CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Dragan Momcilovic, Center for Veterinary Medicine (HFV–226), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5944, *dragan.momcilovic@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

In the **Federal Register** of June 3, 2015 (80 FR 31520), FDA published a notice of availability for a draft guidance entitled ''Veterinary Feed Directive Regulation Questions and Answers'' giving interested persons until August 3, 2015, to comment on the draft guidance. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated June 2015. This guidance also serves as a Small Entity Compliance Guide (SECG) to aid industry in complying with the requirements of the VFD final rule that published in the **Federal Register** on June 3, 2015 (80 FR 31708). FDA has prepared this SECG in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121). This document is intended to provide guidance to small businesses on the requirements of the final rule.

In 1996, Congress enacted the Animal Drug Availability Act (ADAA) to facilitate the approval and marketing of new animal drugs and medicated feeds. In passing the ADAA, Congress created a new regulatory category for certain animal drugs used in animal feed called VFD drugs. VFD drugs are new animal drugs intended for use in or on animal feed which are limited to use under the professional supervision of a licensed veterinarian. FDA published final regulations implementing the VFD-related provisions of the ADAA in 2000. On June 3, 2015, FDA published a VFD final rule that revised those VFD regulations and introduced clarifying changes to specified definitions, and published the draft revised guidance for comment.

## II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on VFD regulation questions and answers. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 558.6 have been approved under OMB control number 0910–0363.

## IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: September 23, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–24685 Filed 9–29–15; 8:45 am]

**BILLING CODE 4164–01–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 870

**[Docket No. FDA–2015–N–3165]**

## Medical Devices; Cardiovascular Devices; Classification of the Steerable Cardiac Ablation Catheter Remote Control System

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

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying the steerable cardiac ablation catheter remote control system into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the steerable cardiac ablation catheter remote control system's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

**DATES:** This order is effective September 30, 2015. The classification was applicable on December 18, 2014.

**FOR FURTHER INFORMATION CONTACT:** Deborah Castillo, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1321, Silver Spring, MD 20993–0002, 301–796–4908.

**SUPPLEMENTARY INFORMATION:**

## I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless, and until, the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate

device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1) of the FD&C Act. Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

On February 14, 2014, Catheter Robotics, Inc. submitted a request for classification of the AMIGO Remote Catheter System under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 18, 2014, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 870.5700.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a steerable cardiac ablation catheter remote control system will need to comply with the special controls named in this final order. The device is assigned the generic name steerable cardiac ablation catheter remote control system, and it is identified as a prescription device that is external to the body and interacts with the manual handle of a steerable cardiac ablation catheter to remotely control the advancement, retraction, rotation, and deflection of a compatible, steerable ablation catheter used for the treatment of cardiac arrhythmias in the right side of the heart. The device allows reversion to manual control of the steerable cardiac ablation catheter without withdrawal of the catheter and interruption of the procedure.

FDA has identified the following risks to health associated specifically with this type of device, as well as the mitigation measures required to mitigate these risks in table 1.

TABLE 1—STEERABLE CARDIAC ABLATION CATHETER REMOTE CONTROL SYSTEM RISKS AND MITIGATION MEASURES

| Identified risk | Mitigation measure |
|---|---|
| Device Failure, Resulting in Patient Injury or Interruption of Procedure | Non-Clinical Mechanical Performance Testing<br>Non-Clinical Electrical Testing:<br>Electromagnetic Compatibility (EMC), Electrical Safety, Electrical System, Performance, Shelf Life Testing, Sterilization Testing, In Vivo Testing, Labeling, Training. |
| Device Alters Catheter Functionality (Advance/Withdrawal, Rotation, Deflection) Resulting in Patient Injury (e.g., Perforation) or Improper Catheter Performance (Positioning and Contact) or Interruption of Procedure. | Non-Clinical Mechanical Performance Testing<br>Non-Clinical Electrical Testing: EMC, Electrical Safety, Electrical System, Performance, In Vivo Testing, Labeling, Post Market Surveillance. |
| Adverse Tissue Reaction | Sterilization Testing. |
| Improper Device Use/Use Error | Labeling, Training, In Vivo Testing, Post Market Surveillance. |
| Interference with Other Electrical Equipment/Devices (e.g., Device Malfunction). | Non-Clinical Mechanical Performance Testing<br>Non-Clinical Electrical Testing: EMC, Electrical Safety, Electrical System, Performance, Labeling. |
| Electrical Shock | Non-Clinical Electrical Testing: Electrical Safety Testing, Labeling. |
| Device Malfunction Resulting in Unanticipated Operation (e.g., Device Stoppage, Unintended Movement). | Non-Clinical Mechanical Performance Testing<br>Non-Clinical Electrical Testing: EMC, Electrical Safety, Electrical System, Performance, In Vivo Testing, Labeling, Training. |

FDA believes that the following special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness:

- Non-clinical mechanical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance testing must be performed:
  - Mechanical performance of the system (without catheter connected);
  - mechanical performance of the system with compatible catheters connected to verify that the system does not impact catheter function or

performance. Assessments must include the following:

- Side-by side remote control and manual comparisons of catheter manipulation (including all ranges of motion of catheter deflection and tip curl) for all compatible catheters; must include testing for worst-case conditions, and
- evaluation of the accuracy and function of all device control safety features; and
- simulated-use testing in a bench anatomic model or animal model.

• Non-clinical electrical testing must include validation of EMC, electrical safety, thermal safety, and electrical system performance. The following performance testing must be performed:

- Electrical performance of the system with compatible catheters connected to verify that the system does not impact catheter function or performance. Assessments must include the following:
- Side-by side remote control and manual comparisons of catheter manipulation (including all ranges of motion of catheter deflection and tip curl) for all compatible catheters; must include testing for worst-case conditions, and
- evaluation of the accuracy and function of all device control safety features; and
- electrical safety between the device and ablation catheter system and with other electrical equipment expected in the catheter lab or operating room.

• In vivo testing must demonstrate that the device performs as intended under anticipated conditions of use, including an assessment of the system impact on the functionality and performance of compatible catheters, and documentation of the adverse event profile associated with clinical use. Evidence must be submitted to address the following:

- Manipulation and positioning: Ability to manipulate compatible catheters to pre-specified cardiac locations and confirm proper anatomic placement and tissue contact, in accordance with the system indications for use and the compatible catheter indications for use;
- Safety: Assess device-related complication rate and major procedural complication rate (regardless of device relatedness) in comparison to literature and/or a manual comparison group for compatible ablation catheters to support the indications for use;
- Efficacy: Assess ablation success in comparison to literature and/or a manual comparison group for compatible ablation catheters to support the indications for use; and
- User assessment of device remote controls and safety features.

• Post-market surveillance (PMS) must be conducted and completed in accordance with FDA-agreed upon PMS protocol.

• A training program must be included with sufficient educational elements that, upon completion of the training program, the clinician and supporting staff can

- Identify the safe environments for device use,
- use all safety features of device, and
- operate the device in simulated or actual use environments representative of indicated environments and use for the indication of compatible catheters.

• Performance data must demonstrate the sterility of the sterile disposable components of the system.

• Performance data must support shelf life by demonstrating continued sterility of the device (of the sterile disposable components), package integrity, and device functionality over the requested shelf life.

• Labeling must include the following:

- Appropriate instructions, warnings, cautions, limitations, and information related to the intended patient population, compatible ablation catheters, and the device safeguards for the safe use of the device;
- specific instructions and the clinical training needed for the safe use of the device, which includes:
- instructions on assembling the device in all available configurations, including installation and removal of compatible catheters;
- instructions and explanation of all controls, inputs, and outputs;
- instructions on all available modes or states of the device;
- instructions on all safety features of the device; and
- validated methods and instructions for reprocessing/disinfecting any reusable components;
- a detailed summary of the mechanical compatibility testing including:
- A table with a complete list of compatible catheters tested (manufacturer trade name and model number), and
- a table with detailed test results, including type of test, acceptance criteria, and test results (*i.e.,* pass for meeting acceptance criteria);
- a detailed summary of the in vivo testing including:
- a table with a complete list of compatible catheters used during testing (manufacturer trade name and model number);
- adverse events encountered pertinent to use of the device under use conditions;
- a detailed summary of the device- and procedure-related complications; and
- a summary of study outcomes and endpoints. Information pertinent to the fluoroscopy times/exposure for the procedure, patient and operator fluoroscopic exposure;
- other labeling items:
- a detailed summary of pertinent non-clinical testing information: EMC, mechanical, electrical, and sterilization of device and components;
- a detailed summary of the device technical parameters; and
- an expiration date/shelf life and storage conditions for the sterile accessories; and
- when available, and according to the timeframe included in the PMS protocol agreed upon with FDA, provide a detailed summary of the PMS data including:
- Updates to the labeling to accurately reflect outcomes or necessary modifications based upon data collected during the PMS experience, and
- inclusion of results and adverse events associated with utilization of the device during the PMS.

The steerable cardiac ablation catheter remote control system is a prescription device restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device; see 21 CFR 801.109 (*Prescription devices*).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the steerable cardiac ablation catheter remote control system they intend to market.

**II. Environmental Impact**

The Agency has determined under 21 CFR 25.33(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment

nor an environmental impact statement is required.

### III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485; and the collections of information in 21 CFR part 820, regarding postmarket surveillance, have been approved under OMB control number 0910–0449.

### IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov.*

1. DEN140009: De Novo Request from Catheter Robotics, Inc., dated February 14, 2014.

### List of Subjects in 21 CFR Part 870

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 870 is amended as follows:

## PART 870—CARDIOVASCULAR DEVICES

■ 1. The authority citation for 21 CFR part 870 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Add § 870.5700 to subpart F to read as follows:

#### § 870.5700 Steerable cardiac ablation catheter remote control system.

(a) *Identification.* A steerable cardiac ablation catheter remote control system is a prescription device that is external to the body and interacts with the manual handle of a steerable cardiac ablation catheter to remotely control the advancement, retraction, rotation, and deflection of a compatible, steerable ablation catheter used for the treatment of cardiac arrhythmias in the right side of the heart. The device allows reversion to manual control of the steerable cardiac ablation catheter without withdrawal of the catheter and interruption of the procedure.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Non-clinical mechanical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance testing must be performed:

(i) Mechanical performance of the system (without catheter connected);

(ii) Mechanical performance of the system with compatible catheters connected to verify that the system does not impact catheter function or performance. Assessments must include the following:

(A) Side-by-side remote control and manual comparisons of catheter manipulation (including all ranges of motion of catheter deflection and tip curl) for all compatible catheters; must include testing for worst-case conditions, and

(B) Evaluation of the accuracy and function of all device control safety features; and

(iii) Simulated-use testing in a bench anatomic model or animal model.

(2) Non-clinical electrical testing must include validation of electromagnetic compatibility (EMC), electrical safety, thermal safety, and electrical system performance. The following performance testing must be performed:

(i) Electrical performance of the system with compatible catheters connected to verify that the system does not impact catheter function or performance. Assessments must include the following:

(A) Side-by-side remote control and manual comparisons of catheter manipulation (including all ranges of motion of catheter deflection and tip curl) for all compatible catheters; must include testing for worst-case conditions, and

(B) Evaluation of the accuracy and function of all device control safety features; and

(ii) Electrical safety between the device and ablation catheter system and with other electrical equipment expected in the catheter lab or operating room.

(3) In vivo testing must demonstrate that the device performs as intended under anticipated conditions of use, including an assessment of the system impact on the functionality and performance of compatible catheters, and documentation of the adverse event profile associated with clinical use. Evidence must be submitted to address the following:

(i) Manipulation and Positioning: Ability to manipulate compatible catheters to pre-specified cardiac locations and confirm proper anatomic placement and tissue contact, in accordance with the system indications for use and the compatible catheter indications for use;

(ii) Safety: Assess device-related complication rate and major procedural complication rate (regardless of device relatedness) in comparison to literature and/or a manual comparison group for compatible ablation catheters to support the indications for use;

(iii) Efficacy: Assess ablation success in comparison to literature and/or a manual comparison group for compatible ablation catheters to support the indications for use; and

(iv) User assessment of device remote controls and safety features.

(4) Post-market surveillance (PMS) must be conducted and completed in accordance with FDA agreed upon PMS protocol.

(5) A training program must be included with sufficient educational elements that, upon completion of the training program, the clinician and supporting staff can:

(i) Identify the safe environments for device use,

(ii) Use all safety features of device, and

(iii) Operate the device in simulated or actual use environments representative of indicated environments and use for the indication of compatible catheters.

(6) Performance data must demonstrate the sterility of the sterile disposable components of the system.

(7) Performance data must support shelf life by demonstrating continued sterility of the device (of the sterile disposable components), package integrity, and device functionality over the requested shelf life.

(8) Labeling must include the following:

(i) Appropriate instructions, warnings, cautions, limitations, and information related to the intended patient population, compatible ablation catheters, and the device safeguards for the safe use of the device;

(ii) Specific instructions and the clinical training needed for the safe use of the device, which includes:

(A) Instructions on assembling the device in all available configurations, including installation and removal of compatible catheters;

(B) Instructions and explanation of all controls, inputs, and outputs;

(C) Instructions on all available modes or states of the device;

(D) Instructions on all safety features of the device; and

(E) Validated methods and instructions for reprocessing/disinfecting any reusable components;

(iii) A detailed summary of the mechanical compatibility testing including:

(A) A table with a complete list of compatible catheters tested (manufacturer trade name and model number), and

(B) A table with detailed test results, including type of test, acceptance criteria, and test results (*i.e.,* pass for meeting acceptance criteria);

(iv) A detailed summary of the in vivo testing including:

(A) A table with a complete list of compatible catheters used during testing (manufacturer trade name and model number);

(B) Adverse events encountered pertinent to use of the device under use conditions;

(C) A detailed summary of the device- and procedure-related complications; and

(D) A summary of study outcomes and endpoints. Information pertinent to the fluoroscopy times/exposure for the procedure, patient, and operator fluoroscopic exposure;

(v) Other labeling items:

(A) A detailed summary of pertinent non-clinical testing information: EMC, mechanical, electrical, and sterilization of device and components;

(B) A detailed summary of the device technical parameters; and

(C) An expiration date/shelf life and storage conditions for the sterile accessories; and

(vi) When available, and according to the timeframe included in the PMS protocol agreed upon with FDA, provide a detailed summary of the PMS data including:

(A) Updates to the labeling to accurately reflect outcomes or necessary modifications based upon data collected during the PMS experience, and

(B) Inclusion of results and adverse events associated with utilization of the device during the PMS.

Dated: September 23, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–24624 Filed 9–29–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

### 32 CFR Part 311

**[Docket ID: DoD–2015–OS–0077]**

### Privacy Act of 1974; Implementation

**AGENCY:** Office of the Secretary, DoD.

**ACTION:** Direct final rule with request for comments.

**SUMMARY:** The Office of the Secretary of Defense (OSD) is exempting those records contained in DPFPA 07, entitled ''Counterintelligence Management Information System (CIMIS),'' pertaining to investigatory material compiled for counterintelligence and law enforcement purposes (under (k)(2) of the Act), other than material within the scope of subsection (j)(2) of the Privacy Act to enable the protection of identities of confidential sources who might not otherwise come forward and who furnished information under an express promise that the sources' identity would be held in confidence. The exemption will allow DoD to provide protection against notification of investigatory material including certain reciprocal investigations which might alert a subject to the fact that an investigation of that individual is taking place, and the disclosure of which would weaken the on-going investigation, reveal investigatory techniques, and place confidential informants in jeopardy who furnished information under an express promise that the sources' identity would be held in confidence. Further, requiring OSD to grant access to records and amend these records would unfairly impede the investigation of allegations of unlawful activities. To require OSD to confirm or deny the existence of a record pertaining to a requesting individual may in itself provide an answer to that individual relating to an on-going investigation. The investigation of possible unlawful activities would be jeopardized by agency rules requiring verification of record, disclosure of the record to the subject, and record amendment procedures.

**DATES:** The rule will be effective on December 9, 2015 unless adverse comments are received by November 30, 2015. If adverse comment is received, the Department of Defense will publish a timely withdrawal of the rule in the **Federal Register**.

**ADDRESSES:** You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate of Oversight and Compliance, Regulatory and Audit Matters Office, 9010 Defense Pentagon, Washington, DC 20301–9010.

*Instructions:* All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

**FOR FURTHER INFORMATION CONTACT:** Ms. Cindy Allard at (571) 372–0461.

**SUPPLEMENTARY INFORMATION:** This direct final rule makes changes to the Office of the Secretary Privacy Program rules. These changes will allow the Department to add an exemption rule to the Office of the Secretary of Defense Privacy Program rules that will exempt applicable Department records and/or material from certain portions of the Privacy Act.

This rule is being published as a direct final rule as the Department of Defense does not expect to receive any adverse comments, and so a proposed rule is unnecessary.

### Direct Final Rule and Significant Adverse Comments

DoD has determined this rulemaking meets the criteria for a direct final rule because it involves non-substantive changes dealing with DoD's management of its Privacy Programs. DoD expects no opposition to the changes and no significant adverse comments. However, if DoD receives a significant adverse comment, the Department will withdraw this direct final rule by publishing a notice in the **Federal Register**. A significant adverse comment is one that explains: (1) Why the direct final rule is inappropriate, including challenges to the rule's underlying premise or approach; or (2) why the direct final rule will be ineffective or unacceptable without a change. In determining whether a comment necessitates withdrawal of this direct final rule, DoD will consider whether it warrants a substantive response in a notice and comment process.