

[FR Doc. E9-17107 Filed 7-20-09; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF COMMERCE

### Bureau of Industry and Security

#### 15 CFR Part 744

[Docket No. 090414651-91046-01]

RIN 0694-AE59

#### **Addition and Removal of Certain Persons on the Entity List: Addition of Persons Acting Contrary to the National Security or Foreign Policy Interests of the United States; Removal of Persons Based on ERC Annual Review and Removal Requests; and Entry Modified for Purposes of Clarification**

**AGENCY:** Bureau of Industry and Security, Commerce.

**ACTION:** Final rule.

**SUMMARY:** This rule amends the Export Administration Regulations (EAR) by adding thirteen additional persons to the Entity List (Supplement No. 4 to Part 744) on the basis of Section 744.11 of the EAR. The persons that are added to the Entity List have been determined by the U.S. Government to be acting contrary to the national security or foreign policy interests of the United States. This rule also amends the Export Administration Regulations by removing three persons from the Entity List. BIS removes one of the three persons from the Entity List as a result of a determination made by the United States Government during the annual review of the Entity List conducted by the End-User Review Committee (ERC). The two remaining persons are removed from the Entity List in response to a request for removal. Finally, this rule makes a correction to the address of one person listed on the Entity List. The Entity List provides notice to the public that certain exports and reexports to parties identified on the Entity List require a license from the Bureau of Industry and Security (BIS) and that availability of License Exceptions in such transactions is limited.

**DATES:** Effective Date: This rule is effective July 21, 2009. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis.

**ADDRESSES:** You may submit comments, identified by RIN 0694-AE59, by any of the following methods:

*E-mail:* [publiccomments@bis.doc.gov](mailto:publiccomments@bis.doc.gov). Include "RIN 0694-AE59" in the subject line of the message.

*Fax:* (202) 482-3355. Please alert the Regulatory Policy Division, by calling (202) 482-2440, if you are faxing comments.

*Mail or Hand Delivery/Courier:* Timothy Mooney, U.S. Department of Commerce, Bureau of Industry and Security, Regulatory Policy Division, 14th St. & Pennsylvania Avenue, NW., Room 2705, Washington, DC 20230, Attn: RIN 0694-AE59.

Send comments regarding the collection of information associated with this rule, including suggestions for reducing the burden, to Jasmeet K. Seehra, Office of Management and Budget (OMB), by e-mail to [Jasmeet\\_K\\_Seehra@omb.eop.gov](mailto:Jasmeet_K_Seehra@omb.eop.gov), or by fax to (202) 395-7285; and to the Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, 14th St., & Pennsylvania Avenue, NW., Room 2705, Washington, DC 20230. Comments on this collection of information should be submitted separately from comments on the final rule (*i.e.*, RIN 0694-AE59)—all comments on the latter should be submitted by one of the three methods outlined above.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Scott Sangine, End-User Review Committee, Office of the Assistant Secretary, Export Administration, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482-3343, Fax: (202) 482-3911, E-mail: [bscott@bis.doc.gov](mailto:bscott@bis.doc.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

The Entity List provides notice to the public that certain exports and reexports to parties identified on the Entity List require a license from the Bureau of Industry and Security (BIS) and that availability of License Exceptions in such transactions is limited. BIS first published the Entity List in February 1997 as part of its efforts to inform the public of entities that have engaged in activities that could result in an increased risk of diversion of exported and reexported items to weapons of mass destruction (WMD) programs. Since its initial publication, grounds for inclusion on the Entity List have expanded to activities sanctioned by the Department of State and activities contrary to U.S. national security and/or foreign policy interests.

##### *ERC Entity List Decisions*

Pursuant to Supplement No. 5 to part 744 (Procedures for End-User Review Committee Entity List Decisions) of the EAR, the ERC, composed of representatives of the Departments of

Commerce, State, Defense, Energy and, where appropriate, the Treasury, makes all decisions to make additions to, removals from or changes to the Entity List. The ERC is chaired by the Department of Commerce and makes all decisions to add an entry to the Entity List by majority vote and all decisions to remove or modify an entry by unanimous vote.

The ERC made a determination to add thirteen persons to the Entity List on the basis of § 744.11 (License Requirements that Apply to Entities Acting Contrary to the National Security or Foreign Policy Interests of the United States) of the EAR. The thirteen entities added to the Entity List consist of three persons in Germany, five persons in Hong Kong and five persons in Ireland.

The ERC reviewed § 744.11(b) (Criteria for revising the Entity List) in making the determination to add these persons to the Entity List. Under that paragraph, entities for which there is reasonable cause to believe, based on specific and articulable facts, that the entity has been involved, is involved, or poses a significant risk of being or becoming involved in activities that are contrary to the national security or foreign policy interests of the United States and those acting on behalf of such entities may be added to the Entity List pursuant to § 744.11.

Paragraph (b) of § 744.11 includes an illustrative list of activities that could be contrary to the national security or foreign policy interests of the United States. This illustrative list of activities of concern is described under paragraphs (b)(1)–(b)(5). The persons being added to the Entity List under this rule have been determined by the ERC to be involved in activities that could be contrary to the national security or foreign policy interests of the United States.

In addition, the ERC made a determination to remove three entities from the Entity List. As outlined in Supplement No. 5 to part 744, under the last paragraph of that Supplement, the ERC conducts a systematic review of the Entity List. Based upon the results of that annual review, the ERC made a determination that one person in Pakistan should be removed from the Entity List, because this person is not engaged in activities that would warrant including the person on the Entity List.

The ERC also made a determination to remove two other persons, located in the United Arab Emirates, as a result of a request for removal submitted by these two listed entities. Based upon the review of the information provided in the removal request, in accordance with § 744.16 and further review that was

conducted by the ERC's member agencies of these end-users, the ERC determined that these two persons should be removed from the Entity List. The ERC decision to remove Feroz Jafar and Teletron took into account these two listed persons' cooperation with the U.S. Government, as well as these listed persons' assurances of future compliance with the EAR. In accordance with § 744.16(c), the Deputy Assistant Secretary for Export Administration has sent written notification to these persons informing them of the ERC's decision to remove them from the Entity List.

#### *Additions to the Entity List*

This rule implements the decision of the ERC to add thirteen persons to the Entity List on the basis of § 744.11 of the EAR. For all of the thirteen persons added to the Entity List, the ERC specified a license requirement for all items subject to the EAR and established a license application review policy of a general policy of denial. The license requirement applies to any transaction in which items are to be exported or reexported to such persons or in which such persons act as purchaser, intermediate consignee, ultimate consignee, or end-user. In addition, no license exceptions are available for shipments to those persons being added to the Entity List.

Specifically, this rule adds the following thirteen persons to the Entity List:

#### *Germany*

(1) *Christof Schneider*, Margaretenweg #10, 42929 Wermelskirchen, Germany;

(2) *Hans Werner Schneider*, Bertha von Suttner Weg #1, 42929 Wermelskirchen, Germany; and

(3) *Schneider GMBH*, Thomas Mann Str. 35–37, 42929 Wermelskirchen, Germany; and P.O. Box 1523, Wermelskirchen, 42908 DE; and Thomas Mann Str., 35–37, P.O. Box 1523, Wermelskirchen, 42908 DE.

#### *Hong Kong*

(4) *Able City Development Limited*, Unit C, 9/F Neich Tower, 128 Gloucester Road, Wanchai, Hong Kong; and Unit 401, Harbour Ctr., Tower 2, 8 Hok Cheung Street, Hung Hom, Kowloon, Hong Kong;

(5) *Sik Yin Ngai, a.k.a., Spencer Ngai*, Unit 401, Harbour Ctr., Tower 2, 8 Hok Cheung Street Hung Hom, Kowloon, Hong Kong;

(6) *Siu Ching Ngai, a.k.a., Terry Ngai*, Unit C, 9/F Neich Tower, 128 Gloucester Road, Wanchai, Hong Kong;

(7) *Sysdynamic Limited*, Unit 716A, 7/F Enterprise Place (Building 9), No. 5

Science Park West Avenue, Hong Kong Science Park, Shatin, New Territories, Hong Kong; and Unit 401, Harbour Ctr., Tower 2, 8 Hok Cheung Street, Hung Hom, Kowloon, Hong Kong; and

(8) *Tam Shue Ngai*, Unit C, 9/F Neich Tower, 128 Gloucester Road, Wanchai, Hong Kong.

#### *Ireland*

(9) *Mac Aviation Group, a.k.a., Mac Aviation Limited*, Cloonmull House, Drumcliffe, County Sligo, Ireland;

(10) *Mac Aviation Nigeria*, Cloonmull House, Drumcliffe, County Sligo, Ireland;

(11) *Sean Byrne*, Cloonmull House, Drumcliffe, County Sligo, Ireland;

(12) *Sean McGuinn*, Cloonmull House, Drumcliffe, County Sligo, Ireland; and

(13) *Thomas McGuinn a.k.a., Tom McGuinn*, Cloonmull House, Drumcliffe, County Sligo, Ireland.

A BIS license is required for the export or reexport of any item subject to the EAR to any of the persons listed above, including any transaction in which any of the listed persons will act as purchaser, intermediate consignee, ultimate consignee, or end-user of the items. This listing of these persons also prohibits the use of License Exceptions (see part 740 of the EAR) for exports and reexports of items subject to the EAR involving such persons.

#### *Removal From the Entity List*

One person being removed from the Entity List with this rule is removed on the basis of the results of the annual review of the Entity List that was conducted by the ERC in accordance with the procedures outlined in Supplement No. 5 to part 744. The entity is located in Pakistan:

#### *Pakistan*

(1) *Karachi CBW Research Institute, University of Karachi's Husein Ebrahim Jamal Research Institute of Chemistry (HEJRIC)*.

Two additional persons are being removed under this rule as a result of the submission of a formal request for removal based upon the procedures outlined in § 744.16 of the EAR. These two entities are located in the United Arab Emirates:

#### *United Arab Emirates*

(2) *Feroz Jafar*, Al Salam St., P.O. Box 2946 Abu Dhabi, U.A.E.; and

(3) *Teletron*, Al Salam St., P.O. Box 2946, Abu Dhabi, U.A.E.

The removal of these three persons from the Entity List eliminates the existing license requirements in Supplement No. 4 to part 744 for

exports and reexports to these persons. However, the removal of these persons from the Entity List does not relieve persons of other obligations under part 744 of the EAR or under other parts of the EAR. Neither the removal of a person from the Entity List nor the removal of Entity List-based license requirements relieves persons of their obligations under General Prohibition 5 in § 736.2(b)(5) of the EAR which provides that, "you may not, without a license, knowingly export or reexport any item subject to the EAR to an end-user or end-use that is prohibited by part 744 of the EAR." Nor do such removals relieve persons of their obligation to apply for export or reexport licenses required by other provisions of the EAR. BIS strongly urges the use of Supplement No. 3 to part 732 of the EAR, "BIS's 'Know Your Customer' Guidance and Red Flags," when persons are involved in transactions that are subject to the EAR.

#### *Correction to the Entity List*

This rule revises the address provided for one person that was listed on the Entity List from the United Arab Emirates. Specifically, this rule to correct an inadvertent removal of the name of the city where the person is located, which occurred in a December 5, 2008 (73 FR 73999) final rule that revised this entry.

This rule revises the name and address of this one listed person, as follows:

#### *United Arab Emirates*

(1) *Advanced Technology General Trading Company*, Dubai, U.A.E. (See alternate address under Kuwait).

#### *Savings Clause*

Shipments of items removed from eligibility for a License Exception or export or reexport without a license (NLR) as a result of this regulatory action that were on dock for loading, on lighter, laden aboard an exporting or reexporting carrier, or en route aboard a carrier to a port of export or reexport, on July 21, 2009, pursuant to actual orders for export or reexport to a foreign destination, may proceed to that destination under the previous eligibility for a License Exception or export or reexport without a license (NLR) so long as they are exported or reexported before August 20, 2009. Any such items not actually exported or reexported before midnight on August 20, 2009, require a license in accordance with this rule.

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order

13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as extended by the Notice of July 23, 2008, 73 FR 43603 (July 23, 2008), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act.

#### Rulemaking Requirements

1. This 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 be 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 the OMB under control numbers 0694–0088, “Multi-Purpose 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. Total burden hours associated with the Paperwork Reduction Act and Office and Management and Budget control number 0694–0088 are expected to increase slightly as a result of this rule.

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 in 15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

■ Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–774) 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; 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).

■ 2. Supplement No. 4 to part 744 is amended:

■ a. By removing under Pakistan, this one Pakistani entity “Karachi CBW Research Institute, University of Karachi’s Husein Ebrahim Jamal Research Institute of Chemistry (HEJRIC)”;

■ b. By removing under United Arab Emirates, these two U.A.E. entities “Feroz Jafar, Al Salam St., P.O. Box 2946, Abu Dhabi, U.A.E.”; and “Telectron, Al Salam St., P.O. Box 2946, Abu Dhabi, U.A.E.”;

■ c. By adding under Germany, in alphabetical order, three German entities;

■ d. By adding under Hong Kong, in alphabetical order, five Hong Kong entities;

■ e. By adding, in alphabetical order, the country of Ireland and five Irish entities; and

■ f. By revising under United Arab Emirates, in alphabetical order, one U.A.E. entity.

The additions and revision read as follows:

#### SUPPLEMENT NO. 4 TO PART 744—ENTITY LIST

| Country   | Entity                                                                                                                                                                                    | License requirement                                          | License review policy | Federal Register citation                     |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|-----------------------|-----------------------------------------------|
| GERMANY   |                                                                                                                                                                                           |                                                              |                       |                                               |
|           | Christof Schneider, Margaretenweg #10, 42929 Wermelskirchen, Germany.                                                                                                                     | For all items subject to the EAR. (See § 744.11 of the EAR). | Presumption of denial | 74 FR [INSERT FR PAGE NUMBER], July 21, 2009. |
|           | Hans Werner Schneider, Bertha von Suttner Weg #1, 42929 Wermelskirchen, Germany.                                                                                                          | For all items subject to the EAR. (See § 744.11 of the EAR). | Presumption of denial | 74 FR [INSERT FR PAGE NUMBER], July 21, 2009. |
|           | Schneider GMBH, Thomas Mann Str. 35–37, 42929 Wermelskirchen, Germany; and P.O. Box 1523, Wermelskirchen, 42908 DE; and Thomas Mann Str., 35–37, P.O. Box 1523, Wermelskirchen, 42908 DE. | For all items subject to the EAR. (See § 744.11 of the EAR). | Presumption of denial | 74 FR [INSERT FR PAGE NUMBER], July 21, 2009. |
| HONG KONG | Able City Development Limited, Unit C, 9/F Neich Tower, 128 Gloucester Road, Wanchai, Hong Kong; and Unit 401, Harbour Ctr., Tower 2, 8 Hok Cheung Street, Hung Hom, Kowloon, Hong Kong.  | For all items subject to the EAR. (See § 744.11 of the EAR). | Presumption of denial | 74 FR [INSERT FR PAGE NUMBER], July 21, 2009. |

## SUPPLEMENT NO. 4 TO PART 744—ENTITY LIST—Continued

| Country               | Entity                                                                                                                                                                                                                                                | License requirement                                          | License review policy | Federal Register citation                                                                   |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|-----------------------|---------------------------------------------------------------------------------------------|
| *                     | *                                                                                                                                                                                                                                                     | *                                                            | *                     | *                                                                                           |
|                       | Sik Yin Ngai, a.k.a. Spencer Ngai, Unit 401, Harbour Ctr., Tower 2, 8 Hok Cheung Street, Hung Hom, Kowloon, Hong Kong.                                                                                                                                | For all items subject to the EAR. (See § 744.11 of the EAR). | Presumption of denial | 74 FR [INSERT FR PAGE NUMBER], July 21, 2009.                                               |
|                       | Siu Ching Ngai, a.k.a. Terry Ngai, Unit C, 9/F Neich Tower, 128 Gloucester Road, Wanchai, Hong Kong.                                                                                                                                                  | For all items subject to the EAR. (See § 744.11 of the EAR). | Presumption of denial | 74 FR [INSERT FR PAGE NUMBER], July 21, 2009.                                               |
| *                     | *                                                                                                                                                                                                                                                     | *                                                            | *                     | *                                                                                           |
|                       | Sysdynamic Limited, Unit 716A, 7/F Enterprise Place (Building 9), No. 5 Science Park West Avenue, Hong Kong Science Park, Shatin, New Territories, Hong Kong; and Unit 401, Harbour Ctr., Tower 2, 8 Hok Cheung Street, Hung Hom, Kowloon, Hong Kong. | For all items subject to the EAR. (See § 744.11 of the EAR). | Presumption of denial | 74 FR [INSERT FR PAGE NUMBER], July 21, 2009.                                               |
|                       | Tam Shue Ngai, Unit C, 9/F Neich Tower, 128 Gloucester Road, Wanchai, Hong Kong.                                                                                                                                                                      | For all items subject to the EAR. (See § 744.11 of the EAR). | Presumption of denial | 74 FR [INSERT FR PAGE NUMBER], July 21, 2009.                                               |
| *                     | *                                                                                                                                                                                                                                                     | *                                                            | *                     | *                                                                                           |
| IRELAND .....         | Mac Aviation Group, a.k.a. Mac Aviation Limited, Cloonmull House, Drumcliffe, County Sligo, Ireland.                                                                                                                                                  | For all items subject to the EAR. (See § 744.11 of the EAR). | Presumption of denial | 74 FR [INSERT FR PAGE NUMBER], July 21, 2009.                                               |
|                       | Mac Aviation Nigeria, Cloonmull House, Drumcliffe, County Sligo, Ireland.                                                                                                                                                                             | For all items subject to the EAR. (See § 744.11 of the EAR). | Presumption of denial | 74 FR [INSERT FR PAGE NUMBER], July 21, 2009.                                               |
|                       | Sean Byrne, Cloonmull House, Drumcliffe, County Sligo, Ireland.                                                                                                                                                                                       | For all items subject to the EAR. (See § 744.11 of the EAR). | Presumption of denial | 74 FR [INSERT FR PAGE NUMBER], July 21, 2009.                                               |
|                       | Sean McGuinn, Cloonmull House, Drumcliffe, County Sligo, Ireland.                                                                                                                                                                                     | For all items subject to the EAR. (See § 744.11 of the EAR). | Presumption of denial | 74 FR [INSERT FR PAGE NUMBER], July 21, 2009.                                               |
|                       | Thomas McGuinn a.k.a. Tom McGuinn, Cloonmull House, Drumcliffe, County Sligo, Ireland.                                                                                                                                                                | For all items subject to the EAR. (See § 744.11 of the EAR). | Presumption of denial | 74 FR [INSERT FR PAGE NUMBER], July 21, 2009.                                               |
| *                     | *                                                                                                                                                                                                                                                     | *                                                            | *                     | *                                                                                           |
| UNITED ARAB EMIRATES. | Advanced Technology General Trading Company, Dubai, U.A.E. (See alternate address under Kuwait).                                                                                                                                                      | For all items subject to the EAR. (See § 744.11 of the EAR). | Presumption of denial | 73 FR 54509 9/22/08<br>73 FR 74001 12/5/08<br>74 FR [INSERT FR PAGE NUMBER], July 21, 2009. |
| *                     | *                                                                                                                                                                                                                                                     | *                                                            | *                     | *                                                                                           |

Dated: July 16, 2009.

**Matthew S. Borman,**

*Acting Assistant Secretary for Export Administration.*

[FR Doc. E9-17295 Filed 7-20-09; 8:45 am]

BILLING CODE 3510-33-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 14

[Docket No. FDA-2009-N-0310]

#### Advisory Committee; Risk Communication Advisory Committee; Termination and Recharter

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the termination and the recharter of the Risk Communication Advisory Committee (the committee). These actions are needed to implement the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Food and Drug Administration Amendments Act of 2007, to change the committee from a discretionary to a statutory committee. This document also amends the agency's regulations which list advisory committees to reflect that the Risk Communication Advisory Committee has been rechartered and to revise the function statement.

**DATES:** This rule is effective July 21, 2009. The committee is being rechartered and the new charter will remain in effect until amended or terminated by the Commissioner of Food and Drugs (the Commissioner) or designee.

**FOR FURTHER INFORMATION CONTACT:** Lee Zwanziger, Office of Policy and Planning (HFP-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2895, FAX: 301-827-4050, or e-mail: [Lee.Zwanziger@fda.hhs.gov](mailto:Lee.Zwanziger@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the Federal Advisory Committee Act of October 6, 1972 (Public Law 92-463 (5 U.S.C. app. 2)); section 904 of the act (21 U.S.C. 394), as amended by the Food and Drug Administration Revitalization Act (Public Law 101-635); and 21 CFR 14.40(b), FDA is announcing the termination and the recharter of the committee by the Commissioner. The committee advises the Commissioner and designees on methods to effectively communicate risks associated with

products regulated by FDA, and in discharging responsibilities as they relate to helping ensure safe and effective drugs for human use and any other product for which FDA has regulatory responsibility. The committee also reviews and evaluates strategies and programs designed to communicate with the public about the risks and benefits of FDA-regulated products so as to facilitate optimal use of these products. In addition, the committee reviews and evaluates research relevant to such communication to the public by both FDA and other entities. It also facilitates interactively sharing risk and benefit information with the public to enable people to make informed independent judgments about using FDA-regulated products.

The committee will be composed of a core of 15 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in fields such as social marketing, health literacy, and other relevant areas. Members will include experts on risk communication; experts on emerging postmarket drug risks; and individuals knowledgeable about and experienced in the work of patient, consumer, and health professional organizations. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. Some members will be selected to provide experiential insight on the communication needs of the various groups who use FDA-regulated products. The latter may include patients and patients' family members; health professionals; communicators in health, medicine, and science; and persons affiliated with consumer, specific disease, or patient safety advocacy groups. The Commissioner or designee shall also have the authority to select from a group of individuals nominated by industry to serve temporarily as nonvoting members who are identified with industry interests. The number of temporary members selected for a particular meeting will depend on the meeting topic(s).

Under 5 U.S.C. 553(b)(3)(B) and (d) and 21 CFR 10.40(d) and (e), the agency finds good cause to dispense with notice and public comment procedures and to proceed to an immediate effective date on this rule. Notice and public comment and a delayed effective date are unnecessary and are not in the public interest as this final rule merely amends the information in § 14.100 (21 CFR 14.100) to reflect the rechartering of the

committee and to revise the function statement.

Therefore, the agency is amending § 14.100(a)(4)(i) and (a)(4)(ii) as set forth in the regulatory text of this document.

#### List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

#### PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

■ 1. The authority citation for 21 CFR part 14 continues to read as follows:

**Authority:** 5 U.S.C. App. 2; 15 U.S.C. 1451-1461, 21 U.S.C. 41-50, 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264; Pub. L. 107-109; Pub. L. 108-155.

■ 2. Section 14.100 is amended by revising paragraphs (a)(4)(i) and (a)(4)(ii) to read as follows:

#### § 14.100 List of standing advisory committees.

\* \* \* \* \*

(a) \* \* \*

(4) \* \* \*

(i) Date Rechartered: July 9, 2009.

(ii) Function: The committee reviews and evaluates strategies and programs designed to communicate with the public about the risks and benefits of FDA-regulated products so as to facilitate optimal use of these products. The committee also reviews and evaluates research relevant to such communication to the public by both FDA and other entities. It also facilitates interactively sharing risk and benefit information with the public to enable people to make informed independent judgments about use of FDA-regulated products.

\* \* \* \* \*

Dated: July 10, 2009.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

[FR Doc. E9-17218 Filed 7-20-09; 8:45 am]

BILLING CODE 4160-01-S