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 (HFPM–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 §20.63 of this chapter, the disclosure of which would constitute an unwarranted invasion of personal privacy.

Margaret M. Dotzel,
Associate Commissioner for Policy.

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.”

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] BILLING CODE 4160–01–F

DEPARTMENT OF DEFENSE

Food and Drug Administration

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.


EFFECTIVE DATE: December 1, 2000.


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

§811.1 Exceptions.

(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/CVAB) or, in some cases, the major command (MAJCOM) Foreign Disclosure Office, must authorize release of classified and unclassified
§ 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:


(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/materail loans.


(1) For unclassified products, use your organization’s letterhead, identify subject title, personal identification number (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.


(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.
[FR Doc. 00–27021 Filed 10–27–00; 8:45 am]
BILLING CODE 5001–05–P

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 its rules on the Visual Information Documentation Program of the Code of Federal Regulations (CFRs) to reflect current policies. These rules