

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3487	190	1.7	324	0.81	262

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

The burden estimates in table 1 of this document resulted from discussions with new animal drug sponsors. The estimated burden includes NFDA's submitted on paper and by e-mail.

Dated: September 14, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1316]

Agency Information Collection Activities: Proposed Collection; Comment Request; Guidance for Industry on How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by October 23, 2000.

ADDRESSES: Submit written comments on the collection of information to Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attention: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation.

Description: As part of new animal drug development, sponsors often meet with the Center for Veterinary Medicine (CVM), scientists to formulate a rational approach for studies to be conducted, and to discuss how they meet the statutory requirements for new animal drug approval under section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b). Requests for meetings and teleconferences about new animal drug submissions are currently submitted to CVM on paper. CVM is responsible for developing and administering a guidance that explains

how to adhere to the Electronic Records; Electronic Signatures regulations (21 CFR part 11). These regulations provide for the voluntary submission of parts or all of regulatory records in electronic format without an accompanying paper copy and complies with the Government Paperwork Elimination Act (GPEA). The GPEA requires Federal agencies, by October 21, 2003, to give persons who are required to maintain, submit, or disclose information, the option of doing so electronically, when practical, as a substitute for paper.

This guidance document describes the procedure for persons who are new animal drug sponsors who wish to submit a request for a meeting or teleconference to the Office of New Animal Drug Evaluation by e-mail on FDA Form No. 3489. The information sponsors should include on the form are: The sponsor's name and address, a list of requested participants, an indication of audiovisual needs, and an agenda.

Description of Respondents: The likely respondents for this collection of information are sponsors who will be conducting clinical investigations under 21 CFR 511.1(b). In the **Federal Register** of June 29, 2000 (65 FR 40108), the FDA announced the availability of this guidance as a draft document and requested public comment on the proposed collection of information. No comments were received on the estimated annual reporting burden. We therefore believe the annual reporting burden of 116 hours should remain unchanged.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Form FDA No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3,489	190	.88	168	0.69	116

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

The estimates in table 1 of this document resulted from discussions with new animal drug sponsors. The estimated burden includes requests for meetings or teleconferences submitted by e-mail and on paper.

Dated: September 14, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R-246]

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: Revision of a currently approved collection;

Title of Information Collection: The Medicare Managed Care CAHPS Survey and Supporting Regulations in 42 CFR 417.126 and 417.470;

Form No.: HCFA-R-246 (OMB# 0938-0732);

Use: The CAHPS data is necessary to hold the Medicare managed care

industry accountable for the quality of care they are delivering. It is critical to HCFA's mission that we collect and disseminate information that will help beneficiaries choose among plans, contribute to improved quality of care through identification of quality improvement opportunities, and assist HCFA in carrying out its responsibilities.

Frequency: On occasion;

Affected Public: Individuals or Households, Business or other for-profit, and Not-for-profit institutions;

Number of Respondents: 168,000;

Total Annual Responses: 168,000;

Total Annual Hours: 55,450.

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 Willingham HCFA-R-246, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: September 11, 2000.

John P. Burke III,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)-443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Scholarships for Disadvantaged Students Program—(OMB No. 0915-0149)—Reinstatement, with change.

The Scholarships for Disadvantaged Students (SDS) Program has as its purpose the provision of funds to eligible schools to provide scholarships to full-time, financially needy students from disadvantaged backgrounds enrolled in health professions and nursing programs.

To qualify for participation in the SDS program, a school must be carrying out a program for recruiting and retaining students from disadvantaged backgrounds, including students who are members of racial and ethnic minority groups (section 737(d)(1)(B) of the PHS Act). A school must meet the eligibility criteria to demonstrate that the program has achieved success based on the number and/or percentage of disadvantaged students who graduate from the school. In awarding SDS funds to eligible schools, funding priorities must be given to schools based on the proportion of graduating students going into primary care, the proportion of underrepresented minority students, and the proportion of graduates working in medically underserved communities (section 737(c) of the PHS Act).

The estimated response burden is as follows:

Form	Number of respondents	Responses per respondent	Hours per response	Total your burden
SDS	450	1	28	12,600