

There are 483 drug applicants that submitted the form. The annual responses are based on submissions received by FDA in 1997 and 1998. The estimated average burden hours for the submissions using Form 356h to CDER

is based on past FDA experience and includes the time to fill out the form and collate the documentation. The estimated burden hours to prepare an NDA (§ 314.50); an ANDA (§ 314.94); supplements (21 CFR 314.70, 314.71,

and 314.97); and amendments (21 CFR 314.60 and 314.96) are approved under OMB Control No. 0910-0001.

FDA estimates the burden of this collection of information as follows:

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS<sup>1</sup>

21 CFR Part/FDA Form	No. of respondents	Total annual responses	Hours per response	Total hours
Form 356h	483	16,221	24	389,304
Total				389,304

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 13, 1999.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning and Legislation.*

[FR Doc. 99-27499 Filed 10-20-99; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99D-4328]

#### Draft Guidance for Industry on Developing Antimicrobial Drugs to Treat Catheter-Related Bloodstream Infections; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Catheter-Related Bloodstream Infections—Developing Antimicrobial Drugs for Treatment." This draft guidance is one in a series of guidances being developed to assist pharmaceutical manufacturers in developing antimicrobial drug products.

**DATES:** Written comments on the draft guidance may be submitted by December 20, 1999. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Copies of this draft guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of the draft guidance entitled "Catheter-Related Bloodstream Infections—Developing Antimicrobial Drugs for Treatment" to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that

office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Renata Albrecht, Center for Drug Evaluation and Research (HFD-590), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2336.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a draft guidance for industry entitled "Catheter-Related Bloodstream Infections—Developing Antimicrobial Drugs for Treatment." This is one of a series of guidances under development to assist manufacturers in planning the necessary clinical studies and designing and implementing the clinical protocols for drug products to treat infections. This draft guidance discusses catheter-related bloodstream infections, i.e., bloodstream infections resulting from an infected vascular access device or contaminated infusate. The issues raised in this draft guidance will be discussed at a meeting of the Anti-Infective Drugs Advisory Committee, scheduled for October 20, 1999 (64 FR 54335, October 6, 1999).

This level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on catheter-related bloodstream infections. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to

be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 15, 1999.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 99-27580 Filed 10-19-99; 11:59 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

#### Privacy Act of 1974; System of Records

**AGENCY:** Department of Health and Human Services (HHS), Health Care Financing Administration (HCFA).

**ACTION:** Notice to delete systems of records.

**SUMMARY:** The Health Care Financing Administration is deleting twenty (20) systems of records from its inventory subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

**EFFECTIVE DATE:** The deletions will be effective on October 21, 1999.

**ADDRESSES:** The public should address comments to: Director, Division of Data Liaison and Distribution, HCFA, Room N2-04-27, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. The telephone number is (410) 786-3573. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.-3 p.m., eastern time zone.

**SUPPLEMENTARY INFORMATION:** We have conducted a review of each Privacy Act systems of records under our control. As a result of this review, notice is hereby given that HCFA is deleting twenty (20)

systems of records. The systems of records are being deleted because they are either obsolete and no longer in use, or the systems have been phased out following the reorganization and replaced with existing or newly designed systems. All records were disposed in compliance with the "Retention and Disposal" section of each notice.

#### Deletions

No. 09-70-0019

System Name: "Actuarial Sample Hospital Stay Record Study (ASHSS) System," HHS/HCFA/BDMS; (Published **Federal Register** on Wednesday, October 13, 1982, Vol. 47, No. 198, pages 45703-45705)

No. 09-70-0020

System Name: "Actuarial Sample of Supplementary Medical Insurance (SMI) Payments," HHS/HCFA/BDMS; (Published **Federal Register** on Wednesday, October 13, 1982, Vol. 47, No. 198, page 45705)

No. 09-70-0029

System Name: "Evaluation of Medicare Competition Demonstration (EMCD)," HHS/HCFA/ORD; (Published **Federal Register** on Thursday, December 22, 1983, Vol. 48, No. 247, pages 56645-56647)

No. 09-70-0034

System Name: "Evaluation of Social/Health Maintenance Organizations (SHMO) Demonstrations," HHS/HCFA/ORD; (Published **Federal Register** on Monday, July 22, 1985, Vol. 50, No. 240, pages 29766-29767)

No. 09-70-0035

System Name: "Aftercare Evaluation System (AES)," HHS/HCFA/ORD; (Published **Federal Register** on Wednesday, September 2, 1987, Vol. 52, No. 170, pages 33290-33292)

No. 09-70-0038

System Name: "Evaluation of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) Health Maintenance Organization (HMO) and Competitive Medical Plans (CMP) Program," HHS/HCFA/ORD; (Published **Federal Register** on Tuesday, January 5, 1983, Vol. 53, No. 2, pages 182-184)

No. 09-70-0041

System Name: "Evaluation of the ORBRA 87 Medicare Payment of Influenza Vaccination (MPIV) Demonstration," HHS/HCFA/ORD; (Published **Federal Register** on Thursday, January 5, 1989, Vol. 54, No. 3, pages 329-331)

No. 09-70-0044

System Name: "Demonstration and Evaluation of the Medicare Insured Group (MIG) Model," HHS/HCFA/ORD; (Published **Federal Register** on Wednesday, November 30, 1998, Vol. 53, No. 230, pages 48314-48315)

No. 09-70-0047

System Name: "HCFA Medicare Mortality Predictor Data (MMPD) File," HHS/HCFA/ORD; (Published **Federal Register** on Tuesday, May 29, 1990, Vol. 55, No. 103, pages 21792-21794)

No. 09-70-0054

System Name: "Evaluation of the United Mine Workers of America Health and Retirement Funds Medicare Part B Capitation (UMWC) Demonstration," HHS/HCFA/ORD; (Published **Federal Register** on Wednesday, March 4, 1992, Vol. 57, No. 43, pages 7765-7767)

No. 09-70-0055

System Name: "Implementation and Evaluation of the Staff-Assisted Home Dialysis (SAHD) Demonstration," HHS/HCFA/ORD; (Published **Federal Register** on Monday, May 18, 1992, Vol. 57, No. 96, pages 21120-21123)

No. 09-70-0056

System Name: "Evaluation of the Medicaid Expansion Demonstrations (EMED)," HHS/HCFA/ORD; (Published **Federal Register** on Thursday, April 23, 1992, Vol. 57, No. 79, pages 14839-14841)

No. 09-70-0061

System Name: "Evaluation of the Medicare Case Management Demonstration (EMCM)," HHS/HCFA/ORD; (Published **Federal Register** on Tuesday, June 8, 1993, Vol. 58, No. 108, pages 32145-32146)

No. 09-70-0062

System Name: "Medicare Cataract Surgery Alternate Payment Demonstration Data Base (MCSAP)," HHS/HCFA/ORD; (Published **Federal Register** on Monday, June 21, 1993, Vol. 58, No. 117, pages 33826-33828)

No. 09-70-0507

System Name: "Health Insurance Microfilm (HIUM)," HHS/HCFA/BDMS; (Published **Federal Register** on Tuesday, October 27, 1981, Vol. 46, No. 207, pages 52703-52705)

No. 09-70-0529

System Name: "Pennsylvania Medicare/Medicaid Duplicate Paid Claims," HHS/HCFA/RO III; (Published **Federal Register** on Friday, January 5, 1990, Vol. 55, No. 4, pages 487-489)

No. 09-70-1514

System Name: "Medicare Severity of Illness Data (MSID) File," HHS/HCFA/HSQB; (Published **Federal Register** on Friday, March 17, 1989, Vol. 54, No. 51, pages 11292-11293)

No. 09-70-1515

System Name: "Resident Assessment System and Data Base for Nursing (RASD)," HHS/HCFA/HSQB; (Published **Federal Register** on Wednesday, January 2, 1991, Vol. 56, No. 1, pages 81-83)

No. 09-70-3003

System Name: "Correspondence Handling and Processing System (CHAPS)," HHS/HCFA/BDMS; (Published **Federal Register** on Wednesday, February 18, 1987, Vol. 52, No. 32, pages 4971-4972)

No. 09-70-4002

System Name: "Beneficiary Inquiry Tracking System (BITS)," HHS/HCFA/OPHC; (Published **Federal Register** on Friday, August 14, 1987, Vol. 52, No. 157, pages 30435-30438)

Dated: October 18, 1999.

**Michael Hash,**

*Deputy Administrator, Health Care Financing Administration.*

[FR Doc. 99-27574 Filed 10-20-99; 8:45 am]

BILLING CODE 4120-03-M

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### Notice of Intent To Prepare a Comprehensive Conservation Plan and Associated Environmental Impact Statement

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice.

**SUMMARY:** This notice advises the public that the U.S. Fish and Wildlife Service (Service) is preparing a Comprehensive Conservation Plan (CCP) and an Environmental Impact Statement for Texas Chenier Plain National Wildlife Refuge Complex, Chambers, Galveston and Jefferson Counties, Texas. The Service is furnishing this notice in compliance with Service CCP policy and the National Environmental Policy Act (NEPA) and implementing regulations for the following purposes: (1) To advise other agencies and the public of our intentions; (2) to obtain suggestions and information to be included in the EIS; and (3) to announce public open house meetings.

**DATES:** Submit comments on or before December 31, 1999. See Supplementary