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[1]

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

[1] 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Draft Guidance for Industry on Developing Antimicrobial Drugs to Treat Catheter-Related Bloodstream Infections; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Catheter-Related Bloodstream Infections—Developing Antimicrobial Drugs for Treatment.'' This draft guidance is one in a series of guidances being developed to assist pharmaceutical manufacturers in developing antimicrobial drug products.

DATES: Written comments on the draft guidance may be submitted by December 20, 1999.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ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance entitled ''Catheter-Related Bloodstream Infections—Developing Antimicrobial Drugs for Treatment'' to the Drug Information Branch (HFD–210), Center for Drug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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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]

BILLING CODE 4160–01–F

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)