

paragraph (c)(2), have been successfully implemented.

(3) The identified test and analysis features in paragraph (c)(4) and (c)(5) have been shown to be effective in validating the successful implementation of the features in paragraph (i)(2).

(4) The additional analysis requirements of paragraph (d) have been completed and the results have been approved.

(5) The additional test requirements of paragraph (e) have been successfully completed.

(6) All significant problems identified in accordance with paragraph (f) have been resolved, and fixes substantiated to be effective have been implemented.

(7) The accelerated engine cyclic endurance test program of paragraph (f)(5) must be in place.

(8) Compliance with the reliability demonstration acceptance criteria of paragraph (h) has been found by the Reliability Assessment Board.

Issued in Renton, Washington, on October 8, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03-26378 Filed 10-17-03; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF COMMERCE

Bureau of the Census

15 CFR Part 30

[Docket Number 030820208-3208-01]

RIN 0607-AA39

Automated Export System Mandatory Filing for Exports (Reexports) of Rough Diamonds

AGENCY: Bureau of the Census, Commerce.

ACTION: Final rule.

SUMMARY: The U.S. Census Bureau (Census Bureau) is amending the Foreign Trade Statistics Regulations (FTSR) to incorporate requirements for the mandatory electronic filing via the Automated Export System (AES) of exports of rough diamonds classified under Harmonized System subheadings 7102.10, 7102.21, and 7102.31 in accordance with the Clean Diamond Trade Act, which authorizes the President to implement the Kimberley Process Certification Scheme (the Kimberley Process) in the United States. The Kimberley Process sets forth an international certification scheme for trade in rough diamonds to combat the

use of diamonds to support conflict in Africa and other world areas. This requirement is mandated by the Clean Diamond Trade Act. Executive Order 13312 of July 29, 2003, implements the Clean Diamond Trade Act. This rule provides for AES mandatory filing in the FTSR.

EFFECTIVE DATE: This rule is effective October 20, 2003.

FOR FURTHER INFORMATION CONTACT: C. Harvey Monk, Jr., Chief, Foreign Trade Division, U.S. Census Bureau, Room 2104, Federal Building 3, Washington, DC 20233-6700, (301) 763-2255, by fax (301) 457-2645, or by e-mail: c.harvey.monk.jr@census.gov.

SUPPLEMENTARY INFORMATION:

Background

Reporting Requirements

The Census Bureau is responsible for collecting, compiling, and publishing export trade statistics for the United States under the provisions of Title 13, United States Code (U.S.C.), chapter 9, section 301. The paper Shipper's Export Declaration (SED) and the AES are the primary media used for collecting such trade data, and the information contained therein is used by the Census Bureau for statistical purposes only. This information is exempt from public disclosure under the provisions of Title 13, U.S.C., chapter 9, section 301(g). The SED and AES records also are used for export control purposes under Title 50, U.S.C., and Title 22, U.S.C., to detect and prevent the export of certain critical or sensitive commodities to unauthorized destinations or end-users.

Conflict Diamonds

On December 1, 2000, the United Nations General Assembly adopted Resolution 55/56. Provisions of Resolution 55/56 charged the international community with developing proposals and procedures to address the potential negative impact of illicit trade in rough diamonds on world peace, safety, and security. Trade in rough diamonds has in the past been linked to the finance of armed conflicts in certain world areas, specifically in some African nations (referred to as "conflict" diamonds). Funds derived from the sale of rough diamonds have been used by rebel groups to finance military activities, overthrow legitimate governments, commit atrocities against unarmed civilians, and subvert international efforts to promote peace and stability within and among the governments of nations.

This trade, if allowed to continue, poses a serious threat to the economies of many producing, processing,

exporting, and importing states. Representatives of nations with a stake in resolving the problem of "conflict" diamonds, including the United States, along with members of the diamond industry and concerned nongovernmental institutions, have worked together for nearly 3 years to develop a certification scheme, designed to control the worldwide movement of illicit rough diamonds. This process, which culminated in the Interlaken Declaration of November 5, 2002, launched the Kimberley Process. Under the Kimberley Process, participating nations or entities, in cooperation with industry, will establish internal control systems designed to eliminate "conflict" diamonds from shipments of rough diamonds imported into and exported from their territories.

Public Law 108-19, April 25, 2003, 117 stat. 631, known as the "Clean Diamond Trade Act," implements the Kimberley Process in the United States by authorizing the President to prohibit the importation into or the exportation from the United States of any rough diamond, from whatever source, unless the rough diamond is controlled through the Kimberley Process Certification Scheme. Executive Order 13312, signed on July 29, 2003, implements these prohibitions, effective July 30, 2003. In accordance with section 15 of the Clean Diamond Trade Act, the President certified in a letter to Congress on July 29, 2003, that an applicable waiver granted by the World Trade Organization is in effect until December 31, 2006.

Section 6 of Public Law 108-19 names the Census Bureau as the exporting authority for the purposes of the Clean Diamond Trade Act. This requires the Census Bureau to validate the Kimberley Process Certificate (the Certificate) for exports of rough diamonds by verifying that an Internal Transaction Number (ITN) provided by the AES is shown on the Certificate. The ITN is the confirmation number provided by the AES when the data transmission for exports of rough diamonds is accepted. Shipments of rough diamonds from the United States must also meet additional Department of the Treasury exporting requirements identified in the Office of Foreign Assets Control's (OFAC) Rough Diamonds Control Regulations, Title 31, Code of Federal Regulations (CFR), part 592. Section 8 of Public Law 108-19 authorizes the Bureau of Customs and Border Protection and the Bureau of Immigration and Customs Enforcement to enforce the provisions of the Clean Diamond Trade Act. OFAC also has enforcement authority pursuant to

section 5(a) of the Clean Diamond Trade Act and the Rough Diamonds Control Regulations (31 CFR part 592).

Program Requirements

To comply with the requirements of the Act and Executive Order 13312, which implements the Clean Diamond Trade Act, the Census Bureau is amending the appropriate sections of the FTSR to specify the requirements for the mandatory electronic filing via the AES for exports of rough diamonds.

The Census Bureau is revising the following sections of the FTSR:

- Section 30.1 is amended to require mandatory filing via AES for exports of rough diamonds;
- Section 30.2 is amended to stipulate that electronic SED filing through the AES is subject to export control regulations;
- Section 30.55 is amended to require filing through AES for all exports of rough diamonds regardless of value;
- Section 30.58 is amended to require filing through AES for exports of rough diamonds destined for Canada;
- Section 30.60 is amended to require mandatory participation in the AES for filers of information on exports of rough diamonds;
- Section 30.61 is amended to require full reporting, that is, reporting of all required information under the AES filing Option 2, prior to exportation for shipments of rough diamonds;
- Section 30.63 is amended to specify the Harmonized System subheadings for rough diamond exports subject to the Clean Diamond Trade Act and the Rough Diamonds Control Regulations (31 CFR part 592) and required to be reported through the AES;
- Section 30.65 is amended to specify the requirements for annotating commercial documents with the proper proof of filing citation when exports of rough diamonds are filed through the AES, and to require the reporting of an AES confirmation number on the Kimberley Process Certificate; and
- Section 30.95 is amended to specify penalty provisions mandated by the Clean Diamond Trade Act.

The Departments of State and Homeland Security concur with the provisions contained in this notice of final rulemaking.

Rulemaking Requirements

Administrative Procedure Act

Executive Order 13312 addresses further threats to international peace and security by the trade in conflict diamonds and implements Public Law 108–19, the Clean Diamond Trade Act. This final rule is issued in response to

Public Law 108–19 and is exempt from requirements of section 553 of the Administrative Procedures Act because it deals with a foreign affairs function of the United States (5 U.S.C. 553 (a)(1)). Therefore, the Census Bureau is not required to solicit public comment on this rule or provide a delay in the rule's effective date. No other law requires a notice of proposed rulemaking and an opportunity for public comment on this rule.

Regulatory Flexibility Act

Because a notice and opportunity for public comment are not required by 5 U.S.C. 553, or any other law for a rule regarding a foreign affairs function, a Regulatory Flexibility Analysis is not required and has not been prepared (5 U.S.C. 603 (a)).

Paperwork Reduction Act

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act (PRA), unless that collection of information displays a current, valid Office of Management and Budget (OMB) control number. In accordance with the PRA, 44 U.S.C., chapter 35, OMB has approved on July 22, 2003, with control number 0607–0152, the collection of all information associated with the AES and the SED under this rule. We estimate that each electronic SED will take approximately 3 minutes to complete; we estimate that each paper SED will take approximately 11 minutes to complete. A decrease of 31 burden hours accounts for the difference in time it takes to complete an AES transaction versus filling out a paper SED.

Executive Order 12866

This rule has been determined to be significant for purposes of Executive Order 12866.

List of Subjects in 15 CFR Part 30

Economic statistics, foreign trade, exports, reporting and recordkeeping requirements.

- For the reasons set out in the preamble, title 15 CFR part 30, is amended as follows:

PART 30—FOREIGN TRADE STATISTICS

- 1. Revise the authority citation for part 30 to read as follows:

Authority: 5 U.S.C. 301; 13 U.S.C. 301–307; 19 U.S.C. 3901–3913; Reorganization Plan 5 of 1950 (3 CFR 1949–1953 Comp.,

1004); E.O. 13312; and Department of Commerce Organization Order No. 35–2A, July 22, 1987, as amended, and No. 35–2B, December 20, 1996, as amended.

Subpart A—General Requirements—U.S. Principal Party in Interest (USPPI)

- 2. In § 30.1, revise paragraph (c) to read as follows:

§ 30.1 General statement of requirement for Shipper's Export Declarations.

* * * * *

(c) In lieu of filing paper SEDs as provided elsewhere in this section, when an SED would be required, the USPPI or the authorized agent is required to file shipper's export information electronically through the AES for the export of items identified on the CCL of the EAR (15 CFR Supp. No. 1 to part 774) or the USML of the ITAR (22 CFR part 121) as provided for in subpart E of this part, Electronic Filing Requirements—Shipper's Export Information. Information for items identified on the USML, including those exported under an export license exemption, must be filed electronically prior to export, unless exempted from the AES filing requirement by the State Department. For USML shipments, refer to the ITAR (22 CFR parts 120–130) for requirements concerning the AES proof of filing citation and filing time requirements. USPPIs or their authorized agents are required to file export information through the AES for shipments of rough diamonds classified under Harmonized System subheadings 7102.10, 7102.21, and 7102.31 and exported (reexported) in accordance with the Clean Diamond Trade Act and the Rough Diamonds Control Regulations (31 CFR part 592) as provided for in subpart E of this part. Use of the SED form is not permitted for reporting exports of rough diamonds. Entities serving as data entry and other forms of processing centers are not authorized to either collect or file export information on shipments of rough diamonds using any export reporting option. The USPPI or the authorized agent filing SEDs for the export of items not on the CCL, the USML, or exported (reexported) under the provisions of the Clean Diamond Trade Act and the Rough Diamonds Control Regulations (31 CFR part 592) has the option of filing this information electronically as provided for in subpart E of this part.

* * * * *

- 3. In § 30.2, add paragraph (c) to read as follows:

§ 30.2 Related export control requirements.

* * * * *

(c) Export shipments to all foreign destinations, including those filed electronically through the AES, are subject to export control regulations. This applies to mandatory, as well as voluntary AES filing. Executive Order 13312, signed July 29, 2003, implements the Clean Diamond Trade Act, which authorizes the President to implement the Kimberley Process Certification scheme in the United States. The Kimberley Process was developed to stem the worldwide movement of rough diamond exports linked to the finance of armed conflicts in certain world areas ("conflict" diamonds), specifically in some Southern African countries. The Kimberley Process Certificate serves as the mechanism to verify the absence of "conflict" diamonds from diamonds exported (reexported) from the United States.

Subpart D—Exemptions From the Requirements for the Filing of Shipper's Export Declarations

■ 4. In § 30.55, add paragraph (h)(2)(vi) to read as follows:

§ 30.55 Miscellaneous exemptions.

* * * * *

(h) * * *

(2) * * *

(vi) Classified as rough diamonds under 6-digit Harmonized System subheadings 7102.10, 7102.21, and 7102.31, regardless of value.

* * * * *

■ 5. Amend § 30.58 as follows:

■ a. Redesignate current paragraph (c)(6) as paragraph (c)(7).

■ b. Add a new paragraph (c)(6).

The addition reads as follows:

§ 30.58 Exemptions for shipments from the United States to Canada.

* * * * *

(c) * * *

(6) Shipments of rough diamonds exported (reexported) to Canada for use or consumption in Canada.

* * * * *

Subpart E—Electronic Filing Requirements—Shipper's Export Information

■ 6. In § 30.60, add a new second sentence to paragraph (a) to read as follows:

§ 30.60 General requirements for filing export and manifest data electronically using the Automated Export System (AES).

* * * * *

(a) *Participation.* * * * Filing using the AES also is mandatory for all exports (reexports) of rough diamonds

regardless of destination, method of transport, or value. * * *

* * * * *

■ 7. In § 30.61, add sentence (a)(5) to read as follows:

§ 30.61 Electronic filing options.

* * * * *

(a) * * *

(5) Shipments of rough diamonds exported (reexported) in accordance with the Clean Diamond Trade Act and the Rough Diamonds Control Regulations (31 CFR part 592).

* * * * *

■ 8. In § 30.63, add a sentence after the second sentence of paragraph (a)(12) to read as follows:

§ 30.63 Information required to be reported electronically through AES (data elements).

* * * * *

(a) * * *

(12) * * * Shipments of rough diamonds at the 10-digit Schedule B level that are classified under 6-digit Harmonized System subheadings 7102.10, 7102.21, and 7102.31 must be reported electronically through the AES.

* * * * *

■ 9. Amend § 30.65 as follows:

■ a. Revise paragraphs (b) introductory text and (b)(1).

■ b. Redesignate current paragraph (b)(2) as paragraph (b)(4).

■ c. Add new paragraphs (b)(2) and (b)(3).

The additions and revisions read as follows:

§ 30.65 Annotating the proper exemption legends or proof of filing citations for shipments transmitted electronically.

(a) * * *

(b) The USPPi or the authorized agent is responsible for annotating the proper exemption legend or proof of filing citation on the bill of lading, air waybill, or other commercial loading document for presentation to the carrier prior to tendering the cargo to the exporting carrier. The carrier is responsible for transmitting the appropriate exemption legend or proof of filing citation to the CBP Port Director at the port of exportation as stated in § 30.21 and § 30.22 of this part. Such transmittal shall be without material change or amendment of the exemption legend or proof of filing citation as provided to the carrier by the USPPi or the authorized agent. The exemption legend or proof of filing citation will identify that the shipment information has been accepted as transmitted and electronically filed using the AES. The exemption legend or proof of filing citation must appear on

the bill of lading, air waybill, or other commercial loading documentation and the manifest and must be clearly visible and include any of the following:

(1) The exemption legend or proof of filing citation will include the statement, "NO SED REQUIRED—AES," followed by the filer's identification number and a unique shipment reference number referred to as the External Transaction Number (XTN) or the returned confirmation number provided by AES when the transmission is accepted, referred to as the Internal Transaction Number (ITN).

(2) Shipments of USML articles must meet the predeparture reporting requirements in the ITAR (22 CFR parts 120–130).

(3) For shipments of rough diamonds, the proof of filing citation shall include the statement, "NO SED REQUIRED—AES," followed by the returned confirmation number provided by the AES when the transmission is accepted, referred to as the ITN. The ITN is required to be shown on the Kimberley Process Certificate for all exports (reexports) of rough diamonds to certify that the diamonds have been controlled through the Kimberley Process Certification Scheme, as defined in section 3 of Public Law 108–19 of the Clean Diamond Trade Act and implemented in the Rough Diamonds Control Regulations (31 CFR part 592).

Subpart H—General Administrative Provisions

■ 10. Revise § 30.95 to read as follows:

§ 30.95 Penalties for violations.

(a) *Exports (reexports) of rough diamonds.*

The Clean Diamond Trade Act, section 8(c), authorizes the Bureau of Customs and Border Protection (CBP) and the Bureau of Immigration and Customs Enforcement (BICE), as appropriate, to enforce the laws and regulations governing exports of rough diamonds, including with respect to the validation of the Kimberley Process Certificate by the exporting authority. The Treasury Department's Office of Foreign Assets Control (OFAC) also has enforcement authority pursuant to section 5(a) of the Clean Diamond Trade Act (the Act), Executive Order 13312, and the Rough Diamonds Control Regulations (31 CFR part 592). The CBP, the BICE, and OFAC, pursuant to section 5(a) of the Act, are further authorized to enforce provisions of section 8(a) of the Act that provide for the following civil and criminal penalties:

(1) A civil penalty not to exceed \$10,000 may be imposed on any person who violates, or attempts to violate, any order or regulation issued under the Act.

(2) A criminal penalty not to exceed \$50,000, or;

(i) If a natural person, imprisonment for not more than 10 years, or both, may be imposed for willful violation of any license, order, or regulation issued under the Act.

(ii) If a corporation, imprisonment for not more than 10 years, or both may be imposed on any officer, director, or agent of the corporation for willful violation of any license, order, or regulation issued under the Act.

(b) *Exports of other than rough diamonds.* Any person who violates any provisions of this part, except for violations of the provisions relating to delayed filing of documents under bond as provided by § 30.24 and violations of section 8 of Public Law 108–19, the Clean Diamond Trade Act, shall be

liable to the United States in an amount not exceeding \$1,000 for each violation, as authorized by section 305, chapter 9, title 13 U.S.C.

Dated: October 10, 2003.

Charles Louis Kincannon,

Director, Bureau of the Census.

[FR Doc. 03–26282 Filed 10–17–03; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, and 529

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the

animal drug regulations to reflect a change of sponsor for 12 approved new animal drug applications (NADAs) and 1 abbreviated new animal drug application (ANADA) from Anthony Products Co. to Cross Vetpharm Group, Ltd.

DATES: This rule is effective October 20, 2003.

FOR FURTHER INFORMATION CONTACT:

David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967, e-mail: dnewkirk@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Anthony Products Co., 5600 Peck Rd., Arcadia, CA 91006, has informed FDA that it has transferred ownership of, and all rights and interest in, the following 12 approved NADAs and one approved ANADA to Cross Vetpharm Group, Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.

Application No.	21 CFR Section	Trade Name
NADA 046–780	522.1720	PHEN–BUTA–VET (phenylbutazone) Injection
NADA 096–671	522.1720	PHEN–BUTA–VET (phenylbutazone) Injection
NADA 096–672	520.1720a	PHEN–BUTA–VET (phenylbutazone) Tablets
NADA 098–288	522.1883	PREDNIS–A–VET (prednisolone sodium phosphate) Injection
NADA 099–604	522.540	DEX–A–VET (dexamethasone sodium phosphate) Injection
NADA 099–605	522.540	DEX–A–VET (dexamethasone sodium phosphate) Injection
NADA 099–606	522.540	DEXAMETH–A–VET (dexamethasone) Injection
NADA 099–607	522.540	DEXAMETH–A–VET (dexamethasone) Injection
NADA 118–550	522.1010	FUROS–A–VET (furosemide) Injection
NADA 119–141	522.1962	TRANQUAZINE (promazine hydrochloride) Injection
NADA 138–405	522.2063	Pyrilamine Maleate Injection
NADA 140–583	522.480	ACTH Gel
ANADA 200–115	529.1044a	GENTAMEX 100 (gentamicin sulfate)

Accordingly, the agency is amending the regulations in 21 CFR 520.1720a, 522.480, 522.540, 522.1010, 522.1720, 522.1883, 522.1962, 522.2063, and 529.1044a to reflect the transfer of ownership. Sections 522.1883 and 522.1962 are also being revised to reflect a current format.

Following these changes of sponsorship, Anthony Products Co. is no longer the sponsor of an approved application. Accordingly, § 510.600(c) is being amended to remove the entries for Anthony Products Co.

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

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, and 529

Animal drugs.

■ 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 parts 510, 520, 522, and 529 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.