4. Should fees collected from industry be used to pay for other costs FDA incurs to ensure that drugs in the American marketplace are safe and effective? Such additional costs might include monitoring adverse drug reactions, monitoring drug advertising, and routine surveillance, inspection and testing of drug manufacturers.

III. Comments

Interested persons may submit written comments to the Dockets Management Branch (address above), or via e-mail to FDADockets@oc.fda.gov, or via the Internet at http://www.accessdata.fda.gov/scripts/oc/dockets/commentsdocket.cfm. by October 31, 2000. Comments are to be identified with the docket number found in brackets in the heading of this document. You may review received comments in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Transcripts

You may request a transcript of the PDUFA public meeting in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 10 cents per page. You may also examine the transcript of the meeting after September 30, 2000, at the Dockets Management Branch between 9 a.m. and 4 pm., Monday through Friday, as well as on the Internet at http://www.fda.gov/oc/pdufa2/meeting2000.html.

Dated: July 25, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–19301 Filed 8–3–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–10015]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New Collection;

Title of Information Collection: Evaluation of the Qualified Medicare Beneficiary (QMB) and Specified Low-Income Medicare Beneficiary (SLMB) Programs—Beneficiary Survey;

Form No.: HCFA–10015 (OMB #0938–NEW);

Use: Medicare beneficiaries eligible for the Qualified Medicare Beneficiary (QMB) and Specified Low-Income Medicare Beneficiary (SLMB) Programs will be surveyed. Numerous studies have shown that large numbers of potentially eligible QMB's and SLMB's do not participate in these programs. To further its goals under GPRA, the Health Care Financing Administration (HCFA) needs information on the effects of the QMB and SLMB programs. This project will help HCFA to develop a better understanding of the reasons for the low participation rates among the potential eligibles for both programs. Also, it will provide HCFA with information on the awareness of the QMB and SLMB programs; the paths and barriers to QMB and SLMB enrollment and the benefits of the QMB and SLMB coverage;

Frequency: Other: One-Time;

Affected Public: Individuals or Households;

Number of Respondents: 1,500;

Total Annual Responses: 1,500;

Total Annual Hours: 500.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan (HCFA–10015), Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

July 13, 2000.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–19308 Filed 8–3–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Privacy Act of 1974; Report of New System

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

ACTION: Notice of new system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new system of records, ''National Emphysema Treatment Trial (NETT) System, HHS/HCFA/CHPP, 09–70–0531.'' HCFA and the National Heart, Lung and Blood Institute, which is part of the National Institutes of Health, are collaborating on an effort to study the effectiveness of lung volume reduction surgery. The study is called ''National Emphysema Treatment Trial.'' The purpose of this multi-center randomized study is to evaluate the long-term outcomes of lung volume reduction surgery on function, morbidity and mortality, and to define appropriate patient selection criteria in order to determine which patients will likely benefit from lung volume reduction surgery.

The primary purpose of the system of records is to maintain data that will allow HCFA to collect and provide secure data on participants in the randomized phase of the study, pay claims, and to monitor and evaluate the clinical trial. Information retrieved from this system of records will also be disclosed to: support regulatory, reimbursement and policy functions performed within the agency or by a contractor or consultant, another federal or state agency to enable such agency to administer a federal health benefits program, or to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health