

PART 747—[AMENDED]

■ 12. The authority citation for 15 CFR part 747 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; Sec 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23 of May 7, 2003, 68 FR 26459, May 16, 2003; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

PART 748—[AMENDED]

■ 13. The authority citation for 15 CFR part 748 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

PART 750—[AMENDED]

■ 14. The authority citation for 15 CFR part 750 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; Sec 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013); Presidential Determination 2003–23 of May 7, 2003, 68 FR 26459, May 16, 2003; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

PART 752—[AMENDED]

■ 15. The authority citation for 15 CFR part 752 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

PART 754—[AMENDED]

■ 16. The authority citation for 15 CFR part 754 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 30 U.S.C. 185(s), 185(u); 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; E.O. 11912, 41 FR 15825, 3 CFR, 1976 Comp., p. 114; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

PART 756—[AMENDED]

■ 17. The authority citation for 15 CFR part 756 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

PART 758—[AMENDED]

■ 18. The authority citation for 15 CFR part 758 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

PART 760—[AMENDED]

■ 19. The authority citation for 15 CFR part 760 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

PART 762—[AMENDED]

■ 20. The authority citation for 15 CFR part 762 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

PART 764—[AMENDED]

■ 21. The authority citation for 15 CFR part 764 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

PART 766—[AMENDED]

■ 22. The authority citation for 15 CFR part 766 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

PART 768—[AMENDED]

■ 23. The authority citation for 15 CFR part 768 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

PART 770—[AMENDED]

■ 24. The authority citation for 15 CFR part 770 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

PART 772—[AMENDED]

■ 25. The authority citation for 15 CFR part 772 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

PART 774—[AMENDED]

■ 26. The authority citation for 15 CFR part 774 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

Dated: December 11, 2013.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2013–30116 Filed 12–18–13; 8:45 am]

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DEPARTMENT OF COMMERCE**Bureau of Industry and Security****15 CFR Parts 730, 740, 744, 756, 758, and 762**

[Docket No. 20524116–3986–02]

RIN 0694–AF70

Revisions to the Export Administration Regulations (EAR): Unverified List (UVL)

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) by: Requiring exporters to file an Automated Export System (AES) record for all exports subject to the EAR involving a party or parties to the transaction who are listed on the Unverified List (the “Unverified List” or UVL); suspending the availability of license exceptions for exports, reexports, and transfers (in-country) involving a party or parties to the transaction who are listed on the UVL; requiring exporters, reexporters, and transferors to obtain a UVL statement from a party or parties to the transaction who are listed on the UVL before proceeding with exports, reexports, and transfers (in-country) involving items subject to the EAR, but where the item does not require a license, i.e., No License Required (NLR); publishing the UVL in the EAR; and adding to the EAR the procedures to request removal or modification of a UVL entry.

These changes to the UVL enhance the U.S. Government’s ability to verify the *bona fides* of parties to exports,

reexports, or transfers (in-country) of items subject to the EAR and provide the U.S. Government increased visibility into such exports, reexports, and transfers involving persons whose *bona fides* could not be verified.

DATES: *Effective Date:* This rule is effective: January 21, 2014.

FOR FURTHER INFORMATION CONTACT:

Kevin Kurland, Director, Office of Enforcement Analysis, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482-2385 or by email at Kevin.Kurland@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

Background

On June 14, 2002, the Bureau of Industry and Security (“BIS”) published a notice in the **Federal Register** (67 FR 40910) establishing (the “Unverified List” or “UVL”), a list of persons in foreign countries who were parties to past export transactions with respect to which pre-license checks or post-shipment verifications could not be conducted for reasons outside the control of the U.S. Government, reasons such as lack of cooperation by the host government authority, the end user, or the ultimate consignee. That **Federal Register** notice also indicated that BIS may add to the UVL names of persons that BIS discovers are affiliated with a person on the UVL by virtue of ownership, control, position of responsibility, or other affiliation or connection in the conduct of trade or business. Since that time, BIS has issued subsequent notices that added to or removed persons from the UVL, as circumstances have warranted. Prior to publication of this rule, the UVL was published in the **Federal Register** in its entirety and updated as foreign persons are added to or removed from that list. The UVL is also available on the BIS Web site at http://www.bis.doc.gov/enforcement/unverifiedlist/unverified_parties.html.

The participation of a person listed on the UVL in any proposed transaction raises a “red flag” for purposes of the “Know Your Customer” guidance set forth in Supplement No. 3 to Part 732 of the EAR. See 67 FR 40910 (June 14, 2002) and 69 FR 42652 (July 16, 2004). Under that guidance, whenever there is a “red flag,” exporters have an affirmative duty to inquire, verify, or otherwise satisfy themselves that the transaction does not involve a proliferation activity prohibited by Part 744 and does not violate other provisions of the EAR.

On July 16, 2004, BIS expanded the criteria for adding persons to the UVL to include situations in which BIS is not

able to verify the existence or authenticity of the end user, intermediate consignee, ultimate consignee, or other party to an export transaction.

On August 21, 2008 (73 FR 49311), BIS expanded the scope of reasons to add persons to the Entity List. That rule amended Section 744.11 of the EAR to provide illustrative examples of the types of conduct that the U.S. Government could determine are contrary to U.S. national security or foreign policy interests for purposes of changes to the Entity List. One example listed in that section is, “[p]reventing accomplishment of an end use check conducted by or on behalf of BIS or the Directorate of Defense Trade Controls of the Department of State by: Precluding access to; refusing to provide information about; or providing false or misleading information about parties to the transaction or the item to be checked.” That notice also included a discussion of the apparent overlap in criteria for adding foreign persons to the Entity List and the Unverified List based on a lack of cooperation with an end-use check.

End-use checks sometimes cannot be completed for reasons unrelated to the cooperation of the foreign party subject to the end-use check. In such situations, BIS has added parties to the UVL where BIS or federal officials acting on BIS’s behalf have been unable to verify a foreign person’s *bona fides* (i.e., legitimacy and reliability relating to the end use and end user of items subject to the EAR), where an end-use check, such as a pre-license check (PLC) or a post-shipment verification (PSV), cannot be completed satisfactorily for such purposes for reasons outside the U.S. Government’s control. For example, BIS sometimes initiates end-use checks and cannot find a foreign party at the address indicated on export documents, and cannot locate the party by telephone or email. Additionally, BIS sometimes is unable to conduct end-use checks when host government agencies do not respond to requests to conduct end-use checks or refuse to schedule them in a timely manner. Under these circumstances, there may not be a basis to add the foreign persons at issue to the Entity List, particularly if there is no nexus between the foreign person’s conduct and the failure to produce a complete, accurate and useful check (see § 744.11(b)(4) of the EAR (Criteria for revising the Entity List)).

Furthermore, BIS sometimes conducts end-use checks but cannot verify the *bona fides* of a foreign party. For example, BIS may be unable to verify *bona fides* if during the conduct of an

end-use check a recipient of items subject to the EAR is unable to produce those items for visual inspection or provide sufficient documentation or other evidence to confirm the disposition of those items. The inability of foreign persons subject to end-use checks to demonstrate their *bona fides* raises concerns about the suitability of such persons as participants in future exports, reexports, or transfers (in-country) and indicates a risk that items subject to the EAR may be diverted to prohibited end uses and/or end users. However, BIS may have insufficient information to establish that such persons are involved in activities described in § 744.11 of the EAR, preventing the placement of the persons on the Entity List. In such circumstances, those foreign persons may be added to the Unverified List.

On September 11, 2013 (78 FR 55664), BIS published a proposed rule to address the issues outlined above. The public comment period for the proposed rule closed on October 11, 2013. BIS received one (1) public comment in response. The comment can be found on the BIS Web site at <http://efoia.bis.doc.gov/index.php/electronic-foia/index-of-documents>.

The recommendations set forth in the comment were broken into two categories: “Suggestions regarding the language of several affected paragraphs” and “Clarify the government’s position regarding the applicability of this proposed rule to intangible exports of technology and software.” The first category included recommended changes to clarify or strengthen the proposed rule by modifying proposed § 744.15(a) to state that exports, reexports, or transfers (in-country) subject to the EAR involving parties to the transaction who are listed on the UVL *must* be made in accordance with the criteria set forth in proposed § 744.15; § 744.15(b)(2) and (b)(2)(i) to require UVL statement signers to provide their titles and all relevant UVL party addresses on the Statement, and sign *and* date the Statement; § 744.15(c)(2) to state that BIS *will* remove persons from the UVL when their *bona fides* are validated; and § 758.1(b)(8) to remove the phrase “regardless of value or destination.” BIS accepted the recommendations covering § 744.15(a), (b)(2), (b)(2)(i), and (c)(2). BIS did not accept the suggested change to § 758.1(b)(8). While BIS agrees that “all exports” is unlimited in scope, BIS does not believe the modifying phrase “regardless of value or destination” is unnecessarily redundant. BIS is including this phrase to avoid confusion with the general Foreign Trade

Regulations exemptions for Automated Export System filings involving low value shipments and exports to Canada not subject to a BIS license. The modifier is included to clarify that the UVL rule requires filings for any shipments to UVL persons, including any low value shipments and exports to Canada. This clarifying language also appears in § 758.1(b)(1) and (b)(2). BIS understands that the removal of the modifier would not change the scope, but it was included to be consistent with other parts of the EAR.

The second public comment category suggested that BIS clarify whether the proposed rule applies to intangible technology and software. BIS intends the provisions of § 744.15 to apply to intangible exports, reexports, and transfers (in-country) of software and technology to persons listed on the UVL. Therefore, BIS made edits to the regulatory text and the preamble to indicate that the newly implemented requirements are applicable to commodities, software, and technology. The term “item” is defined in § 772.1 to include technology and software. The only other word in the regulatory text that could have been interpreted as restricted to tangible commodities was “shipment.” Therefore, BIS removed “shipment” and replaced it with “export, reexport, and transfer (in-country).” This, coupled with the general EAR definition of item, should make it clear that these new requirements are applicable to technology and software, as well as commodities. However, the requirement to file an AES record “for all exports” cannot be fulfilled in the case of intangible technology or software exports. In any case, these exports are exempt from AES filings. Therefore, while the regulation applies to technology and software, in addition to commodities, the amendment to § 758.1(b)(8) only applies to exports of tangible items.

BIS also amended the proposed text of § 744.15(b)(2)(iv). As proposed, the UVL statement required cooperation with a pre-license check. However, under the terms of paragraph (b) of that section, the UVL statement is only necessary when no license is required. As such, this final rule omits the requirement that the UVL statement include an agreement for a pre-license check because no license is required under these circumstances. The UVL statement does retain the proposed rule’s requirement that an end-use check, including a post-shipment verification, must be agreed to and cooperated with.

Reasons for This Rule

This rule eliminates ambiguity for listing foreign persons on the UVL and the Entity List by removing lack of cooperation by a foreign party as a basis for revising the UVL. Where the U.S. Government determines that the foreign party’s lack of cooperation prevented the accomplishment of an end-use check, BIS may add such parties to the Entity List on the basis of § 744.11(b)(4) of the EAR.

Specifically, BIS is amending the EAR to include the criteria for listing persons in the UVL, including examples of actions that could result in a person being listed on the UVL. These amendments, consistent with past practice, will apply to foreign persons who are parties to an export, reexport, and transfer (in-country) subject to the EAR if BIS, or federal officials acting on BIS’s behalf, cannot verify the *bona fides* of such persons because an end-use check, such as a PLC or a PSV, cannot be completed satisfactorily for reasons outside of the U.S. Government’s control. Examples of actions that could result in a person being listed on the UVL include: The subject of the check is unable to demonstrate the disposition of items during an end-use check; the existence or authenticity of the subject of an end-use check cannot be verified because, *inter alia*, the subject of the check cannot be located or contacted; or lack of cooperation by the host government authority.

In addition, BIS is no longer considering affiliation with a person on the UVL as a basis for adding foreign persons without further substantiation (e.g., conduct of an end-use check at the affiliate). A determination to list a particular person on the UVL is premised on BIS’s inability to evaluate the *bona fides* of that person by conducting an end-use check. The fact that another, separate person is affiliated with a person on the UVL will no longer be considered a dispositive criterion forming the basis for listing the affiliate. If BIS discovers a foreign person may be affiliated with a person listed on the UVL, BIS will initiate an end-use check on an export, reexport, or transfer (in-country) to which that person was a party. That person may be listed on the UVL if BIS is unable to verify that person’s *bona fides* through an end-use check in accordance with the criteria described above.

BIS is implementing these changes to the UVL to address concerns raised by the public in the past about how to address a “red flag” identified by the U.S. Government. Accordingly, this

regulation provides guidance on how exporters can conduct business with a UVL person. Any license requirements for exports, reexports, or transfers (in-country) of items subject to the EAR continue to apply. For items not subject to a license requirement, the exporter, reexporter, or transferor (in-country) must receive from the UVL-listed person a UVL statement prior to the export, reexport, or transfer (in-country), in which the UVL-listed party certifies the end use, end user, and country of ultimate destination of items subject to the EAR and consents to an end-use check by the U.S. Government. The end-use check may include checks to any transaction to which that person was a party for items subject to the EAR exported, reexported, or transferred (in country) in the last five years, to enable the U.S. Government to satisfy earlier concerns with the UVL-listed party as well as its concerns with the current transaction.

Changes to the EAR

BIS is amending the EAR by: (1) Requiring exporters to file an AES record for all exports subject to the EAR involving persons listed on the UVL; (2) suspending the availability of license exceptions for exports, reexports, and transfers (in-country) involving persons listed on the UVL; (3) requiring exporters, reexporters and transferors (in-country) to obtain a UVL statement from UVL-listed persons before proceeding with exports, reexports, and transfers (in-country) that are not otherwise subject to a license requirement under the EAR involving such persons; (4) adding the UVL to Supplement No. 6 to Part 744, and (5) adding to the EAR procedures to request removal or modification of a UVL entry.

The first of these changes, requiring the filing of an AES record for all exports to which a person listed on the UVL is a party, as described in § 748.5(d)–(f) of the EAR, increases U.S. Government awareness of exports involving U.S.-origin items to such persons. Under current regulations, an AES filing is only required if an export license is also required or if the transaction is above a certain value. This rule, through a change to § 758.1, implements a requirement to submit an AES filing for all exports, regardless of value or destination, if a person involved in the transaction as described above is listed on the UVL.

Secondly, under § 740.2, this rule suspends license exceptions for exports, reexports, and transfers (in-country) of U.S.-origin items to persons listed on the UVL. The change increases U.S. Government insight into certain

transactions involving such persons of items on the Commerce Control List (set forth in Supplement No. 1 to Part 774 of the EAR) by requiring a license for those transactions. This suspension is also consistent with § 740.2(b) of the EAR, which states, "all License Exceptions are subject to revision, suspension, or revocation, in whole or in part, without notice."

Third, this rule requires exporters to obtain a signed and dated UVL statement from UVL-listed persons before proceeding with any export, reexport, or transfer (in-country) involving such persons, when such persons are parties to a transaction as described in § 748.5 of the EAR, and when the item at issue is subject to the EAR but does not require a license under the EAR.

That section also requires that the statement certify the end use, end user, and country of ultimate destination of the items, and set forth the person's consent to an end-use check by the U.S. Government. To facilitate any future end-use checks by the U.S. Government, the UVL-listed person must also include its complete contact information in the UVL statement, including all relevant physical addresses (e.g., shipping address, corporate address, intended end user address, etc.). This statement establishes that the UVL-listed party knows that it is required to comply with the EAR and agrees to an end-use check. The statement also provides the U.S. Government with some assurance that the U.S.-origin item will be delivered to an identified end user and end use and that the transaction will comply with the EAR. In the absence of such compliance, the UVL statement will assist the U.S. Government's ability to take enforcement action.

The suspension of license exceptions, which will allow prior review by the U.S. Government of exports, reexports, and transfers (in-country) of certain controlled items involving persons listed on the UVL, coupled with the requirement for exporters to obtain a UVL statement for exports, reexports, and transfers (in-country) involving such persons of items not subject to a license requirement, provides greater guidance on what steps are necessary in order to undertake an export, reexport, or re-transfer (in-country) of items subject to the EAR involving a party to the transaction who is listed on the UVL.

Specifically, when an export, reexport, or transfer (in-country) is otherwise eligible for a license exception, if a party to the transaction as described in § 748.5 of the EAR is listed on the UVL, the use of license

exceptions is not authorized. Under these circumstances, an exporter must apply to BIS for a license. If an export, reexport, or transfer (in-country) involving a person listed on the UVL is not subject to a license requirement under the EAR, the possible availability of a license exception does not arise. In such a case, an exporter may proceed with the export, reexport, or transfer (in-country) once the exporter obtains the signed UVL statement described herein and files an AES record in accordance with § 758.1 of the EAR, as amended. The signed UVL statement is not needed for transactions in which a license is required because BIS oversight of the transaction resulting from the grant of the license renders a UVL statement unnecessary.

Fourth, this rule adds the UVL to the EAR in Supplement No. 6 to Part 744, but removes all persons previously listed on the UVL. BIS will add persons to and remove them from the UVL whenever a decision is made in accordance with the criteria for revising the UVL set forth in § 744.15(c). Henceforth, when adding a person to the UVL, BIS will list the person's name and address, and the date on which the person was added to the UVL by publication in the **Federal Register**. Updates to the UVL will continue to be published in the **Federal Register**, and will remain available on the BIS Web site. The UVL will also continue to be included in the Consolidated Screening List, available at www.export.gov.

Supplement No. 6 to Part 744 ("the UVL") contains the names and addresses of foreign persons who are or have been parties to a transaction, as that term is described in § 748.5 of the EAR, involving the export, reexport, or transfer (in-country) of items subject to the EAR, and whose *bona fides* BIS has been unable to verify through an end-use check. Any changes to the UVL will be published in the **Federal Register** as an amendment to the UVL.

In addition to adding the UVL to Supplement No. 6 to Part 744, this rule adds to the regulations an overview of the UVL, the conditions it imposes with respect to exports, reexports, and transfers (in-country) to listed persons, the criteria for revising the UVL, and the procedures for requesting removal or modification of a UVL entry.

BIS adds a person to the UVL under certain circumstances. For example, in some instances, BIS may not be able to conduct an end-use check, such as a PLC or a PSV, at all because, among other potential reasons, BIS was unable to locate or contact the subject of the check or the host government declined to schedule the check in a timely

manner. Alternatively, BIS may not be able to complete a satisfactory end-use check because, *inter alia* the foreign party is unable to demonstrate its *bona fides* or the disposition of the items in question during the end-use check. In either circumstance, BIS may determine to add the foreign person to the UVL.

BIS removes a person listed on the UVL using certain procedures. The successful completion of an end-use check, or, in the limited circumstance where such a check cannot be completed due to lack of host government cooperation, a suitable alternative process to verify the *bona fides* of the foreign party at issue is a prerequisite for removing persons from the UVL. One illustrative example of alternative authentication could involve the U.S. exporter or license applicant visiting the foreign person subject to the end-use check, at that person's request, and providing sufficient information to the U.S. Government to verify the foreign person's *bona fides* and satisfy questions relating to the end use and end user of the items in question. Procedures for requesting an alternative process to verify the *bona fides* of a foreign person in this circumstance are identical to the procedures for requesting removal of a UVL listing, set forth in § 744.15 of the EAR.

If BIS confirms the *bona fides* of a listed person based on the criteria in § 744.15(b)(2) of the EAR, BIS will publish a final rule in the **Federal Register** removing that person from the UVL. A determination to remove a person from the UVL is independent of any determination BIS may make pursuant to § 744.11(b) of the EAR. Once a foreign person is removed from the UVL, the provisions in the EAR regarding persons listed on the Unverified List will no longer apply to that person though other provisions in the EAR will continue to apply as appropriate. BIS will regularly review the UVL for the purpose of identifying and implementing any needed corrections and updates.

Lastly, this rule modifies the procedures for requesting removal of a person listed on the UVL by adding decisions on requests to remove or modify a UVL entry to the list of administrative actions that are not subject to Part 756 appeals. Requests for removal of a UVL entry must be made in accordance with § 744.15(d) of the EAR. Decisions regarding the removal or modification of UVL listings will be made by the Deputy Assistant Secretary for Export Enforcement, based on a demonstration by the listed person of its *bona fides*.

Amendment to Supplement No. 1 to Part 730

Due to this rule's addition to the EAR of § 744.15 below, this rule also amends Supplement No. 1 to Part 730 of the EAR to include references to the two additional information collections: (1) The UVL statement and (2) requests to remove or modify listings on the UVL. The collection and retention of the UVL statement by private parties in connection with the export, reexport, or transfer (in-country) to a person listed on the UVL of items not subject to a license requirement under the EAR shall be made under Office of Management and Budget (OMB) control number 0694-0122 ("Licensing Responsibilities and Enforcement"). The submission of information to BIS by persons listed on the UVL in support of an appeal for removal a UVL listing will be made under OMB control number 0694-0134. Accordingly, this rule amends Supplement No. 1 to Part 730 of the EAR by adding a reference to new § 744.15 in connection with existing collection number 0694-0122, and by changing the title of existing collection number 0694-0134 to "Procedure for parties on the Entity List or Unverified List to Request Removal or Modification of their Listing" and adding a reference to new § 744.15 in connection with that collection number.

Amendments to § 740.2

This rule adds a new paragraph (a)(17) to § 740.2 "Restrictions on all License Exceptions." This paragraph explains that license exceptions may not be used where a party to the transaction as described in § 748.5 of the EAR is listed on the Unverified List.

New § 744.15 and Amendment to § 756.1

This rule adds a new section to Part 744 to set forth the new provisions pertaining to persons listed on the UVL. New § 744.15 provides an overview of the UVL, the conditions it imposes with respect to exports, reexports, and transfers (in-country) to listed persons, and the criteria for revising the UVL. This new section also includes the procedures for requesting removal or modification of a person on the UVL.

This rule excludes appeals for removal of Unverified List entries from the provisions of Part 756 of the EAR. Requests for removal instead must be made according to the procedures set forth in new § 744.15 of the EAR. Accordingly, paragraph (a)(3) of § 756.1 of the EAR is amended by adding a reference to decisions on requests to remove UVL entries made pursuant to new § 744.15

of the EAR. Although the proposed rule did not include a revision to § 744.1, this rule makes an inconsequential revision to § 744.1(a)(1), by adding a description of the new § 744.15 and a reference to the new Supplement No. 6 to Part 744.

New Supplement No. 6 to Part 744

The UVL is added to the EAR in Supplement No. 6 to Part 744. Each listing grouped by country, and accompanied by the person's address(es) as well as the **Federal Register** citation and date the person was added to the UVL. In addition, the UVL includes a citation to § 744.15, indicating that exports, reexports, and transfers (in-country) where parties to the transactions are listed on the Unverified List are subject to the provisions of § 744.15.

Amendment to § 758.1

This rule adds a new § 758.1(b)(8) of the EAR, which states that filing an AES record is required for all exports of items subject to the EAR where a party to the transaction as described in § 748.5(d)-(f) is listed on the Unverified List, regardless of value or destination.

Amendment to § 762.2

Section 762.2(b) of the EAR contains references to parts, sections, and supplements of the EAR which require the retention of records or contain recordkeeping provisions. New § 744.15 of the EAR contains a recordkeeping requirement related to the retention of UVL statements. Therefore, this rule modifies reserved paragraph § 762.2(b)(13) of the EAR to reference the UVL statement recordkeeping requirement in new § 744.15 of the EAR.

Export Administration Act

Since August 21, 2001, the Export Administration Act of 1979, as amended, has been in lapse. However, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013), and as extended by the Notice of August 8, 2013, 78 FR 49107 (August 12, 2013) has continued the EAR in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*). BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222 as amended by Executive Order 13637.

Rulemaking Requirements

1. 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, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under section 3(f) of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor is subject to a penalty for failure to comply with, a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves collections previously approved by OMB under the following control numbers: 0694-0088, 0694-0122, 0694-0134, and 0694-0137. Specifically, BIS has requested a revision and extension of existing collection OMB 0694-0134 (Procedure for parties on the Entity List to Request Removal or Modification of their Listing) and non-substantive changes to OMB Control Numbers 0694-0088 (Simplified Network Application Processing and Multipurpose Application Form), 0694-0122 (Licensing Responsibilities and Enforcement), and 0694-0137 (License Exemptions and Exclusions).

This rule slightly increases public burden in a collection of information approved by OMB under control number 0694-0088, which authorizes, among other things, export license applications. The removal of license exceptions for listed parties on the Unverified List will result in increased license applications being submitted to BIS by exporters. Total burden hours associated with the Paperwork Reduction Act and OMB control number 0694-0088 are expected to increase minimally, as the suspension of license exceptions will only affect transactions involving parties listed on the Unverified List and not all export transactions. Since license exceptions are restricted from use, this rule decreases public burden in a collection of information approved by OMB under control number 0694-0137 minimally,

as this will only affect a very small number of individual listed parties. The increased burden under 0694–0088 is reciprocal to the decrease of burden under 0694–0137, and results in no change of burden to the public. This rule also increases public burden in a collection of information under OMB control number 0694–0122, as a result of the exchange of UVL statements between private parties, and under OMB control number 0694–0134 as a result of appeals from persons listed on the UVL for removal of their listing. The total increase in burden hours associated with both of these collections is expected to be minimal, as they involve a limited number of persons listed on the UVL.

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

4. The Chief Counsel for Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that this rule will not have a significant economic impact on a substantial number of small entities.

Number of Small Entities

Currently, BIS does not collect data on the size of entities that apply for and are issued export licenses. Although BIS is unable to estimate the exact number of small entities that will be impacted by this rule, it acknowledges that this rule will impact some unknown number. This rule will affect exporters and freight forwarders, with obligations to apply for export licenses, obtain and retain UVL statements, and/or file AES records in connection with exports, reexports, or transfers (in-country) in which a person listed on the UVL is a party to the transaction. These requirements apply to all entities proceeding with such transactions, regardless of size.

Economic Impact

BIS is unable to determine whether there are a substantial number of small entities affected by this rule. However, this rule is not expected to affect a disproportionate number of small entities because it is directed at a limited number of foreign persons and will impact all export transactions to these persons, regardless of whether the exports are made or intended to be made by small, medium, or large entities. BIS has administered the UVL based on listing criteria similar to those set forth in this rule since 2002. This rule will impact transactions involving persons listed on the UVL, which currently has 36 persons listed. Due to

the limited number of persons expected to be maintained on the UVL, BIS estimates that the number of transactions involving these persons represents only a small fraction of the total number of transactions recorded in AES. BIS estimates that regulated entities will incur minimal economic burdens on transactions involving UVL persons as a result of this rule because there are few transactions involving such persons and for those transactions where they are involved, there is no monetary fee to apply for a BIS license or file a record in AES. Moreover, obtaining a signed UVL statement from UVL persons for items not subject to a license requirement will result in minimal burden to U.S. exporters, as the statement can simply be copied from the EAR and forwarded to the UVL person for review and signature. The maintenance of any such UVL statement also will have minimal burden on U.S. exporters as the EAR already has similar recordkeeping requirements under Section 762.2 of the EAR. As a result, the requirements of this rule will amount to very little economic burden.

For the reasons above, the Chief Counsel for Regulation certified that this rule will not have a significant economic impact on a substantial number of small entities.

No comments were received regarding the economic impact of this final rule. As a result, a final regulatory flexibility analysis is not required and one was not prepared.

List of Subjects

15 CFR Part 730

Administrative practice and procedure, Advisory committees, Exports, Reporting and recordkeeping requirements, Strategic and critical materials.

15 CFR Part 740

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

15 CFR Part 756

Appeals.

15 CFR Part 758

Export clearance requirements.

15 CFR Part 762

Recordkeeping.

Accordingly, Parts 730, 740, 744, 756, 758, and 762 of the Export Administration Regulations (15 CFR parts 730–774) are amended as follows:

PART 730—[AMENDED]

■ 1. The authority citation for 15 CFR Part 730 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c; 22 U.S.C. 2151 note; 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 11912, 41 FR 15825, 3 CFR, 1976 Comp., p. 114; E.O. 12002, 42 FR 35623, 3 CFR, 1977 Comp., p. 133; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12214, 45 FR 29783, 3 CFR, 1980 Comp., p. 256; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 179; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 12981, 60 FR 62981, 3 CFR, 1995 Comp., p. 419; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p. 168; E.O. 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013); Notice of January 17, 2013, 78 FR 4303 (January 22, 2013); Notice of May 7, 2013, 78 FR 27301 (May 9, 2013); Notice of August 8, 2013, 78 FR 49107 (August 12, 2013); Notice of September 18, 2013, 78 FR 58151 (September 20, 2013); Notice of November 7, 2013, 78 FR 67289 (November 12, 2013).

■ 2. Supplement No. 1 to Part 730 is amended by:

■ a. Removing the phrase “Part 758, and § 748.4” and adding in its place “§§ 744.15(b) and 748.4 and Part 758” in the “Reference in the EAR” column of 0694–0122 row;

■ b. Removing the Title “Procedure for parties on the Entity List to Request Removal or Modification of their Listing” and adding in its place “Procedure for parties on the Entity List or the Unverified List to Request Removal or Modification of their Listing” in the Title Column of the 0694–0134 row; and

■ c. Removing the reference “§ 744.16” and adding in its place “§§ 744.15 and 744.16” in the Reference in the EAR column of the 0694–0134 row.

PART 740—[AMENDED]

■ 3. The authority citation for 15 CFR Part 740 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. 7201 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

■ 4. Section 740.2 is amended by adding paragraph (a)(17) to read as follows:

§ 740.2 Restrictions on all license exceptions.

(a) * * *

(17) A party to the transaction, as described in § 748.5 of the EAR, is listed on the Unverified List in Supplement No. 6 to Part 744, see § 744.15 of the EAR.

* * * * *

PART 744—[AMENDED]

■ 5. 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; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; 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. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of January 17, 2013, 78 FR 4303 (January 22, 2013); Notice of August 8, 2013, 78 FR 49107 (August 12, 2013); Notice of September 18, 2013, 78 FR 58151 (September 20, 2013); Notice of November 7, 2013, 78 FR 67289 (November 12, 2013).

■ 6. Section 744.1 is amended by adding the sentence set forth below after the tenth sentence in paragraph (a)(1).

§ 744.1 General provisions.

(a)(1) * * * Section 744.15 sets forth the conditions for exports, reexports, and transfers (in-country) to persons listed on the Unverified List (UVL) in Supplement No. 6 of this part, the criteria for revising the UVL, as well as procedures for requesting removal or modification of a listing on the UVL.

* * *

■ 7. Adding § 744.15 to read as follows:

§ 744.15 Restrictions on exports, reexports and transfers (in-country) to persons listed on the unverified list.

(a) *General requirement.* In addition to the requirements set forth elsewhere in the EAR, exports, reexports, or transfers (in-country) subject to the EAR involving parties to the transaction who are listed on the Unverified List (UVL) must be made in accordance with paragraph (b) of this section. The names and addresses of foreign persons subject to end-user controls based on the criteria described in paragraph (c) of this section are identified in the Unverified List found in Supplement No. 6 to this part. Requirements found elsewhere in the EAR also apply, including but not limited to any license

requirements, the record filing requirements pursuant to § 758.1(b)(8), and the restrictions on license exceptions described in § 740.2(a)(17) of the EAR.

(b) *UVL statement.* Before proceeding with any export, reexport, or transfer (in-country) subject to the EAR that is not subject to a license requirement, involving a person listed on the Unverified List as a party described in § 748.5 of the EAR, an exporter, reexporter, or transferor (in-country) must obtain a UVL statement from such person, according to the provisions set forth in this section. The statement must be retained in accordance with part 762 of the EAR.

(1) One UVL statement may be used for multiple exports, reexports, and transfers (in-country) of the same items between the same parties, so long as the party names, the description(s) of the items and the ECCNs are correct. If one UVL statement is used for multiple exports, reexports, and transfers (in-country), the exporter, reexporter, and transferor must maintain a log or other record that identifies each export, reexport, and transfer (in-country) made pursuant to this section and the specific UVL statement that is associated with each. The log or record must be retained in accordance with Part 762 of the EAR.

(2) The UVL statement must be in writing, signed and dated by an individual of sufficient authority to legally bind the UVL party, and state the following:

(i) Name of UVL party; complete physical address, to include shipping, corporate, and end user addresses, if different (simply listing a post office box is insufficient); telephone number; fax number; email address; Web site (if available); and name and title of individual signing the UVL statement.

(ii) Agrees not to use the item(s) for any use prohibited by the United States Export Administration Regulations (EAR), 15 CFR Parts 730–772, and agrees not to reexport or transfer (in-country) the item(s) to any destination, use or user prohibited by the EAR.

(iii) Declares that the end use, end user, and country of ultimate destination of the item(s) subject to the EAR are as follows: [INSERT END USE, END USER, AND COUNTRY OF ULTIMATE DESTINATION].

(iv) Agrees to cooperate with end-use checks, including a Post-Shipment Verification, conducted by or on behalf of the Bureau of Industry and Security, U.S. Department of Commerce, for any item subject to the EAR in transactions to which they were a party in the last five years. This cooperation includes facilitating the timely conduct of the

check and providing full and accurate information concerning the disposition of items subject to the EAR.

(v) Agrees to provide copies of this document and all other export, reexport or transfer (in-country) records required to be retained in part 762 of the EAR.

(vi) Certifies that the individual signing the UVL statement has sufficient authority to legally bind the party.

(c) *Criteria for revising the Unverified List.* (1) Foreign persons who are parties to an export, reexport, and transfer (in-country) subject to the EAR may be added to the Unverified List if BIS or federal officials acting on BIS's behalf cannot verify the *bona fides* (i.e., legitimacy and reliability relating to the end use and end user of items subject to the EAR) of such persons because an end-use check, such as a pre-license check (PLC) or a post-shipment verification (PSV), cannot be completed satisfactorily for reasons outside of the U.S. Government's control. Examples in paragraphs (c)(1)(i) through (iii) of this section provide an illustrative list of those circumstances.

(i) During the conduct of an end-use check, the subject of the check is unable to demonstrate the disposition of items subject to the EAR.

(ii) The existence or authenticity of the subject of an end-use check cannot be verified (e.g., the subject of the check cannot be located or contacted).

(iii) Lack of cooperation by the host government authority prevents an end-use check from being conducted.

(2) BIS will remove a person from the Unverified List when BIS is able to verify the *bona fides* of the listed person as an end user, consignee, or other party to exports, reexports, or transfers (in-country) involving items subject to the EAR by completing a PLC or PSV. In the limited circumstance involving a PLC or PSV that cannot be completed due to lack of host government cooperation, an alternative *bona fides* verification process may be determined by BIS to be sufficient. A determination to remove a person from the Unverified List based on the criteria in this paragraph is separate from any determination made by BIS pursuant to § 744.11(b) of the EAR, and must be requested through paragraph (d) of this section.

(d) *Procedure for requesting removal of a person on the Unverified List.* Any person listed on the Unverified List may request that its listing be amended or removed.

(1) All such requests, including reasons therefor and information that verifies the *bona fides*, i.e., legitimacy and reliability of the person listed on the Unverified List as an end user, consignee or other party to exports,

reexports, and transfers (in-country) of items subject to the EAR, must be in writing and sent to: Director, Office of Enforcement Analysis, Bureau of Industry and Security, U.S. Department of Commerce, 14th Street and Pennsylvania Avenue NW., Room 4065, Washington, DC 20230, via fax to (202) 482-0971, or by email to UVLRequest@bis.doc.gov.

(2) The Deputy Assistant Secretary for Export Enforcement will review such requests and will convey the decision on the request to the requester in writing based on an assessment of the listed person's *bona fides* as a party to exports, reexports, and transfers (in-country) subject to the EAR. That decision will be the final agency action on the request.

■ 8. Supplement No. 6 to Part 744 is added to read as follows:

Supplement No. 6 to Part 744—Unverified List

Exports, reexports, and transfers (in-country) involving parties to the transaction who are listed in this supplement are subject to the restrictions outlined in § 744.15 of the EAR.

Country	Listed person and address	Federal Register citation and date of publication
Reserved	Reserved	Reserved.

PART 756—[AMENDED]

■ 9. The authority citation for 15 CFR Part 756 continues to read as follows:

Authority: 50 U.S.C. app 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

■ 10. Section 756.1 is amended by revising paragraph (a)(3) to read as follows:

§ 756.1 Introduction.

(a) * * *

(3) A decision on a request to remove or modify an Entity List entry made pursuant to § 744.16 of the EAR or a decision on a request to remove an Unverified List entry made pursuant to § 744.15 of the EAR.

* * * * *

PART 758—[AMENDED]

■ 11. The authority citation for 15 CFR Part 758 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

■ 12. Section 758.1 is amended by adding paragraph (b)(8) to read as follows:

§ 758.1 The Automated Export System (AES) record.

* * * * *

(b) * * *

(8) For all exports of tangible items subject to the EAR where parties to the transaction, as described in § 748.5(d)–(f) of the EAR, are listed on the Unverified List (Supplement 6 to Part 744 of the EAR), regardless of value or destination.

* * * * *

PART 762—[AMENDED]

■ 13. The authority citation for 15 CFR Part 762 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

■ 14. Section 762.2 is amended by revising paragraph (b)(13) to read as follows:

§ 762.2 Records to be retained.

* * * * *

(b) * * *

(13) § 744.15(b), UVL statement as well as any logs or records created for multiple exports, reexports, and transfers (in-country);

* * * * *

Dated: December 12, 2013.

Kevin J. Wolf,
Assistant Secretary for Export Administration.

[FR Doc. 2013-30117 Filed 12-18-13; 8:45 am]

BILLING CODE 3510-33-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 10

[Docket No. FDA 2013-S-0610]

Citizen Petition Submission; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is modernizing its administrative regulations regarding submission of citizen petitions to explicitly provide for electronic submission. The current regulation does not recognize electronic methods for

submitting citizen petitions; thus, this action will enable efficiency and ease in the filing of citizen petitions.

DATES: This final rule is effective December 19, 2013.

FOR FURTHER INFORMATION CONTACT: Lisa M. Helmanis, Office of Policy, Regulations Policy Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-9135.

SUPPLEMENTARY INFORMATION: FDA is updating its administrative regulations in 21 CFR part 10 to include an electronic method for citizen petition submissions and to remove references only to written documents. The Agency still allows for non-electronic submissions, however, electronic submissions of a citizen petition to a specific electronic docket presents a simpler and straightforward approach. FDA has created a single docket on <http://www.regulations.gov>, the U.S. Government's consolidated docket Web site for Federal Agencies, for the initial electronic submission of all citizen petitions. The FDA Electronic Method for Submission of Citizen Petitions Docket, Docket No. FDA 2013-S-0610, allows the petitioner to create an electronic submission through <http://www.regulations.gov> and provides an alternative to the current system of submission for citizen petitions. Electronic submissions through <http://www.regulations.gov> will provide the submitter with an immediate record of the time of submission. FDA's Division of Dockets Management (DDM) (<http://www.fda.gov/RegulatoryInformation/Dockets/default.htm>) will continue to inform the submitter of formal filing; however, tracking will be more easily accomplished through electronic submission.

DDM will receive the electronically submitted citizen petition through the Federal Dockets Management System, the Agency component of <http://www.regulations.gov>. Subsequently, DDM will review the electronic submission and when it accepts the citizen petition for filing, DDM will assign a docket number to that petition, different from the FDA electronic submission docket number. This unique docket number from DDM identifies the docket for that particular citizen petition for all future filings and submissions related only to that citizen petition. Subsequent submissions associated with that citizen petition will refer to the assigned unique docket number. The advantage to this change is that it ensures efficiency and ease in communication, quicker interaction between citizen petitioners and FDA,