscribed destinations.

DATES: Effective Date: This rule is effective December 31, 2012.

FOR FURTHER INFORMATION CONTACT: Ms. Candace M. J. Goforth, Director, Office of Defense Trade Controls Policy, U.S. Department of State, telephone (202) 663–2792, or email DDTCResponseTeam@state.gov. ATTN: Regulatory Change, Afghanistan and 126.1.

SUPPLEMENTARY INFORMATION: On July 6, 2012, President Obama exercised his authority under section 517 of the Foreign Assistance Act of 1961 (FAA) to designate the Islamic Republic of Afghanistan as a major non-NATO ally (MNNA) for purposes of the FAA and the Arms Export Control Act. This final rule amends ITAR §120.32, which lists major non-NATO allies, to account for this designation. Section 126.1 is amended to except the exemptions at ITAR §§126.4 and 126.6 from the prohibitions therein and the text is further amended to clarify the requirements therein. Additionally, §126.1(g) is amended to clarify references to United Nations Security Council resolutions.

Regulatory Analysis and Notices

Administrative Procedure Act

The Department of State is of the opinion that controlling the import and export of defense articles and services is a foreign affairs function of the United States Government and that rules implementing this function are exempt from sections 553 (rulemaking) and 554 (adjudications) of the Administrative Procedure Act. Since the Department is of the opinion that this rule is exempt from 5 U.S.C. 553, it is the view of the Department that the provisions of section 553(d) do not apply to this rulemaking. Therefore, this rule is effective upon publication. The Department also finds that, given the national security issues surrounding U.S. policy towards Afghanistan, notice and public procedure on this rule would be impracticable, unnecessary, or contrary to the public interest; for the same reason, the rule will be effective immediately.

Regulatory Flexibility Act

Since the Department is of the opinion that this rule is exempt from the rulemaking provisions of 5 U.S.C. 553, it does not require analysis under the Regulatory Flexibility Act.

Unfunded Mandates Act of 1995

This rulemaking does not involve a mandate that will result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rulemaking has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996.

Executive Orders 12372 and 13132

This rulemaking 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 13132, it is determined that this rulemaking does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this rulemaking.

Executive Orders 12866 and 13563

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributed impacts, and equity). These Executive Orders stress the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated “significant regulatory actions,” although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, this rule has been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988

The Department of State has reviewed this rulemaking in light of sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13175

The Department of State has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not pre-empt tribal law. Accordingly, the requirement of Executive Order 13175 does not apply to this rulemaking.

Paperwork Reduction Act

This rule does not impose any new reporting or recordkeeping requirements