

Pl., Rockville, MD 20855, 240-276-8341, email: cindy.burnsteel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Novartis Animal Health U.S., Inc. (Novartis), 3200 Northline Ave., suite 300, Greensboro, NC 27408, has requested that FDA withdraw approval of those parts of NADA 139-472 for DENAGARD (tiamulin) Type A medicated article pertaining to the production indications for use of increased rate of weight gain and improved feed efficiency in swine. Novartis requested voluntary withdrawal of approval of these indications for use because the product is no longer marketed for these uses. Revised product labeling reflecting the withdrawal of these indications has been approved in a supplement to NADA 139-472.

Elsewhere in this issue of the **Federal Register**, FDA gave notice that the approval of those parts of NADA 139-472 pertaining to the production indications for use of increased rate of

weight gain and improved feed efficiency in swine is withdrawn, effective April 17, 2012. As provided for in the regulatory text of this document, the animal drug regulations are amended to reflect this withdrawal of approval.

With the withdrawal of approval of the production indications for tiamulin, the lowest concentration of the drug in feed now has a preslaughter withdrawal period. In accordance with 21 CFR 558.3(b)(1)(ii), tiamulin is now a Category II drug, and the table in 21 CFR 558.4(d) is revised to reflect that change. However, the maximum concentration of tiamulin in Type B feeds is not being increased from the current 3.5 grams per pound (g/lb) because there is an approved 5-g/lb Type A medicated article.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 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 Director of 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: 21 U.S.C. 360b, 371.

■ 2. In paragraph (d) of § 558.4, in the “Category I” table, remove the entry for “Tiamulin”; and in the “Category II” table, alphabetically add a new entry for “Tiamulin” to read as follows:

§ 558.4 Requirement of a medicated feed mill license.

* * * * *
(d) * * *

CATEGORY II

Drug	Assay limits percent ¹ Type A	Type B maximum (100x)	Assay limits percent ¹ Type B/C ²
Tiamulin	113.4 g/lb, 100-108 5 and 10 g/lb, 90-115	3.5 g/lb (0.8%)	90-115 70-130

¹ Percent of labeled amount.

² Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make Type C medicated feed.

* * * * *

§ 558.600 [Amended]

■ 3. In § 558.600, in the table, remove and reserve paragraph (e)(1)(i).

Dated: March 21, 2012.

Bernadette Dunham,
Director, Center for Veterinary Medicine.
[FR Doc. 2012-9196 Filed 4-16-12; 8:45 am]
BILLING CODE 4160-01-P

DEPARTMENT OF STATE

22 CFR Parts 120 and 123

RIN 1400-AC85

[Public Notice: 7846]

Amendment to the International Traffic in Arms Regulations: International Import Certificate BIS-645P/ATF-4522/DSP-53 and Administrative Changes

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is amending the International Traffic in Arms Regulations (ITAR) to remove reference to the International Import Certificate (Form BIS-645P/ATF-4522/DSP-53). This amendment ceases the Department’s practice of accepting DSP-53 submissions. Instead, the DSP-61 is to be used by importers when necessary. The Department also is making

administrative changes to other sections.

DATES: *Effective Date:* This rule is effective May 17, 2012.

FOR FURTHER INFORMATION CONTACT: Ms. Candace M. J. Goforth, Acting Director, Office of Defense Trade Controls Policy, Department of State, telephone (202) 663-2792, email DDTCResponseTeam@state.gov. ATTN: International Import Certificate, ITAR Section 123.4.

SUPPLEMENTARY INFORMATION: The Arms Export Control Act authorizes the President to control the import and export of defense articles. Executive Order 11958, as amended, delegated the authority to regulate permanent and temporary exports and temporary imports of defense articles to the Secretary of State, and delegated the authority to regulate permanent imports of defense articles to the Attorney

General. The International Import Certificate Form BIS-645P/ATF-4522/DSP-53 is identified as a form issued by the Department of Commerce's Bureau of Industry & Security (BIS); the Department of Justice's Bureau of Alcohol, Tobacco, Firearms and Explosives (BATFE); and the Department of State's Directorate of Defense Trade Controls (DDTC). It is meant to standardize procedures used to facilitate international trade.

DDTC receives a few hundred DSP-53 submissions a year, and typically they are submitted by persons claiming the temporary import licensing exemption available at § 123.4, but who need documentation of U.S. Government approval of the temporary import. The Department of State's DSP-61 (Application/License for Temporary Import of Unclassified Defense Articles) is the primary means by which the Department exercises its authority to control the temporary import of defense articles. Therefore, DDTC revises § 123.4 to implement its decision to no longer accept submissions of the International Import Certificate (DSP-53). For temporary imports of defense articles meeting the conditions of the exemption at § 123.4, but for which the foreign exporter requires documentation, the U.S. importer will be required to obtain a DSP-61. BATFE and BIS will continue to adjudicate International Import Certificate submissions for items under their jurisdiction. DDTC also revises § 123.3 to specify that a DSP-61 is accepted to support the use of a temporary import exemption but not in satisfaction of requirements for a permanent import. And § 120.28(b)(1) is amended to remove reference to the DSP-53.

Section 120.31 is amended to update the list of NATO countries by adding Albania and Croatia. Section 123.1(c)(4) is amended to replace reference to an obsolete form ("Department of Defense Form 1513") with reference to the proper documentation ("Letter of Offer and Acceptance"). Section 123.4(c)(1) is amended to provide a correct reference (§ 120.1(c) rather than § 120.1(b)). Section 123.4(c)(2) is amended to provide updated terminology ("Electronic Export Information" replaces "Shipper's Export Declaration"). Section 123.4(c)(3) is amended to provide updated terminology (proscribed "area" and "person," in addition to "proscribed country"). And § 123.25(b) is amended by removing the word "that" in the statement before the colon.

The Department of State's intention to discontinue accepting submissions of the DSP-53 was first published as a

proposed rule on July 14, 2011, soliciting public comment (76 FR 41438). The comment period ended August 29, 2011. Three parties filed comments. The Department's evaluation of the written comments and recommendations follows.

Three commenting parties noted that many foreign governments view the International Import Certificate as a means of providing not only certification by the U.S. Government of proposed imports, but also of providing end-use assurances in a manner similar to the Department's form DSP-83 (Nontransfer and Use Certificate). Similarly, one commenting party suggested the Department should provide U.S. exporters with an explanatory notice that can be presented to foreign officials that request an International Import Certificate subsequent to this rulemaking. The intent of the International Import Certificate is not to provide end-use assurances; it is intended to provide U.S. government acknowledgment of a proposed import. For items under their import jurisdiction, BIS and BATFE will continue to adjudicate International Import Certificate submissions, and therefore will continue to provide applicants documentation regarding U.S. government acknowledgment of proposed imports. For items under Department of State import jurisdiction, an approved DSP-61 serves as U.S. government acknowledgment and approval of a proposed temporary import.

Three commenting parties expressed concern that the Department's proposal to cease issuing International Import Certificates could inadvertently disrupt international trade. Two of the commenting parties recommended the Department coordinate with the international community to ensure alternative means of assurances are acceptable. The Department accepts this recommendation and notes that it has previously expressed the intent to discontinue the DSP-53 with the international community at various international conferences and at the Wassenaar Arrangement. In these forums, no concerns were expressed to the Department.

One commenting party stated that the requirement to obtain a DSP-61, if documentation is required by a foreign exporter, will lead to cumbersome and unnecessary licensing reviews. The Department acknowledges that in a relatively small number of cases, license review will occur when with use of the DSP-53 it would have been avoided. The Department notes that the DSP-61 is the appropriate means by which a

person may obtain documentation of U.S. Government approval for the temporary import of defense articles otherwise eligible for the license exemption at ITAR § 123.4.

One commenting party requested guidance on the means by which it can fulfill a foreign exporter's requirement for documentation of U.S. Government authorization for the permanent import of defense articles not listed on the U.S. Munitions Import List ("USMIL," a subset of the USML). BATFE has jurisdiction over the permanent import of defense articles, even when those defense articles are not listed on the USMIL. Therefore, an International Import Certificate may be submitted to BATFE in such instances.

One commenting party recommended the removal of reference in the final rule to the form DSP-85 (Application/License for Permanent/Temporary Export or Temporary Import of Classified Defense Articles and Related Classified Technical Data), noting § 123.4 applies only to unclassified articles and that the ITAR is already clear that temporary imports of classified defense articles require use of the DSP-85. The Department accepted this recommendation.

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 § 553 (Rulemaking) and § 554 (Adjudications) of the Administrative Procedure Act. Although the Department is of the opinion that this rule is exempt from the rulemaking provisions of the APA, the Department published this rule with a 45-day provision for public comment and without prejudice to its determination that controlling the import and export of defense services is a foreign affairs function.

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 Reform Act of 1995

This amendment 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.

Executive Order 13175

The Department has determined that this rule will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not preempt tribal law. Accordingly, Executive Order 13175 does not apply to this rule.

Small Business Regulatory Enforcement Fairness Act of 1996

This amendment 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 amendment 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 amendment 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 amendment.

Executive Order 12866

The Department 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 governing the conduct of this function are exempt from the requirements of Executive Order 12866. However, the Department has reviewed this rule to ensure its consistency with the regulatory philosophy and principles set forth in the Executive Order.

Executive Order 13563

The Department of State has considered this rule in light of Executive Order 13563, dated January 18, 2011, and affirms that this regulation is consistent with the guidance therein.

Executive Order 12988

The Department of State has reviewed this amendment 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.

Paperwork Reduction Act

By this rulemaking, the Department of State will discontinue accepting one form (DSP-53) for the certification of a proposed temporary import of defense articles, and require the submission of another form (DSP-61) when there is the requirement for documentation of U.S. Government approval of the temporary import of defense articles that otherwise would be eligible for an available license exemption. Therefore, while in a limited number of instances this rule will result in different reporting and recordkeeping requirements, it does not impose any new reporting or recordkeeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. chapter 35.

List of Subjects in 22 CFR Parts 120 and 123

Arms and munitions, Exports.

Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, parts 120 and 123 are amended as follows:

PART 120—PURPOSE AND DEFINITIONS

■ 1. The authority citation for part 120 continues to read as follows:

Authority: Secs. 2, 38, and 71, Pub. L. 90-629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); 22 U.S.C. 2794; E.O. 11958, 42 FR 4311; E.O. 13284, 68 FR 4075; 3 CFR, 1977 Comp. p. 79; 22 U.S.C. 2651a; Pub. L. 105-261, 112 Stat. 1920.

■ 2. Section 120.28 is amended by revising paragraph (b)(1), redesignating paragraph (b)(3) as paragraph (c), and revising newly redesignated paragraph (c) as follows:

§ 120.28 Listing of forms referred to in this subchapter.

* * * * *

(b) Department of Commerce, Bureau of Industry and Security:

(1) International Import Certificate (Form BIS-645P/ATF-4522).

* * * * *

(c) Department of Defense, Defense Security Cooperation Agency: Letter of Offer and Acceptance.

■ 3. Section 120.31 is amended by revising it to read as follows:

§ 120.31 North Atlantic Treaty Organization.

North Atlantic Treaty Organization (NATO) is comprised of the following member countries: Albania, Belgium, Bulgaria, Canada, Croatia, Czech Republic, Denmark, Estonia, France,

Germany, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Luxembourg, The Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Turkey, United Kingdom, and the United States.

PART 123—LICENSES FOR THE EXPORT OF DEFENSE ARTICLES

■ 4. The authority citation for part 123 continues to read as follows:

Authority: Secs. 2, 38, and 71, Pub. L. 90-629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); 22 U.S.C. 2753; E.O. 11958, 42 FR 4311; 3 CFR, 1977 Comp. p. 79; 22 U.S.C. 2651a; 22 U.S.C. 2776; Pub. L. 105-261, 112 Stat. 1920; Sec. 1205(a), Pub. L. 107-228.

■ 5. Section 123.1 is amended by revising paragraph (c)(4) to read as follows:

§ 123.1 Requirement for export or temporary import licenses.

* * * * *

(c) * * *

(4) An application for a license under this part for the permanent export of defense articles sold commercially must be accompanied by a copy of a purchase order, letter of intent, or other appropriate documentation. In cases involving the U.S. Foreign Military Sales program, three copies of the relevant Letter of Offer and Acceptance are required, unless the procedures of § 126.4(c) or § 126.6 of this subchapter are followed.

* * * * *

■ 6. Section 123.3 is amended by adding paragraph (c), to read as follows:

§ 123.3 Temporary import licenses.

* * * * *

(c) A DSP-61 license may be obtained by a U.S. importer in satisfaction of § 123.4(c)(4) of this subchapter. If a foreign exporter requires documentation for a permanent import, the U.S. importer must contact the Department of Justice's Bureau of Alcohol, Tobacco, Firearms and Explosives for the appropriate documentation. A DSP-61 will not be approved to support permanent import requirements.

■ 7. Section 123.4 is amended by revising paragraphs (c)(1) through (c)(3), and adding paragraph (c)(4), to read as follows:

§ 123.4 Temporary import license exemptions.

* * * * *

(c) * * *

(1) The importer must meet the eligibility requirements set forth in § 120.1(c) of this subchapter;

(2) At the time of export, the ultimate consignee named on the Electronic

Export Information (EEI) must be the same as the foreign consignee or end-user of record named at the time of import;

(3) A stated in § 126.1 of this subchapter, the temporary import must not be from or on behalf of a proscribed country, area, or person listed in that section unless an exception has been granted in accordance with § 126.3 of this subchapter; and

(4) The foreign exporter must not require documentation of U.S. Government approval of the temporary import. If the foreign exporter requires documentation for a temporary import that qualifies for an exemption under this subchapter, the U.S. importer will not be able to claim the exemption and is required to obtain a DSP-61 Application/License for Temporary Import of Unclassified Defense Articles.

* * * * *

■ 8. Section 123.25 is amended by revising paragraph (b) to read as follows:

§ 123.25 Amendments to licenses.

* * * * *

(b) The following types of amendments to a license will be considered: Addition of U.S. freight forwarder or U.S. consignor; change due to an obvious typographical error; change in source of commodity; and change of foreign intermediate consignee if that party is only transporting the equipment and will not process (e.g., integrate, modify) the equipment. For changes in U.S. dollar value see § 123.23.

* * * * *

Dated: April 6, 2012.

Rose E. Gottemoeller,

Acting Under Secretary, Arms Control and International Security, Department of State.

[FR Doc. 2012-9081 Filed 4-16-12; 8:45 am]

BILLING CODE 4710-25-P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 183

[DOD-2009-OS-0039; RIN 0790-AI55]

Defense Support to Special Events

AGENCY: Department of Defense.

ACTION: Final rule.

SUMMARY: This rule establishes procedures and assigns responsibilities for Special Events, sets forth procedural guidance for the execution of Special Events support when requested by civil authorities or qualifying entities and approved by the appropriate DoD

authority, or as directed by the President, within the United States, including the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and any other territory or possession of the United States or any political subdivision thereof and elsewhere if properly approved.

DATES: This rule is effective May 17, 2012.

FOR FURTHER INFORMATION CONTACT: Ms. Carol Corbin, 571-256-8319.

SUPPLEMENTARY INFORMATION: The Department of Defense published a proposed rule on November 26, 2010 (75 FR 72767-72771). One comment was received and addressed below:

Comment: "This comment pertains to Page 72770, Section A(iiii)G reference to DOD support to the "National Boy Scout Jamboree". Recommend that DOD not support this event. The Boy Scouts of America are an organization that discriminates based on sex, sexual orientation, and religion. DOD support is contrary to policies of state governments and the federal government. Material support is against the general principle of separation of church and state and the important elements of the constitution of the United States. DOD support essentially demonstrates an "establishment of religion" and is contrary to anti-discrimination policies [sic]."

Response: The Department of Defense has valid statutory authority, 10 U.S.C. 2554, for providing support to the Boy Scout jamboree.

Executive Order 12866, "Regulatory Planning and Review" and Executive Order 13563, "Improving Regulation and Regulatory Review"

It has been certified that 32 CFR Part 183 does not:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a section of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in these Executive Orders.

Sec. 202, Pub. L. 104-4, "Unfunded Mandates Reform Act"

It has been certified that 32 CFR part 183 does not contain a Federal mandate that may result in the expenditure by State, local, and tribal governments, in aggregate, or by the private sector, of \$100 million or more in any one year.

Public Law 96-354, "Regulatory Flexibility Act" (5 U.S.C. 601 et seq.)

It has been certified that 32 CFR part 183 is not subject to the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. This rule establishes procedures and assigns responsibilities within DoD for Special Events in support of civil and non-governmental entities; therefore, it is not expected that small entities will be affected because there will be no economically significant regulatory requirements placed upon them.

Public Law 96-511, "Paperwork Reduction Act" (44 U.S.C. Chapter 35)

It has been certified that 32 CFR part 183 does not impose reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995.

Executive Order 13132, "Federalism"

It has been certified that 32 CFR part 183 does not have federalism implications, as set forth in Executive Order 13132. This rule does not have substantial direct effects on:

- (1) The States;
- (2) The relationship between the national government and the States; or
- (3) The distribution of power and responsibilities among the various levels of government.

List of Subjects in 32 CFR Part 183

Armed forces, Special events.

Accordingly, 32 CFR part 183 is added to subchapter I to read as follows:

PART 183—DEFENSE SUPPORT OF SPECIAL EVENTS

Sec.

- 183.1 Purpose.
- 183.2 Applicability and scope.
- 183.3 Definitions.
- 183.4 Policy.
- 183.5 Responsibilities.
- 183.6 Procedures.

Authority: 2 U.S.C. 1966, 2 U.S.C. 1970, 10 U.S.C. 372-374, 10 U.S.C. 377, 10 U.S.C. 2012, 10 U.S.C. 2553-2555, 10 U.S.C. 2564, 18 U.S.C. 1385, 18 U.S.C. 3056, 31 U.S.C. 1535-1536, 32 U.S.C. 502, 32 U.S.C. 508, Pub. L. 94-524, and Section 5802 of Pub. L. 104-208, as amended.

§ 183.1. Purpose.

This part: