DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Part 744

[Docket No. 010220046–1046–01]

RIN 0694–AC40

Entity List: Removal of Two Russian Entities

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Final rule.

SUMMARY: This rule removes two Russian entities from the Entity List: INOR Scientific Center, Moscow, Russia; and Polyus Scientific Production Association, 3 Ulitsa Vvedenskogo, 117342, Moscow. The Export Administration Regulations (EAR) provide that the Bureau of Export Administration (BXA) may inform exporters, individually or through amendment to the EAR, that a license is required for exports or reexports to certain entities. The EAR contain a list of such entities called the Entity List.

EFFECTIVE DATE: This rule is effective December 21, 2001.

FOR FURTHER INFORMATION CONTACT: Eileen M. Albanese, Office of Exporter Services, Bureau of Export Administration, Telephone: (202) 482–0436.

SUPPLEMENTARY INFORMATION:

Background

Consistent with Section 6 of Executive Order 12938 of November 14, 1994, as amended, this action removes the following Russian entities, their sub-units and successors from the Entity List found in Supplement No 4. to Part 744 of the EAR: INOR Scientific Center, Moscow, Russia; and, Polyus Scientific Production Association, 3 Ulitsa Vvedenskogo, 117342, Moscow.

BXA maintains an Entity List to provide notice to the public of export license requirements for such entities. These two Russian entities were added to BXA's Entity List on July 29, 1998 (63 FR 40363), due to an investigation then underway by the Russian government of these entities for suspected activities involving weapons of mass destruction and missile technology. However, the State Department determined on November 17, 2000, that it is in the foreign policy and national security interests of the United States to remove nonproliferation measures on these two entities. These entities have taken action on the issues that caused the U.S. to impose these measures in 1998. Removing these additional license requirements and restoring the previous license review policy for these entities in light of the action taken by them will support U.S. nonproliferation policy.

Although the Export Administration Act expired on August 20, 2001, Executive Order 13222 of August 17, 2001 (66 FR 44025, August 22, 2001) continues the Regulations in effect under the International Emergency Economic Powers Act.

Rulemaking Requirements

1. This final rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid Office of Management and Budget Control Number. This rule involves a collection of information subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). This collection has been approved by the Office of Management and Budget under control number 0694–0088, ''Multi-Purpose Application,'' which carries a burden hour estimate of 45 minutes for a manual submission and 40 minutes for an electronic submission.

3. This rule does not contain policies with Federalism implications as this term is defined under Executive Order 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military and foreign affairs function of the United States (5 U.S.C. 553(a)(1)). Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this interim rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under the Administrative Procedure Act or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Sharron Cook, Office of Exporter Services, Bureau of Export Administration, Department of Commerce, P.O. Box 273, Washington, DC 20044, or scook@bxa.doc.gov.

List of Subjects in 15 CFR Part 744

Exports, Foreign trade, Reporting and recordkeeping requirements.

Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–799) is amended as follows:

PART 744—[AMENDED]

1. The authority citation for 15 CFR part 744 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, August 22, 2001; Notice of November 9, 2000, 65 FR 68063, 3 CFR, 2000 Comp., p. 408.

2. Supplement No. 4 to part 744 is amended removing the entities ''INOR Scientific Center, Moscow, Russia''; and ''Polyus Scientific Production Association, 3 Ulitsa Vvedenskogo, 117342, Moscow'' listed under ''Russia'' in the table.

Dated: December 17, 2001.

James J. Jochum,

Assistant Secretary for Export Administration.

[FR Doc. 01–31508 Filed 12–20–01; 8:45 am]

BILLING CODE 3510–33–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Child-Resistant Packaging for Certain Over-the-Counter Drug Products; Correction

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule; correction.

SUMMARY: The Consumer Product Safety Commission (CPSC or Commission) corrects the rule published in the **Federal Register** of August 2, 2001 that requires child-resistant (CR) packaging of certain previously prescription-only oral drug products approved by the Food and Drug Administration (FDA) for over-the-counter (OTC) sale. Drug products that are the subject of the August 2 rule are members of the category known as ''OTC switched drug products.''

The Commission intended that the August 2 rule apply to an oral drug product that is granted OTC status as

the result of an application to switch the product from prescription to OTC status (an OTC switch application) submitted to the FDA on or after the January 29, 2002 effective date of the CPSC rule, except in the following circumstances. The rule was not intended to cover a drug product that contains only active ingredients covered by prior OTC switch applications submitted by the same or any other applicant before the effective date of the CPSC rule. Since publication of the August 2 rule, the Commission has become aware that a correction is necessary to avoid confusion over this point and is thus issuing a clarifying amendment.

DATES: Effective on January 29, 2002.

FOR FURTHER INFORMATION CONTACT: Suzanne Barone, Ph.D., Directorate for Health Sciences, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301)504–0477 ext. 1196 or Geri Smith, Office of Compliance, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301)504–0608 ext. 1160.

SUPPLEMENTARY INFORMATION:

A. The Technical Correction

The Commission published, in the **Federal Register** of August 2, 2001, a regulation to require CR packaging of oral drug products approved by the FDA for OTC sale that contain active ingredients previously available only by prescription. 66 FR 40111. The regulation as proposed and as issued in final form was intended to apply only to an OTC drug product containing one or more previously prescription-only active ingredients first granted OTC status as a result of applications submitted to the FDA on or after the January 29, 2002 effective date of the final OTC-switch rule.

Nevertheless, the August 2, 2001 rule can be read to require CR packaging of a drug product approved for the switch to OTC status after the rule becomes effective on January 29, 2002, even if that drug product contains only an active ingredient or ingredients for which application(s) for OTC switch were submitted to the FDA by any manufacturer(s) prior to the effective date. The CR packaging requirement of the rule could also be interpreted to be triggered by non-prescription active ingredients in previously prescription-only drug products. This was not the intent of the rule.

The following examples are intended to clarify the scope of the rule as corrected today:

Example 1: Manufacturer A submitted an application to the FDA in December 2001 for OTC switch of an oral drug product containing only prescription-only active ingredient X. Manufacturer A's application is approved by the FDA after the January 29, 2002 effective date of this rule. Manufacturer B submits an application to the FDA in February 2002 for OTC switch of another oral drug product containing only the same active ingredient X.

Neither drug product is subject to this rule. Manufacturer A's drug product is not subject to this rule because the OTC switch application was submitted before the January 29, 2002 effective date. Manufacturer B's drug product is not subject to this rule because it contains only formerly prescription-only active ingredients for which an OTC switch application was submitted to the FDA by some manufacturer before the effective date of the rule.[1]

Example 2: Manufacturer A submits an application to the FDA in February 2002 for OTC switch of an oral drug product containing prescription-only oral active ingredient X. Active ingredient X is not the subject of an OTC switch application submitted by any manufacturer prior to the January 29, 2002 effective date of this rule.

Manufacturer A's drug product must be in CR packaging under this rule because no application for OTC switch of prescription-only active ingredient X was submitted to the FDA by any manufacturer prior to the January 29, 2002 effective date of the rule.

Example 3: Manufacturer A obtained FDA approval in December 2001 for OTC switch of an oral drug product containing formerly prescription-only active ingredient X. Manufacturer B submits an application to the FDA in February 2002 for OTC switch of an oral drug product containing active ingredient X and prescription-only active ingredient Y. Active ingredient Y is not the subject of any OTC switch application submitted by any manufacturer prior to the effective date of this rule.

Manufacturer A's drug product is not subject to this rule. Manufacturer B's drug product must be in CR packaging under this rule because no OTC switch application for prescription-only active ingredient Y was submitted to the FDA by any manufacturer prior to the January 29, 2002 effective date of the rule.

Each of these examples pertains only to the scope of this rule. Any other special packaging requirements of 16 CRF 1700.14 otherwise applicable to a drug product remain in full force and effect.

B. The Administrative Procedure Act (APA)

Section 553(b)(3)(B) of the APA authorizes an agency to dispense with certain notice procedures for a rule when it finds ''good cause'' to do so. 5 U.S.C. 553(b)(3)(B). Specifically, under section 553(b)(3)(B), the requirement for notice and an opportunity to comment does not apply when the agency, for good cause, finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' This amendment does not alter the intended scope of the August 2, 2001 rule or otherwise widen its applicability. Accordingly, the Commission hereby finds that notice of, and public comment on, this technical amendment are unnecessary.

C. Other Rulemaking Requirements

Because this amendment makes no change in the intended scope or applicability of the August 2, 2001 rule, the Commission hereby incorporates by reference the findings made with respect to it concerning the Regulatory Flexibility Act, 5 U.S.C. 601, et seq., the National Environmental Policy Act, 42 U.S.C.4321, et seq., and Executive Order No. 12988. See 66 FR 40114–5 (August 2, 2001).

For the foregoing reasons, the Commission corrects rule FR Doc. 01–19225 published in the **Federal Register** on August 2, 2001, (66 FR 40111) by making the following correcting amendment. On page 40115, in the third column, revise paragraph (a)(30)(i) in § 1700.14 to read as follows:

§ 1700.14 Substances requiring special packaging.

(a) * * *

* * * * *

(30) *Over-the-Counter Drug Products.* (i) Any over-the-counter (OTC) drug product in a dosage form intended for oral administration that contains any active ingredient that was previously available for oral administration only by prescription, and thus was required by paragraph (a)(10) of this section to be in special packaging, shall be packaged in accordance with the provisions of § 1700.15(a),(b), and (c). This requirement applies whether or not the amount of that active ingredient in the OTC drug product is different from the amount of that active ingredient in the prescription drug product. This requirement does not apply if the OTC drug product contains only active ingredients of any oral drug product or products approved for OTC marketing based on an application for OTC marketing submitted to the Food and Drug Administration (FDA) by any entity before January 29, 2002. Notwithstanding the foregoing, any special packaging requirement under this § 1700.14 otherwise applicable to an OTC drug product remains in effect.

* * * * *

[1] Of course the situation where the OTC switch application has been submitted to the FDA and also approved prior to the effective date of the CPSC rule is covered by this example.

Dated: December 17, 2001.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 01–31400 Filed 12–20–01; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP TAMPA–01–139]

RIN 2115–AA97

Security Zones; Tampa Bay, Florida

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary fixed security zones in all waters extending 100 feet around all bridge supports and rocky outcroppings at the base of the supports for the Sunshine Skyway Bridge in Tampa Bay. These security zones are needed for national security reasons to protect the bridge and passing marine traffic from potential subversive acts. Entry into these zones is prohibited, unless specifically authorized by the Captain of the Port, Tampa, Florida or his designated representative.

DATES: This regulation is effective at 6 p.m. EST on December 7, 2001 and will remain in effect until 6 p.m. EDT on June 15, 2002.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket number COTP Tampa 01–139 and are available for inspection or copying at Marine Safety Office Tampa, 155 Columbia Drive, Tampa, Florida 33606–3598 between 8 a.m. and 3 p.m. Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LT David G. McClellan, Coast Guard Marine Safety Office Tampa, at (813) 228–2189 extension 102.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a NPRM. Publishing a NPRM and delaying the rule's effective date would be contrary to the public interest since immediate action is needed to protect the public, ports and waterways of the United States. As appropriate the Coast Guard will issue a broadcast notice to mariners and place Coast Guard or other law enforcement vessels in the vicinity of these zones to advise mariners of the restriction.

For the same reasons, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

Background and Purpose

Based on the September 11, 2001, terrorist attacks on the World Trade Center buildings in New York and the Pentagon in Arlington, Virginia, there is an increased risk that subversive activity could be launched by vessels or persons in close proximity to the Sunshine Skyway Bridge in Tampa Bay, located at approximate position 27° 37′12″ N Latitude, 82° 39′20″ W Longitude. These security zones will encompass all waters extending 100 feet around all bridge supports and rocky outcroppings at the base of the supports for the Sunshine Skyway Bridge in Tampa Bay. Entry into these security zones is prohibited, unless specifically authorized by the Captain of the Port, Tampa, Florida or his designated representative.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. The Office of Management and Budget has not reviewed it under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979) because this will only affect a small group of recreational fisherman that occasionally fish next to the bridge supports and they may be allowed to enter these zones with the permission of the Captain of the Port.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), the Coast Guard considered whether this rule would have a significant economic effect upon a substantial number of small entities. ''Small entities'' include small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities because small entities may be allowed to enter these zones on a case by case basis with the authorization of the Captain of the Port.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process. If the rule will affect your small business, organization, or government jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** for assistance in understanding this rule.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This rule calls for no new collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501–3520).

Federalism

A rule has implication for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.