

section has changed since the previous report.

(c) *When to report.* Annual progress reports for postmarketing study commitments entered into by applicants shall be reported to FDA within 60 days of the anniversary date of the U.S. approval of the application for the product.

(d) *Where to report.* Submit two copies of the annual progress report of postmarketing studies to the Food and Drug Administration, Center for Biologics Evaluations and Research, Document Control Center (HFM-99), 1401 Rockville Pike, Rockville, MD 20852-1448.

(e) *Public disclosure of information.* Except for the information described in this paragraph, FDA may publicly disclose any information concerning a postmarketing study, within the meaning of this section, if the agency determines that the information is necessary to identify an applicant or to establish the status of the study including the reasons, if any, for failure to conduct, complete, and report the study. Under this section, FDA will not publicly disclose trade secrets, as defined in § 20.61 of this chapter, or information, described in § 20.63 of this chapter, the disclosure of which would constitute an unwarranted invasion of personal privacy.

Dated: October 13, 2000.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 00-27731 Filed 10-26-00; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 876

[Docket No. 94N-0380]

#### Gastroenterology and Urology Devices; Effective Date of the Requirement for Premarket Approval of the Implanted Mechanical/Hydraulic Urinary Continence Device; Correction

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

**ACTION:** Final rule; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of September 26, 2000 (65 FR 57726). The final rule requires the filing of a premarket approval application or a notice of completion of a product development protocol for the implanted

mechanical/hydraulic urinary continence device, a generic type of medical device intended for the treatment of urinary incontinence. In the final rule, the effective date was stated incorrectly. This document corrects that error.

#### FOR FURTHER INFORMATION CONTACT:

Nicole L. Wolanski, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2194.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 00-24632 appearing on page 57726 in the **Federal Register** of September 26, 2000, the following correction is made:

1. On page 57726, in the second column, under the **EFFECTIVE DATE** caption, the date "October 26, 2000" is corrected to read "September 26, 2000."

Dated: October 19, 2000.

**Linda S. Kahan,**

*Deputy Director for Regulations Policy, Center for Devices and Radiological Health.*

[FR Doc. 00-27736 Filed 10-27-00; 8:45 am]

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## DEPARTMENT OF DEFENSE

### Department of the Air Force

#### 32 CFR Part 811

RIN 0701-AA62

#### Release, Dissemination, and Sale of Visual Information Materials

**AGENCY:** Department of the Air Force, DoD.

**ACTION:** Final rule.

**SUMMARY:** The Department of the Air Force is revising our rules on the Release, Dissemination, and Sale of Visual Information Materials to reflect current policies. These rules implement Air Force Instruction (AFI) 33-117, Visual Information Management, and apply to all Air Force activities.

**EFFECTIVE DATE:** December 1, 2000.

**ADDRESSES:** Mr. Raymond Dabney, HQ AFCIC/ITSM, 1250 Air Force Pentagon, Washington, DC 20330-1250, 703-588-6136.

**FOR FURTHER INFORMATION CONTACT:** Mr. Raymond Dabney, HQ AFCIC/ITSM, 703-588-6136.

**SUPPLEMENTARY INFORMATION:** The Department of the Air Force is revising our rules on the Release, Dissemination, and Sale of Visual Information Materials of the Code of Federal Regulations (CFRs) (32 CFR part 811) to reflect current policies. This part implements Air Force Instruction (AFI) 33-117,

Visual Information Management, and apply to all Air Force activities. This part was published as a proposed rule in the **Federal Register** on December 28, 1999 (64 FR 72621, FR Doc. 99-33604). Comments were solicited for 60 days ending on February 28, 2000. No comments were received.

#### List of Subjects in 32 CFR Part 811

Archives and records, Motion pictures.

For the reasons stated in the preamble, the Department of the Air Force is revising 32 CFR Part 811 to read as follows:

#### PART 811—RELEASE, DISSEMINATION, AND SALE OF VISUAL INFORMATION MATERIALS

Sec.

811.1 Exceptions.

811.2 Release of visual information materials.

811.3 Official requests for visual information productions or materials.

811.4 Selling visual information materials.

811.5 Customers exempt from fees.

811.6 Visual information product/material loans.

811.7 Collecting and controlling fees.

811.8 Forms prescribed and availability of publications.

**Authority:** 10 U.S.C. 8013.

#### § 811.1 Exceptions.

The regulations in this part do not apply to:

(a) Visual information (VI) materials made for the Air Force Office of Special Investigations for use in an investigation or a counterintelligence report. (See Air Force Instruction (AFI) 90-301, The Inspector General Complaints, which describes who may use these materials.)

(b) VI materials made during Air Force investigations of aircraft or missile mishaps according to AFI 91-204, Safety Investigations and Reports. (See AFI 90-301.)

#### § 811.2 Release of visual information materials.

(a) Only the Secretary of the Air Force for Public Affairs (SAF/PA) clears and releases Air Force materials for use outside Department of Defense (DoD), according to AFI 35-205, Air Force Security and Policy Review Program.

(b) The Secretary of the Air Force for Legislative Liaison (SAF/LL) arranges the release of VI material through SAF/PA when a member of Congress asks for them for official use.

(c) The International Affairs Division (HQ USAF/CVAII) or, in some cases, the major command (MAJCOM) Foreign Disclosure Office, must authorize release of classified and unclassified

materials to foreign governments and international organizations or their representatives.

### **§ 811.3 Official requests for visual information productions or materials.**

(a) Send official Air Force requests for productions or materials from the DoD Central Records Centers by letter or message. Include:

(1) Descriptions of the images needed, including media format, dates, etc.

(2) Visual information record identification number (VIRIN), production, or Research, development, test, and evaluation (RDT&E) identification numbers, if known.

(3) Intended use and purpose of the material.

(4) The date needed and a statement of why products are needed on a specific date.

(b) Send inquiries about motion picture or television materials to the Defense Visual Information Center (DVIC), 1363 Z Street, Building 2730, March ARB, CA 92518-2703.

(c) Send Air Force customer inquiries about still photographic materials to 11 CS/SCUA, Bolling AFB, Washington, DC 20332-0403 (the Air Force accessioning point).

(d) Send non-Air Force customers' inquiries about still photographic materials to the DVIC.

### **§ 811.4 Selling visual information materials.**

(a) Air Force VI activities cannot sell materials.

(b) HQ AFCIC/ITSM may approve the loan of copies of original materials for federal government use.

(c) Send requests to buy:

(1) Completed, cleared, productions, to the National Archives and Records Administration, National Audiovisual Center, Information Office, 8700 Edgeworth Drive, Capitol Heights, MD 20722-3701.

(2) Nonproduction VI motion media to the DVIC. The center may sell other Air Force VI motion picture and television materials, such as historical and stock footage. When it sells VI motion media, the DVIC assesses charges, unless § 811.5 exempts the requesting activity.

(3) VI still media to the DoD Still Media Records Center (SMRC), Attn: SSRC, Washington, DC 20374-1681. When SMRC sells VI still media, the SMRC assesses charges, unless § 811.5 exempts the requesting activity.

### **§ 811.5 Customers exempt from fees.**

Title III of the 1968 Intergovernmental Cooperation Act (42 U.S.C. 4201, 4231, and 4233) exempts some customers

from paying for products and loans. This applies if the supplier has sufficient funds and if the exemption does not impair its mission. The requesting agency must certify that the materials are not commercially available. When requests for VI material do not meet exemption criteria, the requesting agency pays the fees. Exempted customers include:

(a) DoD and other government agencies asking for materials for official activities (see DoD Instruction 4000.19, Interservice, and Intergovernmental Support, August 9, 1995, and DoD Directive 5040.2, Visual Information (VI), December 7, 1987.

(b) Members of Congress asking for VI materials for official activities.

(c) VI records center materials or services furnished according to law or Executive Order.

(d) Federal, state, territorial, county, municipal governments, or their agencies, for activities contributing to an Air Force or DoD objective.

(e) Nonprofit organizations for public health, education, or welfare purposes.

(f) Armed Forces members with a casualty status, their next of kin, or authorized representative, if VI material requested relates to the member and does not compromise classified information or an accident investigation board's work.

(g) The general public, to help the Armed Forces recruiting program or enhance public understanding of the Armed Forces, when SAF/PA determines that VI materials or services promote the Air Force's best interest.

(h) Incidental or occasional requests for VI records center materials or services, including requests from residents of foreign countries, when fees would be inappropriate. AFI 16-101, International Affairs and Security Assistance Management, tells how a foreign government may obtain Air Force VI materials.

(i) Legitimate news organizations working on news productions, documentaries, or print products that inform the public on Air Force activities.

### **§ 811.6 Visual information product/material loans.**

(a) You may request unclassified and classified copies of current Air Force productions and loans of DoD and other Federal productions from JVISDA, ATTN: ASQV-JVIA-T-AS, Bldg. 3, Bay 3, 11 Hap Arnold Blvd., Tobyhanna, PA 18466-5102.

(1) For unclassified products, use your organization's letterhead, identify subject title, PIN, format, and quantity.

(2) For classified products, use your organization's letterhead, identify

subject title, personal identification number (PIN), format, and quantity. Also, indicate that either your organization commander or security officer, and MAJCOM VI manager approve the need.

(b) You may request other VI materials, such as, still images and motion media stock footage, from DVIC/OM-PA, 1363 Z Street, Building 2730, March ARB, CA 92518-2703.

### **§ 811.7 Collecting and controlling fees.**

(a) The DoD records centers usually collect fees in advance. Exceptions are sales where you cannot determine actual cost until work is completed (for example, television and motion picture services with per minute or per footage charges).

(b) Customers pay fees, per AFR 177-108, Paying and Collecting Transactions at Base Level, with cash, treasury check, certified check, cashier's check, bank draft, or postal money order.

### **§ 811.8 Forms prescribed and availability of publications.**

(a) AF Form 833, Visual Information Request, AF Form 1340, Visual Information Support Center Workload Report, DD Form 1995, Visual Information (VI) Production Request and Report, DD Form 2054-1, Visual Information (VI) Annual Report, and DD Form 2537, Visual Information Caption Sheet are prescribed by this part.

(b) Air Force publications and forms referenced in this part are available from NTIS, 5285 Port Royal Road, Springfield, VA 22161 or online at <http://www.afpubs.hq.af.mil>. DoD publications are available at <http://www.defenselink.mil/pubs>.

**Janet A. Long,**

*Air Force Federal Register Liaison Officer.*

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## **DEPARTMENT OF DEFENSE**

### **Department of the Air Force**

### **32 CFR Parts 811a and 813**

**RIN 0701-AA63**

### **Visual Information Documentation Program**

**AGENCY:** Department of the Air Force, DoD.

**ACTION:** Final rule.

**SUMMARY:** The Department of the Air Force is revising our rules on the Visual Information Documentation Program of the Code of Federal Regulations (CFRs) to reflect current policies. These rules