

will be based on an updated version of the previously fielded paper-and-pencil survey instrument. The target population for the national survey is all facilities in the U.S. that use lower gastrointestinal flexible endoscopic equipment for the detection of colorectal cancer in adults. Information will be collected from a random sample of 1,440 facilities, stratified by U.S. Census region and urban/rural location.

Additional state-level surveys will be conducted from approximately 2010–2012 and will include a census survey of up to 18 selected states, based on methodology employed with the previously fielded state-based survey. An average of 135 facilities will be selected to participate in each state. A total of approximately 1,680 completed state surveys will be collected over the three years of the project.

Facilities will be recruited and screened through a telephone interview. Participation is voluntary. The information collection will inform planning efforts for national and state colorectal cancer screening.

There are no costs to respondents other than their time. The total estimated burden hours are 732.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Medical Facilities that Perform CRC Screening.	National Survey Recruitment Interview	700	1	5/60
	National SECAP Survey	480	1	35/60
	State Survey Recruitment Interview	800	1	5/60
	State SECAP Survey	560	1	35/60

Carol Walker,
Acting Reports Clearance Officer, Centers for Disease Control and Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0043]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on How to Use E-Mail to Submit a Request for a Meeting or Teleconference in Electronic Format to the Center for Veterinary Medicine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by June 14, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–0452. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–3793.

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 in Electronic Format to the Center for Veterinary Medicine—(OMB Control Number 0910–0452)—Extension

CVM holds meetings and/or teleconferences when a sponsor requests a presubmission conference under 21

CFR 514.5, or requests a meeting to discuss general questions. Generally, meeting requests are submitted to CVM on paper. However, CVM now allows registered sponsors to submit information electronically, and to request meetings electronically, if they determine this is more efficient and time saving for them. CVM’s guidance on “How to Submit a Request for a Meeting or Teleconference in Electronic Format to CVM,” provides sponsors with the option to submit a request for a meeting or teleconference as an e-mail attachment by the Internet. The likely respondents are sponsors for new animal drug applications.

In the **Federal Register** of February 5, 2010 (75 FR 6035), FDA published a 60-day notice requesting public comment on the proposed collection of information.

In response, two comments were received. One comment was completely outside the scope of the notice and the other requested that FDA meet openly with industry rather than closed sessions. Neither comment addressed the paperwork involved in the information collection.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section/ FDA Form 3489	No. of Respondents	Annual Frequency per Response	Total Annual Responses ²	Hours per Response	Total Hours
10.64	40	2.4	96	.08	7.7

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

² Electronic submissions received between January 1, 2008, and December 31, 2008.

The number of respondents in table 1 of this document is the number of sponsors registered to make electronic submissions (40). The number of total annual responses is based on a review of the actual number of such submissions made between January 1, 2008, and December 31, 2008 (96 x hours per response (.08) = 7.7 total hours).

Dated: May 10, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0088]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reporting and Recordkeeping Requirements and Availability of Sample Electronic Products for Manufacturers and Distributors of Electronic Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information 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: Fax written comments on the collection of information by June 14, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0025. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, email: Daniel.Gittleston@fda.hhs.gov.

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.

Reporting and Recordkeeping Requirements and Availability of Sample Electronic Products for Manufacturers and Distributors of Electronic Products (OMB Control Number 0910-0025)—Extension

Under sections 532 through 542 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360ii through 360ss), FDA has the responsibility to protect the public from unnecessary exposure of radiation from electronic products. The regulations issued under these authorities are listed in title 21 of the Code of Federal Regulations, chapter I, subpart J, parts 1000 through 1050 (parts 1002 through 1050).

Section 532 of the act directs the Secretary of the Department of Health and Human Services (the Secretary), to establish and carry out an electronic product radiation control program, including the development, issuance, and administration of performance standards to control the emission of electronic product radiation from electronic products. The program is designed to protect the public health and safety from electronic radiation, and the act authorizes the Secretary to procure (by negotiation or otherwise) electronic products for research and testing purposes and to sell or otherwise dispose of such products. Section 534(g) of the act directs the Secretary to review and evaluate industry testing programs on a continuing basis; and section 535(e) and (f) of the act directs the Secretary to immediately notify manufacturers of, and ensure correction of, radiation defects or noncompliances with performance standards. Section 537(b) of the act contains the authority to require manufacturers of electronic products to establish and maintain records (including testing records), make reports, and provide information to determine whether the manufacturer has acted in compliance.

The regulations under parts 1002 through 1010 specify reports to be provided by manufacturers and distributors to FDA and records to be maintained in the event of an investigation of a safety concern or a product recall.

FDA conducts laboratory compliance testing of products covered by regulations for product standards in parts 1020, 1030, 1040, and 1050.

FDA details product-specific performance standards that specify information to be supplied with the

product or require specific reports. The information collections are either specifically called for in the act or were developed to aid the Agency in performing its obligations under the act. The data reported to FDA and the records maintained are used by FDA and the industry to make decisions and take actions that protect the public from radiation hazards presented by electronic products. This information refers to the identification of, location of, operational characteristics of, quality assurance programs for, and problem identification and correction of electronic products. The data provided to users and others are intended to encourage actions to reduce or eliminate radiation exposures.

FDA uses the following forms to aid respondents in the submission of information for this information collection:

- FDA Form 2579 "Report of Assembly of a Diagnostic X-Ray System"
- FDA Form 2767 "Notice of Availability of Sample Electronic Product"
- FDA Form 2877 "Declaration for Imported Electronic Products Subject to Radiation Control Standards"
- FDA Form 3649 "Accidental Radiation Occurrence (ARO)"
- FDA Form 3626 "A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components"
- FDA Form 3627 "Diagnostic X-Ray CT Products Radiation Safety Report"
- FDA Form 3628 "General Annual Report (Includes Medical, Analytical, and Industrial X-Ray Products Annual Report)"
- FDA Form 3629 "Abbreviated Report"
- FDA Form 3630 "Guide for Preparing Product Reports on Sunlamps and Sunlamp Products"
- FDA Form 3631 "Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products"
- FDA Form 3632 "Guide for Preparing Product Reports on Lasers and Products Containing Lasers"
- FDA Form 3633 "General Variance Request"
- FDA Form 3634 "Television Products Annual Report"
- FDA Form 3635 "Laser Light Show Notification"
- FDA Form 3636 "Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products"
- FDA Form 3637 "Laser Original Equipment Manufacturer (OEM) Report"
- FDA Form 3638 "Guide for Filing Annual Reports for X-Ray Components and Systems"