ESTIMATED ANNUALIZED BURDEN TABLE

Report	Number of respondents	Responses per respondent	Average burden per response (in hours)
Screening MDE Report	15	2	16
Intervention MDE Report	15	2	8
Cost Report	15	2	16
Quarterly Report	15	4	16

Dated: December 15, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E6–21809 Filed 12–20–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0348]

Guidance for Industry and Food and Drug Administration Staff; Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Procedures for Handling Post-Approval Studies Imposed by PMA Order.'' The guidance provides a standard format and content for submitting post-approval studies. The guidance is issued to help ensure that sponsors provide adequate information about the conduct of post-approval studies and that the Center for Devices and Radiological Health (CDRH) can properly track and evaluate post-approval studies.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Procedures for Handling Post-Approval Studies Imposed by PMA Order'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Steven H. Chasin, Center for Devices and Radiological Health (HFZ– 520), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3421.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance provides recommendations to sponsors and CDRH staff on expectations concerning format, content, and review of reports related to post-approval studies imposed by premarket approval application order to help ensure that the studies are conducted effectively and efficiently, and in a least burdensome manner. The guidance has been drafted in response to concerns by Congress, the Institute of Medicine, and FDA about the agency's ability to monitor and track these studies and industry's requests for more clarity about the agency's expectations. FDA received a few comments on the draft document (announced at 70 FR 54561, September 15, 2005) and has made minor changes to the guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on post-approval studies. 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 and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive ''Procedures for Handling Post-Approval Studies Imposed by PMA Order,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number (1561) to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA's regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 814 have been approved under OMB Control No. 0910–0231; the collections of information in 21 CFR part 822 have been approved under OMB Control No. 0910–0449.

V. Comments

Interested persons may submit to the Division of Dockets Management (See **ADDRESSES**), written or electronic

comments regarding this document at any time. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* Submit two paper copies of any mailed comments, 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. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 13, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–21901 Filed 12–20–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

OFFICE OF INSPECTOR GENERAL

Statement of Organization, Functions, and Delegations of Authority

This notice amends Part A (Office of the Secretary), chapter AF of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (HHS) to reflect title changes and responsibilities within the Office of Inspector General's (OIG) Office of Evaluation and Inspections (OEI), Office of Management and Policy (OMP), Office of Investigations (OI), and Office of Audit Services (OAS). The statement of organization, functions, and delegations of authority conforms to and carries out the statutory requirements for operating OIG. Chapter AF was last published in its entirety on April 18, 2005 (70 FR 20147).

These organizational changes are primarily to realign the functions of OMP, OAS, OI, and OEI to better reflect the current work environment and priorities and to more clearly delineate responsibilities for the various activities within these offices.

As amended, sections AFC.00, AFC.10, AFC20, AFE.10, AFE.20, AFH10, AFH.20, and AFJ.20 of Chapter AF now reads as follows:

* * * * *

Section AFC.00, Office of Management and Policy—Mission

The Office of Management and Policy (OMP) provides mission support services to the Inspector General and other OIG components by formulating and executing the budget, developing policy, disseminating OIG information in the form of publications, managing information technology, human resources, executive resources and OIG space management. OMP also executes and maintains an internal quality assurance system, which includes quality control reviews of OMP processes and products, to ensure that OIG policies and procedures are followed effectively and function as intended.

Section AFC.10, Office of Management and Policy—Organization

The office is comprised of the following components.

A. Immediate Office
B. Budget Operations
C. Information Technology
D. Planning, Reporting, and Analysis
E. Administrative Services

Section AFC.20, Office of Management and Policy—Functions

A. Immediate Office of the Deputy Inspector General for OMP

This office is directed by the Deputy Inspector General for OMP who, aided by an Assistant Inspector General, is responsible for assuring that the OIG has the financial and administrative resources necessary to fulfill its mission. The Deputy Inspector General supervises the Directors for the Budget Division, Corporate Business Division, and Service and Support Division within the Office of Information Technology, Planning, Reporting and Analysis Division, and Administrative Services Division.

B. Budget

This office formulates and oversees the execution of the budget and confers with the Office of the Secretary, the Office of Management and Budget, and Congress on budget issues. It also issues quarterly grants to States for Medicaid Fraud Control Units and arranges internal control reviews for OIG, including the development of Government Performance and Results Act goals.

C. Information Technology

This office is directed by the Assistant Inspector General for Management and Policy who also serves as the Chief Information Officer for the Office of Inspector General. The office is responsible to support the Office of Inspector General and its components in completing their missions, by providing quality services for managing and processing information through the selected application of technology in a collaborative and secure manner. The office operates under the guidelines of Federal regulations, mandates, and directives for the development and operation of information technology systems. Organizational focus includes four key areas of (1) Technology planning and governance, (2) information assurance, (3) infrastructure and communications, and (4) systems and applications support. Technology projects provide a basic network infrastructure for a widely distributed organization across the nation, and mission-related technology to conduct the business of OIG.

D. Planning, Reporting, and Analysis

This office is responsible for coordinating the development and preparation of the work plan, including coordinating strategic long-range planning, tactical planning, and the annual work plan organization and production. It compiles the *Office of Inspector General Semiannual Report to Congress* and manages updates of the *Unimplemented OIG Recommendations* report, which is a compendium of significant OIG recommendations to reduce fraud, waste and abuse that have not been fully implemented.

E. Administrative Services

This office is responsible for overseeing emergency operations and national security classification policy. The office conducts management studies and analyzes, establishes, and coordinates general management policies for OIG and publishes those policies in the *OIG Administrative Manual.* This office is also accountable for the OIG framework for the organizational assessment, and space management for Washington, DC headquarters and over 90 geographic locations nationwide.

The office serves as OIG liaison to the Office of the Secretary for personnel issues and other administrative policies and practices; including human resources (HR), training, facilities, asset management, executive resources, and the performance management system, in addition to equal employment opportunity and other civil rights matters. These functions support all components of the OIG organization, except the HR function, which services all OMP staff.

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Section AFE.10, Office of Evaluation and Inspections—Organization

This office is comprised of the following components:

A. Immediate Office
B. Budget and Administrative Resources Division
C. Evaluation Planning and Support Division
D. Regional Operations