burden of the collection on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Postmarketing Adverse Event Reporting and Recordkeeping for Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act

Description of Respondents: Respondents to this collection of information are manufacturers, packers, and distributors whose name (pursuant to section 502(b)(1) of the act) appears on the label of a nonprescription drug marketed in the United States.

Burden Estimate: FDA is requesting public comment on estimates of annual submissions from these respondents, expected in 2008, as required by Public Law 109–462 and described in this guidance. This guidance document discusses what should be included in a serious adverse drug event report submitted under section 760(b)(1) of the act, including follow-up reports under 760(c)(2) of the act, and how to submit these reports. The estimates for annual reporting burden and recordkeeping are based on FDA's knowledge of adverse drug experience reports historically submitted per year for prescription drug products and for nonprescription drug products marketed under an approved application, including knowledge about the time needed to prepare the reports and to maintain records.

FDA receives approximately 2,500 serious adverse event reports for nonprescription drug products marketed under approved applications, which comprise approximately 20 percent of the overall nonprescription drug market. Based on this experience, we estimate between 10,000 and 15,000 (i.e., 12,500) total annual responses for nonprescription drugs marketed without an approved application. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Reports of serious adverse drug events (21 U.S.C. 379aa((b) and (c))	50	250	12,500	2	25,000
Total					25,000

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

Section 760(e) of the act also requires that responsible persons maintain records of nonprescription adverse event reports, whether or not the event is serious, for a period of 6 years. The draft guidance recommends that responsible persons maintain records of efforts to obtain the minimum data elements for a report of a serious adverse drug event and any followup reports. Although the guidance does not provide recommendations on recordkeeping activities generally under section 760(e) of the act, FDA is providing an estimate for the burden of this collection. Historically, serious adverse event reports comprise approximately two-thirds, and nonserious adverse event reports comprise approximately one-third, of the total number of postmarketing adverse event reports associated with drugs and biologic therapeutics (except vaccines) received by FDA. Based on this generalization, FDA estimates the total annual records to be approximately 20,000 records per year. FDA estimates that it takes 5 hours to maintain each record and the recordkeeping burden as follows:

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

	No. of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
Recordkeeping (21 U.S.C. 379aa(e)(1))	200	100	20,000	5	100,000
Total					100,000

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

Therefore, the estimated annual reporting burden for this information is 25,000 hours, and the estimated annual recordkeeping burden is 100,000 hours.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: October 10, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–5073 Filed 10–11–07; 11:34 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Statement of Organization, Functions, and Delegations of Authority

Part M of the Substance Abuse and Mental Health Services Administration (SAMHSA) Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services at 72, Number 188, page 55232, September 28, 2007, is

amended to reflect changes to the structure and functional statements for the Office of Program Services (OPS), Division of Management Systems (DMS). This amendment reflects the deletion of references to the information technology (IT) functions within the functional statement of DMS. In addition, it reflects the establishment of a new Division of Technology Management (DTM), within OPS. These changes will strengthen the management of this key function (IT) and provide better customer service and program coordination. The changes are as follows:

Section M.20, Functions is amended as follows:

The functional statements for the Office of Program Services (OPS), Division of Management Systems (DMS) is replaced, and a new functional statement within OPS is established for the new Division of Technology Management (DTM).

Division of Management Systems (MBC)

(1) Provides leadership in the development of policies for and the analysis, performance measurement, and improvement of SAMHSA administrative and management systems; (2) coordinates with other service providers the provision of human resource management services, equal employment opportunity services, and personnel security services, working with HHS service components and outside organizations as necessary and monitoring their performance; (3) manages the SAMBHSA ethics program; (4) coordinates and serves as a focal point for SAMHSA intern and summer employment programs; (5) provides advisory services to managers and supervisors in such matters as organizational development, analysis, performance, and performance measurement; (6) coordinates General Accounting Office and Office of the Inspector General reviews and information requests, internal control reviews, and Federal Managers Financial Integrity Act responses; (7) plans and coordinates various management activities such as records management, forms management, Privacy Act, and OPS Freedom of Information Act requests; (8) coordinates the Competitive Sourcing program for the agency, including the annual Federal Activities Inventory Reform Act (FAIR Act) Inventory, and activities and studies conducted in accordance in OMB Circular A–76, regarding competition of commercial activities; (9) develops, maintains, and manages administrative management systems regarding policies and procedures.

Division of Technology Management (MBJ)

(1) Provides leadership in the development of policies for and the analysis, performance measurement, and improvement of SAMHSA information systems; (2) Manages, operates, and enhances SAMHSA-wide administrative applications software systems; (3) coordinates with other service providers the provision of IT services, including operation of the local and wide area networks, personal computers, network servers, electronic mail and faxes, and general computer repairs, working with HHS service components and outside organizations as necessary and monitoring their performance; (4) serves as the Agency focal point for IT policy, strategic planning, budget preparation, coordination with the Department regarding these issues, and the submission of required reports to the Department on a timely basis; (5) makes certain that the appropriate level of IT security is in place so that the safety of Agency data can be assured; (6) oversees Agency-wide database administration and systems configuration management, providing advice, assistance, and training to Agency staff to obtain maximum utilization of and services from its information/application systems and databases; (7) exercises clearance authority for Agency IT management projects; and (8) reviews and analyzes new IT management developments and ensures necessary support services are provided.

Delegation of Authority

All delegations and redelegations of authority to officers and employees of SAMHSA which were in effect immediately prior to the effective date of this reorganization shall continue to be in effect pending further redelegations, providing they are consistent with the reorganization.

These organizational changes are effective: October 9, 2007.

Terry L. Cline,

Administrator.

[FR Doc. 07–5060 Filed 10–12–07; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form I–566, Extension of an Existing Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review: Form I–566, Interagency Record of Individual Requesting Change/Adjustment to or From A or G Status or Requesting A, G, or NATO Dependent Employment Authorization; OMB Control No. 1615–0027.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on July 30, 2007, at 72 FR 41515. The notice allowed for a 60-day public comment period. No comments were received on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until November 14, 2007. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), USCIS, Chief, Regulatory Management Division, Clearance Office, 111 Massachusetts Avenue, 3rd floor, Washington, DC 20529. Comments may also be submitted to DHS via facsimile to 202–272–8352 or via e-mail at *rfs.regs@dhs.gov*, and to the OMB USCIS Desk Officer via facsimile at 202–395–6974 or via e-mail at *kastrich@omb.eop.gov*.

When submitting comments by e-mail please make sure to add OMB Control Number 1615–0027 in the subject box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;