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Robert Sturgell,

Acting Administrator.

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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 742, 744 and 746

[Docket No. 0811241505-81513-01]

RIN 0694-AE50

License Requirements Policy for Iran and for Certain Weapons of Mass Destruction Proliferators

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Interim final rule.

SUMMARY: This rule revises and clarifies the Export Administration Regulations (EAR) provisions that apply specifically to Iran in order to promote consistency, reduce redundancy and clarify the role of the Bureau of Industry and Security (BIS) in connection with the implementation of United States export control policy towards Iran. It establishes a new license requirement for reexports of items classified under ten Export Control Classification Numbers (ECCNs) that previously did not require a license for reexport to Iran under the EAR. This rule also imposes license requirements on parties who have been listed as proliferators of weapons of mass destruction or as supporters of such proliferators pursuant to Executive Order 13382. BIS is making these changes to provide greater clarity and consistency with respect to policies towards Iran and to harmonize BIS license requirements with Department of the Treasury license requirements regarding proliferators of weapons of mass destruction.

DATES: This rule is effective January 15, 2009.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

Background

The EAR imposes license requirements on certain exports and reexports to Iran. These license requirements apply in addition to any requirements for authorization to export

or reexport to Iran that are imposed by the Department of the Treasury, Office of Foreign Assets Control (OFAC), which maintains a comprehensive embargo against Iran, as described in the Iranian Transactions Regulations (31 CFR part 560). The EAR license requirements and licensing policy that apply specifically and expressly to Iran are in parts 742 and 746 of the EAR. This rule makes changes to those parts to promote consistency, reduce redundancy and to clarify the role of the Bureau of Industry and Security (BIS) in connection with the enforcement of United States export control policy towards Iran. It establishes a license requirement for reexports of items classified under ten Export Control Classification Numbers (ECCNs) that previously did not require a license for reexport to Iran under the EAR. This rule also adds a new § 744.8 to the EAR that imposes a license requirement on exports and reexports to parties listed by OFAC in Appendix A to 31 CFR Chapter V with the bracketed suffix [NPWMD].

Revisions to Part 742—Anti-Terrorism (AT) Controls

Section 742.8 of the EAR describes the license requirements and licensing policy for items controlled for anti-terrorism (AT) reasons to Iran. Prior to publication of this rule, reexports of items classified under ECCNs 2A994, 3A992.a, 5A991.g, 5A992, 6A991, 6A998, 7A994, 8A992.d, .e, .f, and .g, 9A990.a and .b, 9A991.d and .e, were not subject to license requirements under the EAR when reexported to Iran. In addition, the items controlled under these ECCNs were not treated as “controlled U.S. content” when incorporated into foreign made items being exported from abroad to Iran for purposes of determining whether the foreign made item had sufficient “controlled U.S. content” to be subject to the EAR. This rule revises § 742.8 to make those items subject to reexport license requirements under the EAR and to treat them as “controlled U.S. content.”

This rule also adds ECCNs 1C350, 1C355 and 1C395 to the license requirements paragraph in § 742.8. These three ECCNs contain license requirements that state “anti-terrorism” as a reason for control and that apply to Iran either by name or as part of Country Group E:1. However, prior to publication of this rule, these three ECCNs were not referenced in § 742.8(a). Adding these three ECCNs § 742.8(a) make that section consistent with BIS’s policy of stating all anti-

terrorism license requirements that apply to Iran in that section.

In addition, this rule moves all descriptions of transactions that are subject to the requirements of section 6(j) of the Export Administration Act and those that are subject to the requirements of section 6(a) of that Act from Supplement No. 2 to part 742 into § 742.8(a)(4). Section 6(j) applies when the Secretary of State determines that the export of an item could make a significant contribution to the military potential of a country that has repeatedly provided support for acts of international terrorism, or could enhance the ability of such country to support acts of international terrorism. BIS may not issue a license for transactions subject to section 6(j) without giving 30 days advance notice to certain committees of Congress. License applications for items controlled to designated terrorist-supporting countries under Section 6(a) are also reviewed to determine whether section 6(j) applies.

Finally, this rule removes all references to “contract sanctity” dates applicable to Iran from Supplement No. 2 to part 742. The “contract sanctity” dates refer to the dates on which reports that are prerequisites to imposing, expanding or extending foreign policy controls pursuant to Section 6 of the Export Administration Act were delivered to Congress. Transactions to fulfill contracts entered into prior to those dates may be subject to the rules that were in effect prior to delivery of the report. Removing the dates from Supplement No. 2 to Part 742 has no effect on the rights of any person to assert that a transaction is subject to earlier rules.

Revisions to Part 744—Control Policy: End-Use and End-User Based

This rule adds a new § 744.8, which imposes a license requirement on certain parties whom the Department of the Treasury, Office of Foreign Assets Control (OFAC) has listed in Appendix A to 31 CFR Chapter V with the bracketed suffix [NPWMD]. OFAC also provides lists of these parties in a variety of data formats at <http://www.treas.gov/offices/enforcement/ofac/sdn/index.shtml>. OFAC lists such parties pursuant to its authority under Executive Order 13382 of June 28, 2005. Executive Order 13382 blocks the property and interests in property of certain parties determined to be weapons of mass destruction proliferators or their supporters.

This rule complements OFAC’s regulatory authority under Executive Order 13382. For transactions requiring

authorization from both OFAC and BIS (pursuant to Section 744.8 of the EAR), authorization from OFAC will serve to meet EAR license requirements. However, for exports and reexports involving listed parties in situations where OFAC authorization is not required and where the item being exported or reexported is subject to the Export Administration Regulations, a BIS license must be obtained.

This rule also makes a technical and conforming change by referring to the new § 744.8 in § 744.1(a).

Revisions to Part 746—Embargoes and Special Controls

This rule removes from the introductory paragraph of § 746.7, the extensive discussion of the authority of the Department of the Treasury to implement comprehensive trade sanctions against Iran. That discussion has no legal effect for purposes of the EAR and could be a source of confusion.

As noted in the discussion of the revisions to part 742 described above, prior to publication of this rule, reexports of items classified under ECCNs 2A994, 3A992.a, 5A991.g, 5A992, 6A991, 6A998, 7A994, 8A992.d, .e, .f, and .g, 9A990.a and .b, 9A991.d and .e, were not subject to license requirements under the EAR when being reexported to Iran. This rule revises § 746.7 to make those items subject to reexport license requirements.

This rule also adds ECCNs 0A982, 0A985, 0E982, 1C355, 1C395, 2A994, 2D994, 2E994 to the license requirements paragraph in § 746.7. These eight ECCNs contain license requirements that are not based on the Commerce Country Chart, but that apply to Iran either by name or as part of Country Group E:1. BIS's policy is to state all of the Commerce Control List based license requirements that apply to Iran in § 746.7. However, prior to publication of this rule, these eight ECCNs were not referenced in the license requirements paragraph in § 746.7. Adding these eight ECCNs to that license requirements paragraph makes § 746.7 consistent with BIS's policy of stating all license requirements that apply to Iran in that section.

In addition, this rule removes the definition of "U.S. person" from § 746.7 because that term is not used with respect to any BIS license requirements in that section.

This rule also adds a statement of licensing policy to § 746.7 indicating that applications for licenses for transactions for humanitarian reasons or for the safety of civil aviation and safe operation of U.S.-origin aircraft will be considered on a case-by-case basis.

Applications for other purposes generally will be denied. This addition aligns § 746.7 more closely with OFAC's Iranian Transactions Regulations.

Finally this rule revises for clarity and precision a prohibition against exporting or reexporting items that are subject to the EAR if the transaction is prohibited by the Iranian Transactions Regulations and not authorized by OFAC that, prior to publication of this rule appeared in the introductory paragraph of § 746.7. This rule also moves that statement to its own designated paragraph. BIS is making this change to place emphasis on that prohibition with a view towards enhancing its enforceability.

Consistent with the provisions of section 6 of the Export Administration Act of 1979, as amended (EAA), a foreign policy report was submitted to Congress on January 9, 2009, notifying Congress of the imposition of foreign policy-based licensing requirements reflected in this rule.

Although the EAA expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), which has been extended by successive Presidential Notices, the most recent being that of July 23, 2008, 73 FR 43603 (July 25, 2008), has continued the EAR 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 that has been approved by the OMB under control number 0694-0088, "Simplified Network Application Processing + System (SNAP+) and the Multipurpose Export License Application" which carries a burden hour estimate of 58 minutes to prepare and submit form BIS-748. Miscellaneous and recordkeeping activities account for 12 minutes per submission. BIS believes that this rule will make no change in the number of submissions under this collection or in the estimated burden. Send comments regarding these burden estimates or any other aspect of these collections of information, including suggestions for reducing the burden, to

Jasmeet Seehra Office of Management and Budget, by e-mail at jseehra@omb.eop.gov or by fax to (202) 395-7285; and to the Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, Room 2705, 14th Street and Pennsylvania Ave., NW., Washington, DC 20230.

3. This rule does not contain policies with Federalism implications as that term is defined in 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 or foreign affairs function of the United States (see 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 rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are not applicable.

List of Subjects

15 CFR Part 742

Exports, Terrorism.

15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

15 CFR Part 746

Exports, Reporting and recordkeeping requirements.

■ Accordingly, the Export Administration Regulations (15 CFR parts 730-774) are amended as follows.

PART 742—[AMENDED]

■ 1. The authority citation for part 742 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; Sec 1503, Public Law 108-11, 117 Stat. 559; 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, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003-23 of May 7, 2003, 68 FR 26459, May 16, 2003; Notice of July 23, 2008, 73 FR 43603 (July 25, 2008); Notice of November 10, 2008, 73 FR 67097 (November 12, 2008).

■ 2. Revise § 742.8(a)(1), remove and reserve § 742.8(a)(2), and revise § 742.8(a)(4) and § 742.8(c) to read as follows:

§ 742.8 Anti-terrorism: Iran.

(a) *License Requirements.* (1) A license is required for anti-terrorism purposes to export or reexport to Iran any item for which AT column 1 or AT column 2 is indicated in the Country Chart column of the applicable ECCN or any item described in ECCNs 1C350, 1C355, 1C395, 2A994, 2D994 and 2E994. See paragraph (a)(5) of this section for controls maintained by the Department of the Treasury. See § 746.7 of the EAR for additional EAR license requirements that apply to Iran.

(2) [Reserved]

* * * * *

(4) In support of U.S. foreign policy applicable to terrorism-supporting countries, the EAR imposes anti-terrorism license requirements on exports and reexports to Iran pursuant to sections 6(j) and 6(a) of the Export Administration Act.

(i) *Section 6(j) anti-terrorism controls.* Section 6(j) requirements apply to all exports and reexports destined to the police, military or other sensitive end-users of items listed on the Commerce Control List (Supp. No. 1 to part 774 of the EAR) for which any listed reason for control in the applicable ECCN is NS (national security), CB (chemical or biological weapons proliferation), MT (missile proliferation), NP (nuclear weapons proliferation) or an Export Control Classification Number ending in “18” (military related items). BIS may not issue a license for a transaction subject to section 6(j) controls until 30 days after the notification described in Section 6(j)(2) of the Export Administration Act is delivered to the committees of Congress specified in that section. License applications for all other items controlled under section 6(a) are also reviewed to determine whether section 6(j) applies.

(ii) *Section 6(a) anti-terrorism controls.* Section 6(a) requirements apply to all exports and reexports regardless of the end user of items described in paragraph (a)(1) of this section. * * *

(c) *Contract Sanctity.* Section 6(f) of the Export Administration Act requires that a report be delivered to Congress before foreign policy based export controls are imposed, expanded or extended. Consistent with section 6(p) of the Export Administration Act, certain exports or reexports in fulfillment of contracts entered into before such delivery of the report applicable to a particular license

requirement or licensing policy may be subject to the license requirements and licensing policy that were in force before the report was delivered. License applicants who wish to have their application considered under such pre-existing requirements or policy must include evidence of the pre-existing contract with their license applications.

* * * * *

Supplement No. 2 to Part 742—[Amended]

■ 3. Amend Supplement No. 2 to Part 742 by:

■ a. Removing “Iran,” from the heading;

■ b. Removing “Iran,” from paragraph (a), paragraph (b)(1) and paragraph (b)(3), introductory text;

■ c. Removing the phrase “for Iran, items in paragraphs (c)(6) through (c)(44) of this Supplement,” from paragraph (b)(3)(ii);

■ d. Removing “Iran,” and “742.8,” from the first sentence of paragraph (c), introductory text;

■ e. Removing “Iran” from each place that it appears in the second sentence of paragraph (c), introductory text;

■ f. Removing the third, fourth and fifth sentences of paragraph (c) introductory text;

■ g. Removing and reserving paragraph (c)(1)(i);

■ h. Removing “Iran,” from the first sentence of paragraph (c)(2) and the phrase “Iran and” from the second sentence of paragraph (c)(2);

■ i. Removing “Iran,” from the first sentence of paragraph (c)(3);

■ j. Removing “Iran and” from the second sentence of paragraph (c)(3);

■ k. Removing and reserving paragraphs (c)(4)(i), (c)(5)(i), (c)(6)(i), (c)(7)(i), (c)(8)(i), (c)(9)(i), (c)(10)(i), (c)(11)(i), (c)(12)(i), (c)(13)(i), (c)(14)(i), (c)(15)(i), (c)(16)(i), (c)(17)(i), (c)(18)(i), (c)(19)(i), (c)(20)(i), (c)(21)(i), (c)(22)(i), (c)(23)(i), (c)(24)(i), (c)(25)(i), (c)(26)(i)(A);

■ l. Removing “Iran,” from paragraph (c)(27); and

■ m. Removing and reserving paragraphs (c)(27)(i), (c)(28)(i), (c)(29)(i), (c)(30)(i), (c)(31)(i), (c)(32)(i), (c)(33)(i), (c)(34)(i), (c)(35)(i), (c)(36)(i), (c)(37)(i), (c)(38)(i), (c)(39)(i)(A), (c)(39)(ii)(A), (c)(40)(i), (c)(41)(i), (c)(42)(i), (c)(43)(i) and (c)(44)(i).

PART 744—[AMENDED]

■ 4. The authority citation for 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 July 23, 2008, 73 FR 43603 (July 25, 2008); Notice of November 10, 2008, 73 FR 67097 (November 12, 2008).

■ 5. In § 744.1 revise the fifth sentence of paragraph (a)(1) and add a new sentence between the current fifth and sixth sentences to read as follows:

§ 744.1 General provisions.

(a)(1) * * * Section 744.7 prohibits exports and reexports of certain items for certain aircraft and vessels. Section 744.8 prohibits exports and reexports without authorization to certain parties who have been designated as proliferators of weapons of mass destruction or as supporters of such proliferators pursuant to Executive Order 13382.

* * * * *

■ 6. Add a § 744.8 to read as follows:

§ 744.8 Restrictions on exports and reexports to persons designated pursuant to Executive Order 13382—Blocking Property of Weapons of Mass Destruction Proliferators and Their Supporters.

BIS maintains restrictions on exports and reexports to persons designated in or pursuant to Executive Order 13382 of June 28, 2005 (Weapons of Mass Destruction Proliferators and their Supporters). Executive Order 13382 blocks the property and interests in property of persons named in or designated pursuant to Executive Order 13382 in the United States or that comes within the United States or within the possession or control of United States persons. The parties whose property or interests in property are blocked pursuant to Executive Order 13382 are identified by the Department of the Treasury, Office of Foreign Assets Control (OFAC) in Appendix A to 31 CFR Chapter V with the bracketed suffix [NPWMD]. This section imposes export and reexport license requirements for items subject to the EAR on those same parties to further the objectives of Executive Order 13382.

(a) *License requirement(s) and authorization.*

(1) *EAR license requirement.* A license is required for the export or reexport of any item subject to the EAR to any party listed in Appendix A to 31 CFR Chapter V with the bracketed suffix [NPWMD].

(2) *BIS authorization.* (i) To avoid duplication, U.S. persons are not required to seek separate authorization from BIS for an export or reexport to a

party listed in Appendix A to 31 CFR Chapter V with the bracketed suffix [NPWMD] of an item subject to the EAR. If OFAC authorizes an export from the United States or an export or reexport by a U.S. person to a party listed in Appendix A to 31 CFR Chapter V with the bracketed suffix [NPWMD], such authorization constitutes authorization for purposes of the EAR as well.

(ii) U.S. persons must seek authorization from BIS for the export or reexport to a party listed in Appendix A to 31 CFR Chapter V with the bracketed suffix [NPWMD] of any item subject to the EAR that is not subject to OFAC's regulatory authority pursuant to Executive Order 13382.

(iii) Non-U.S. persons must seek authorization from BIS for any export from abroad or reexport to a party listed in Appendix A to 31 CFR Chapter V with the bracketed suffix [NPWMD] of any item subject to the EAR.

(iv) Any export or reexport to a party listed in Appendix A to 31 CFR Chapter V with the bracketed suffix [NPWMD] of any item subject to the EAR and not authorized by OFAC is a violation of the EAR.

(v) Any export or reexport by a U.S. person to a party listed in Appendix A to 31 CFR Chapter V with the bracketed suffix [NPWMD] of any item subject to the EAR that is not subject to regulation by OFAC and not authorized by BIS is a violation of the EAR. Any export from abroad or reexport by a non-U.S. person to a party listed in Appendix A to 31 CFR Chapter V with the bracketed suffix [NPWMD] of any item subject to the EAR and not authorized by BIS is a violation of the EAR.

(3) *Relation to other EAR license requirements.* The license requirements in this section supplement any other requirements set forth elsewhere in the EAR.

(b) *License exceptions.* No license exceptions are available for the EAR license requirements imposed in this section.

(c) *Licensing policy.* Applications for EAR licenses required by this section generally will be denied. You should consult with OFAC concerning transactions subject to OFAC licensing requirements.

(d) *Contract sanctity.* Contract sanctity provisions are not available for license applications reviewed under this section.

PART 746—[AMENDED]

■ 7. The authority citation for part 746 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. 287c; Sec 1503,

Public Law 108–11, 117 Stat. 559; 22 U.S.C. 6004; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 614; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 13222, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23 of May 7, 2003, 68 FR 26459, May 16, 2003; Presidential Determination 2007–7 of December 7, 2006, 72 FR 1899 (January 16, 2007); Notice of July 23, 2008, 73 FR 43603 (July 25, 2008).

■ 8. Revise § 746.7 to read as follows:

§ 746.7 Iran.

The Treasury Department's Office of Foreign Assets Control (OFAC) administers a comprehensive trade and investment embargo against Iran. This embargo includes prohibitions on exports and certain reexport transactions involving Iran, including transactions dealing with items subject to the EAR. These prohibitions are set forth in OFAC's Iranian Transactions Regulations (31 CFR part 560). In addition, BIS maintains licensing requirements on exports and reexports to Iran under the EAR as described in paragraph (a)(1) of this section or elsewhere in the EAR (*See, e.g.*, § 742.8—Anti-terrorism: Iran).

(a) *License requirements.*

(1) *EAR license requirements.* A license is required under the EAR to export or reexport to Iran any item on the CCL containing a CB Column 1, CB Column 2, CB Column 3, NP Column 1, NP Column 2, NS Column 1, NS Column 2, MT Column 1, RS Column 1, RS Column 2, CC Column 1, CC Column 2, CC Column 3, AT Column 1 or AT Column 2 in the Country Chart Column of the License Requirements section of an ECCN or classified under ECCNs 0A980, 0A982, 0A983, 0A985, 0E982, 1C355, 1C395, 1C980, 1C981, 1C982, 1C983, 1C984, 2A994, 2D994, 2E994, 5A980, 5D980, or 5E980.

(2) *BIS authorization.* To avoid duplication, exporters or reexporters are not required to seek separate authorization from BIS for an export or reexport subject both to the EAR and to OFAC's Iranian Transactions Regulations. Therefore, if OFAC authorizes an export or reexport, such authorization is considered authorization for purposes of the EAR as well. Transactions that are not subject to OFAC regulatory authority may require BIS authorization.

(b) *Licensing Policy.* Applications for licenses for transactions for humanitarian reasons or for the safety of civil aviation and safe operation of U.S.-origin aircraft will be considered on a case-by-case basis. Licenses for other purposes generally will be denied.

(c) *License Exceptions.* No license exceptions may be used for exports or reexports to Iran.

(d) *EAR Anti-terrorism controls.* The Secretary of State has designated Iran as a country that has repeatedly provided support for acts of international terrorism. Anti-terrorism license requirements and licensing policy regarding Iran are set forth in § 742.8 of the EAR.

(e) *Prohibition on exporting or reexporting EAR items without required OFAC authorization.* No person may export or reexport any item that is subject to the EAR if such transaction is prohibited by the Iranian Transactions Regulations (31 CFR part 560) and not authorized by OFAC. The prohibition of this paragraph (e) applies whether or not the EAR requires a license for the export or reexport.

Dated: January 9, 2009.

Christopher R. Wall,
Assistant Secretary for Export
Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 56

[Docket No. FDA–2004–N–0117] (formerly Docket No. 2004N–0242)

RIN 0910–AB88

Institutional Review Boards; Registration Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, we) is issuing a final rule to require institutional review boards (IRBs) to register through a system maintained by the Department of Health and Human Services (HHS). The registration information includes contact information (such as addresses and telephone numbers), the number of active protocols involving FDA-regulated products reviewed during the preceding 12 months, and a description of the types of FDA-regulated products involved in the protocols reviewed. The IRB registration requirements will make it easier for FDA to inspect IRBs and to convey information to IRBs.

DATES: This rule is effective July 14, 2009. This effective date is necessary to allow refinement of the electronic