TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
100.2(d)	1	1	1	10	10

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The reporting burden for § 100.2(d) is insignificant because enforcement notifications are seldom submitted by States requesting the agency take enforcement action under the act against a particular food. Over the last 3 years, FDA has not received any enforcement notifications. Since the enactment of section 403A(b) of the act (21 U.S.C. 343–1(b)) as part of the Nutrition Labeling and Education Act of 1990, FDA has received only a few enforcement notifications.

Although FDA believes that the burden will be insignificant, it believes these information collection provisions should be extended to provide for the potential future obligation of a State to notify FDA of an enforcement action under the provisions of section 310(b) of the act.

Dated: August 18, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–21853 Filed 8–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Microbiological Safety of Drug Residues in Food; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of workshop.

The Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM) will sponsor a workshop entitled ''Microbiological Safety of Drug Residues in Food.'' The workshop will discuss the use of model systems to establish acceptable daily intakes (ADI's) for antimicrobial drug residues in food. The workshop will focus on human consumption of new animal drug residues in food and their direct effects on human intestinal microflora.

The document entitled ''A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food–Producing Animals'' (the ''framework'' document) will not be discussed at this workshop. Information about workshops on the framework document will be announced in a future **Federal Register** notice, CVM update(s), and on CVM's Internet home page, at ''http://www.fda.gov/cvm/fda/mappgs/antitoc.html''.

Date and Time: The workshop will be held on Monday and Tuesday, September 20 to 21, 1999, from 8 a.m to 6 p.m. on Monday and from 8 a.m. to 2 p.m. on Tuesday.

Location: The workshop will be held at The DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD, 20852, 301–468–1100.

Contact: Lynda W. Cowatch, Center for Veterinary Medicine (HFV–150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5281.

Registration: The registration for the workshop is free. However, registration is required. For additional information and a registration form, please contact Lynda W. Cowatch at the above address. A registration form is also available on the CVM home page at ''http://www.fda.gov/cvm/fda/mappqs/registration.html''.

If you need special accommodations for a disability, please contact the DoubleTree Hotel at least 7 days in advance.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 30, 1996 (61 FR 3043), CVM published a notice of availability of a guidance document entitled ''Microbiological Testing of Antimicrobial Drug Residues in Food.'' This guidance document defines when antimicrobial drugs would be exempt from additional microbiological testing and when additional testing may be necessary to establish the safety of antimicrobial drug residues in food. The document also establishes 1.5 milligrams/person/day as the ADI of microbiologically active residues that would be allowed in food without additional microbiological testing. CVM also expressed the intention of validating model systems that could be used to evaluate the effect of low levels of antimicrobial drugs on the human intestinal microflora.

In 1995 and 1996, CVM initiated research to validate an in vitro and an in vivo model system that could be used to set ADI's for antimicrobial drug residues in food based on perturbations of the human intestinal microflora. The results of this research will be presented at the September workshop. In addition, other methods for determining ADI's for antimicrobial residues used internationally and in Europe will be presented and discussed.

Based on the information presented and discussed at the workshop, CVM intends to reevaluate its guidance document for testing microbiological effects of antimicrobial residues on the human intestinal microflora.

Dated: August 17, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–21854 Filed 8–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1076–N]

Medicare Program; September 16, 1999, Meeting of the Competitive Pricing Advisory Committee

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Competitive Pricing Advisory Committee (the CPAC) on September 16, 1999. The Balanced Budget Act of 1997 (BBA) requires the Secretary of the Department of Health and Human Services (the Secretary) to establish a demonstration project under which payments to Medicare+Choice organizations in designated areas are determined in accordance with a competitive pricing methodology. The BBA requires the Secretary to create the CPAC to make recommendations on demonstration area designation and appropriate research designs for the project. The CPAC meetings are open to the public.

DATES: The CPAC is scheduled to meet on September 16, 1999, from 9 a.m. until 4 p.m., e.d.s.t.