

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: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

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.

Food Labeling; Notification Procedures for Statements on Dietary Supplements—(OMB Control Number 0910-0331)—Extension

Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act) (21

U.S.C 343(r)(6)) requires that FDA be notified by manufacturers, packers, and distributors of dietary supplements that they are marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in section 403(r)(6) of the act. Section 403(r)(6) of the act requires that FDA be notified, with a submission about such statements, no later than 30 days after the first marketing of the dietary supplement. Information that is required in the submission includes the following: (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) a signature of a responsible individual who can certify the accuracy of the information presented, and who must certify that the

information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

FDA established § 101.93 (21 CFR 101.93) as the procedural regulation for this program. Section 101.93 provides details of the procedures associated with the submission and identifies the information that must be included in order to meet the requirements of section 403 of the act.

Description of Respondents: Businesses or other for-profit organizations.

In the **Federal Register** of July 24, 2006 (71 FR 41818), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received before the comment period closed.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
101.93	2,500	1	2,500	.75	1,875

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

FDA believes that there will be minimal burden on the industry to generate information to meet the requirements of section 403 of the act in submitting information regarding section 403(r)(6) of the act statements on labels or in labeling of dietary supplements. FDA is requesting only information that is immediately available to the manufacturer, packer, or distributor of the dietary supplement that bears such a statement on its label or in its labeling. This estimate is based on the average number of notification submissions received by FDA in the preceding 12 months.

Dated: November 21, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Navajo Area Indian Health Service (GFJ); Organization, Functions, and Delegations of Authority

Office of the Area Director (GFJ1)

(1) Plans, develops and directs the Area Program within the framework of Indian Health Service (IHS) policy in pursuit of the IHS mission; (2) delivers and ensures the delivery of high quality comprehensive health services; (3) coordinates the IHS activities and resources internally and externally with those of other governmental and nongovernmental programs; (4) promotes optimum utilization of health care services through management and delivery of services to American Indians and Alaska Natives; (5) encourages the full application of the principles of Indian preference and Equal Employment Opportunity (EEO); and (6) provides Indian Tribes and other Indian community groups with optional ways of participating in the Indian Health programs including an opportunity to participate in developing the mission, values and goals for the Navajo Area Indian Health Service (NAIHS).

Equal Employment Opportunity Staff (GFJ1)

(1) Advises the Area Director and other key management officials in the execution of their IHS responsibilities; (2) provides program direction and leadership for the Area EEO program and procedures; and (3) ensures the elimination of discrimination practices in employment, promotion, training, treatment of applicants, and employees, because of race, color, religion, national origin, sex, age, and handicapping conditions.

Office of Administration and Management (GFJ2)

(1) Plans, directs, and coordinates NAIHS activities in the areas of policy, internal controls reviews, financial management, personnel management, third-party reimbursements; contract health services (CHS) funds; contracts management, procurement, personal property accountability/management, and administrative services; (2) serves as the Navajo Area principal advisor on all Area organization and management policy activities; and (3) provides guidance and assistance to service units in the overall development, planning and implementation of administrative functions.

Third-Party Resources Staff (GFJ2)

(1) Establishes liaison and coordinates Medicare/Medicaid activities with States agencies; (2) plans and coordinates the third-party activities of NAIHS facilities, develops policy pertaining to third-party activities, and coordinates and develops overall policy and plans for the implementation of Title IV, Public Law (Pub. L.) 94-437, Indian Health Care Improvement Act; and (3) provides technical assistance and guidance to service unit third-party staff.

Contract Health Services Branch (GFJ21)

(1) Establishes and provides organization, coordination, and implementation of policies and procedures for CHS operations, utilizing managed care concepts; (2) coordinates the development of an annual budget, with advice of allowance, for CHS fund control activities; (4) coordinates and evaluates medical, preventive, and hospital services provided through formal contractual procedures; (5) implements and administers a CHS quality assurance program that is data based and verifiable, for monitoring the quality of CHS; (6) establishes strategic CHS plans that are developed to support organizations, issues, or work processes; (7) coordinates and implements information resource related processes that integrates selected techniques/methods with CHS systems to solve processes/problems; and (8) coordinates and analyzes appeal cases, high cost care cases, and deferred CHS services.

Division of Financial Management (GFJ22)

(1) Provides direction for the organization, coordination, and execution of all budget and financial operations of the Area; (2) monitors fund control operations of service units, and program offices; (3) develops and implements budget, fiscal, and accounting procedures; (4) conducts reviews and analyses to ensure compliance with Area policy; (5) interprets policies, guidelines, manual issuances, Office of Management and Budget (OMB) circulars, directives and other instructions issued by IHS, Health Resources Services Administration (HRSA), Public Health Service (PHS), Department of Health Human Services (HHS), OMB, and Congress as it related to the formulation of Area and service units budgets and budget execution; (6) develops and makes recommendations of Area budget execution by service unit; (7) establishes and maintains memorandum accounts of obligations for allowances through use of

commitment registers; and (8) monitors and ensure proper obligation of prior year funds.

Travel and Debt Management (GFJ22)

(1) Provides interpretation and ensure compliance with operating policies, procedures, guidelines via Federal Travel Regulations, Federal Property Management Regulations, Joint Travel Regulations, HHS Travel Manual, Indian Health Manual—Travel Management, etc.; and (2) develops and implements Area-wide internal controls and ensures compliance with established policies, procedures and regulations.

Budget Branch (GFJ221)

(1) Ensures that accurate and current information is available at all times for the Navajo Area Executive Staff, Division Chiefs, and service unit management teams; and (2) ensures that funds are allotted properly and accounted for in line with acceptable Federal accounting practices. Analyzes obligation trends and prepares periodic reports.

Accounting Branch (GFJ222)

(1) Provides advice and guidance to Area and service unit staff in the areas of collection, imprest funds, accounts receivable, and internal audit. Advises Area and service unit staff on the interpretation of accounting data and reports received from IHS Headquarters (HQ); and (2) assures that accounting transactions are entered properly and prepares periodic or special purpose reports and financial statements for Area Divisions and service units.

Division of Administrative Services (GFJ23)

(1) Plans, develops, coordinates, and provides internal audit activities, office services, records management and delegation/directives control, personal property management, and other administrative services in support of Area programs; (2) provides guidance to service units in the operation and evaluation of procurement and acquisition of equipment, office services, telecommunications (voice), and transportation; (3) develops and executes administrative management systems, methods, and techniques designed to organize, maintain, monitor, evaluate, and report on the administrative aspects of the Area-wide supply management program in support of requirements and authorities of IHS, PHS, and HHS; (4) serves as the administrative authority on Federal personal property management laws, rules, regulations, policies, procedures, and practices; and (5) organizes,

maintains, monitors, evaluates, and reports on the acquisition, control, utilization, and disposition of personal property.

*Directives Controls—Delegations & Records Management**Directives and Delegations Control*

(1) Advises staff on the procedures for the development, revision, or cancellation of Area-issued directives and delegations; (2) ensures that Area and service unit personnel are afforded the opportunity to comment on draft IHS and NAIHS directives; (3) provides policy interpretation of Area-issued directives and delegations; and (4) maintains complete sets of IHS and NAIHS directives and delegations.

Records Management

(1) Must ensure comprehensive knowledge of regulatory and statutory requirements associated with the three records management processes of creation, maintenance, and disposition of records; (2) plans, develops, and implements uniform records management practices, training, and compliance reviews; (3) provides technical assistance as requested at individual file stations; (4) assists in the transfer and retrieval of Area and service unit records with the National Archives and Records Administration and other Federal agencies; and (5) ensures that the maintenance and disposition of records is in accordance with records schedules approved by the Archivist of the United States.

Office Services

(1) Provides leadership, direction, and supervision in the planning, development, and operation of printing/duplicating management, security management, vehicle management, mail systems management, telecommunications management (voice); (2) ensures transportation management for household goods (HHG) protocols are followed specific to regulatory requirements for both commissioned corps and civil service employees by providing guidance on HHG practices, training, and reviews; (3) maintains inventories of office supplies at the Gallup Regional Supply Service Center (GRSSC); and (4) provides forms/correspondence management and monitors form accountability in conjunction with the GRSSC.

Internal Audit Branch

(1) Plans, implements, coordinates and monitors all audit functions applicable to programs and operations; (2) provides annually an assessment on

the adequacy and effectiveness of processes for controlling activities and managing risks in program areas; (3) reports significant issues related to the processes for controlling the activities of the Area and its affiliates, including potential improvements to those processes, and provides information concerning such issues through resolution; (4) periodically provides information on the status and results of an annual audit plan and the sufficiency of department resources; (5) coordinates with other control and monitoring functions (risk management, compliance, security, legal, ethics, environmental, external audit); and (6) performs evaluations, development, implementation, technical assistance and consultation in accordance with audit standards established by Comptroller and Office of Inspector General for audits of Federal organizations, program activities, and functions.

Property Management Branch (GFJ232)

(1) Provides leadership, direction and overall management of all personal property in key areas of accountability, utilization, control, and disposal; (2) provides guidance on Area property management procedures including property accounting and reporting instructions; (3) executes physical inventories including the reconciliation of inventory reports and standard general ledger accounts; (4) documents all transactions affecting personal property; and (5) provides technical assistance Area-wide on property software packages, e.g. Sunflower Assets, FoxPro.

Supply Management Branch (GRSSC) (GFJ234)

(1) Provides overall management of expendable supplies to include reliability, timeliness, quality, service and cost effectiveness; (2) directs and supplies pharmaceutical, laboratory, dental, medical, administrative, subsistence, and general supply items; (3) plans, develops, and manages the supply budget; (operational stores and prime vendor); and (4) provides technical and staff assistance to Area and service units on matters related to the acquisition, utilization, disposition, and accountability of supplies.

Division of Acquisition Management and Contracts (GFJ24)

(1) Plans, develops, and coordinates the execution of administrative systems, methods, and techniques for Area procurement activities; (2) provides guidance to service units on the administrative aspects of Federal

contracting, procurement, and grant requirements; (3) participates with Tribes in developing administrative structures, procedures, and skills related to contract, procurement, and grants management; (4) serves as the principle focus for liaison activities regarding the administrative aspects of procurements; intra and inter-agency agreements, collaborative agreements, memorandum of agreements (MOA) and memorandum of understanding (MOU), etc.; (5) determines and delegates procurement authority; and (6) administers the International Merchant Purchase Authorization Card (IMP AC) program.

Business Policy Staff

(1) Plans, develops, and coordinates the execution of administrative systems, methods, and techniques for both Area Office and service unit procurement activities; (2) audits in-progress and completed work of Area Office and service units; (3) prepares and issues internal and field policies and guidance; (4) provides acquisition support through cost/price analysis and proposal and bid evaluation; (5) serves as staff advisor/ auditor for Area Office on all service related acquisitions and other; (6) serves as NAIHS Ombudsman for development and fostering of contractual relationships; (7) reviews and processes other agreements, including intra and inter-agency agreements, collaborative agreements, MOA and MOU, etc.; (8) reviews and processes justifications for other than full and open competition; (9) reviews and processes ratifications; (10) assists in administration of the IMPAC program; and (11) reviews and processes protests.

Small Purchase Staff

(1) Awards and monitors procurement actions for supplies and services below the simplified acquisition threshold; (2) provides technical assistance to non-acquisition personnel in the Government and private sector; (3) ensures compliance with applicable Federal regulations and statutes; (4) prepares closeout documentation, reviews and processes claims, disputes, and termination actions; and (5) coordinates and prepares necessary acquisition reports.

Contract Performance and Evaluation (GFJ24)

Pre-Award: (1) Establishes quality assurance provisions and surveillance systems for supply and service contracts; (2) coordinates site visits for developing future contracts; (3) assists Project Officers in developing statements of work; (4) serves as a technical expert for performance-based

service acquisitions; and (5) ensures independent Government cost estimates are supported by historical data or other factual information.

Post Award: (1) Oversees contractual terms pertaining to quality assurance and quality control; (2) performs field inspections to ensure compliance with contractual terms; (3) evaluates contractor performance on a wide variety of contractual issues and obligations; (4) maintains contractor past performance databases; and (5) assists with administration of performance-based contracts (PBC) to ensure proper application of PBC deductions or incentives.

General Acquisition Branch (GFJ242)

(1) Awards and monitors formally advertised and negotiated contracts for supplies and services; (2) provides technical assistance to non-acquisition personnel in the Government and private sector; (3) ensures compliance with applicable Federal regulations and statutes; (4) prepares closeout documentation on all contracts, reviews and processes claims, disputes, and termination actions; (5) coordinates and prepares necessary acquisition reports; and (6) conducts on-site acquisition program reviews in accordance with current HHS standards.

Medical Contracts and Other Agreements Branch (GFJ243)

(1) Coordinates the award and administration of all formally advertised and negotiated medical contracts; (2) provides planning, direction, monitoring, and evaluation assistance to service units on procurement functions; (3) ensures compliance with applicable Federal regulations and statutes; (4) prepares closeout documentation on all contracts, review and process claims, disputes, and termination actions; and (5) evaluates and administers compliance and closeout of contracts.

Division of Human Resources (GFJ25)

(1) Provides the full range of personnel management and personnel administrative services including manpower planning and utilization, staffing, recruitment, compensation and classification, training, career development, labor and employee relations; (2) provides advice, consultation, and assistance to Navajo Area Office and service unit managers, and Tribal officials on personnel policy issues associated with the implementation of Pub. L. 93-638; (3) develops Area/Service Unit level training programs; and (4) represents NAIHS in personnel management

matters within and outside the Navajo Area.

Public Law 93-638 Staff Support

(1) Implements personnel servicing responsibilities for the Pub. L. 93-638 human resources programs covered by the Area's appointing authority; (2) processes personnel actions and appointing of all civil service and commissioned corps employees; (3) implements the application of the principles, practices and techniques of personnel recruitment, examination, selection and/or placement; and (4) advises management regarding merit promotion principles and various Federal personnel regulations, as well as Indian preference law/policies, basic personnel management concepts in determining career patterns, identifying promotional and reassignment opportunities.

Staffing Branch (GFJ252)

(1) Implements personnel servicing responsibilities for the NAIHS human resources programs covered by the Area's appointing authority; (2) processes personnel actions and appointing of all civil service and commissioned corps employees; (3) implements the application of the principles, practices and techniques of personnel recruitment, examination, selection and/or placement; and (4) advises management regarding merit promotion principles and various Federal personnel regulations, as well as Indian preference law/policies, basic personnel management concepts in determining career patterns, identifying promotional and reassignment opportunities.

Classification and Training Branch (GFJ253).

Classification

(1) Establishes and maintains the Area Position Classification Program assuring positions are classified according to Office of Personnel Management classification standards, techniques, and guides; (2) conducts regulatory classification reviews and provides technical guidance and assistance on special position reviews for service unit managers; and (3) provides advice to managers on position management techniques and practices.

Training

(1) Assesses organizational training needs; (2) conducts or coordinates training of Area/Service Unit staff; (3) manages clearances of training requests for the NAIHS and manages nominations for long-term training; (4) coordinates applications for Pub. L. 93-

437 scholarships and monitors student progress after scholarship award; and (5) evaluates training and career development activities throughout the Navajo Area.

Employee, Labor Relations and Benefits Branch (GFJ254)

(1) Provides guidance, consultation, and assistance to management and employees on employee relations matters (i.e., life insurance, health insurance, retirement, leave), on grievances and appeals, adverse actions, employee discipline, and related matters; (2) provides advice on employee performance plans, incentive awards; and (3) represents management in meetings with labor organizations, and before third-party officials.

Division of Management Information Systems (GFJ26)

(1) Provides direction, supervision and management of all activities related to data processing, word processing, networking, video-conferencing, digital imaging transmission, computer security, telecommunications and archiving; (2) provides direct services through operation and management of associated automated data processing (ADP) hardware and software; (3) provides technical assistance in related activities involving systems design, development, implementation, testing and training throughout the NAIHS, including staff assistance to Area and service unit staff; (4) provides data processing services, including computer operations, and information retrieval and analysis for operational data systems within the NAIHS; and (5) performs systems analysis, computer programming, computer systems security, system implementation and user training for the Area's data systems.

Systems Administration Branch (GFJ261)

(1) Provides overall system administration support functions for the Navajo Area Office and service unit Resource and Patient Management System, NT, Win 2k, Unix and Commercial Off The Shelf operating systems; (2) plans, develops, and manages the NAIHS Web site; (3) monitors and ensures all Security requirements are met or exceeded; (4) develops applications for administrative, financial and clinical reporting requirements; and (5) evaluates new technologies and internet services.

Policy Planning and Management Branch (GFJ262)

(1) Coordinates and promotes the NAIHS information technology (IT) strategic planning initiatives; (2) monitors, develops and manages the NAIHS information systems policies and procedures; (3) consults with administrative services and management regarding information systems initiatives and provides IT support; (4) maintains, monitors and coordinates the RPMS system-wide data elements requirements; and (5) assembles performance improvement measurements required by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or Centers for Medicare and Medicaid Services (CMS).

Information Systems Security Branch (GFJ263)

(1) Develops and monitors information systems security requirements for NAIHS; (2) plans, develops, and monitors security policies, procedures and requirements for the Area Office and service units; (3) installs, manages and monitors security systems to protect patient privacy and confidentiality; (4) plans, designs and implements network and telecommunications systems to provide optimum voice, video and data transmission; and (5) manages and monitors wide area network and local area networks for optimum digital imaging/telehealth utilization and availability.

Office of Environmental Health and Engineering (GFJ3)

(1) Establishes policies related to NAIHS health care and sanitation facilities planning, construction, operations, and maintenance; (2) provides leadership, guidance and coordination to the overall Navajo facilities management programs; (3) develops and coordinates program requirements for planning, design and evaluation of health care and sanitation facilities; (4) develops, coordinates, and evaluates technical standards, guides, plans and requirements for health care and sanitation facilities constructing requirements within the Navajo Area; (5) provides leadership, guidance, and coordination to the overall Area Biomedical Engineering Program, and the Occupational Health and Safety Management Programs; and (6) allocates appropriation funds to all Office of Environmental Health and Engineering programs and projects.

Division of Environmental Health Services (GFJ32)

(1) Plans, develops and appraises Area-wide environmental health services programs; (2) provides technical assistance to the service units and the Tribes on the implementation of comprehensive environmental health programs and services among Indian families and communities; (3) provides technical assistance on environmental health including institutional environmental health and plan reviews, vector control, epidemiology, sanitary facilities, and food sanitation to the IHS, Tribes and other State and Federal agencies; (4) plans and implements an integrated Area-wide injury prevention and control program designed to reduce injury deaths and hospitalizations; (5) coordinates environmental responses to emerging diseases with Tribes, States, and other Federal agencies; and (6) manages and administers a Web-based environmental health database that helps determine resource requirement allocations.

Division of Sanitation Facilities Construction Services (GFJ33)

(1) Administers the Indian Sanitation Facilities Construction Program through Pub. L. 86–121; (2) plans, develops, coordinates, appraises and evaluates Area-wide sanitation facilities construction activities conducted in cooperation with Tribal groups and other agencies; (3) provides engineering consultation regarding environmentally related public health programs; and (4) provides technical liaison with other Governmental agencies, foundations and groups relative to public health engineering and environmental health. As part of the Pub. L. 86–121 program, the Division provides the following:

- Personnel staffing, training, orientation, and development.
- Professional/technical/environmental standards compliance and support.
- National Environmental Policy Act (NEP A) compliance documentation, approval, and support.
- Right-of-way easement documents, approval, and support.
- Specialty use/construction permits, approval, and support.
- Project funding document preparation, production, approval, and support.
- Multi-agency funded projects coordination, procurement, and task tracking.
- Procurement/warehousing/inventory of office and special order project materials/ equipment/services.
- Project services, materials, equipment, and construction via

MOA638 contracts with Navajo Engineering Consulting Association and Navajo Tribal Utility Association.

- Vehicle fleet maintenance, management, and support.
- Project electrical design, services, and support.
- Project accounting and payment services and/or support.
- Project final inspection/transfer process documentation, tracking, approval, and support.
- Technical support for writing, completion, and distribution of project final reports.
- Coordination of feasibility studies related to Tribal, chapter, and outside agency requests.

Division of Facilities Management and Engineering (GFJ34)

(1) Develops and coordinates program requirements for planning, design and evaluation of health care facilities in the Navajo Area; (2) develops, coordinates, and evaluates technical standards, guidelines, plans, and requirements for health care facilities construction requirements within IHS, HRSA and PHS; (3) develops and coordinates facility construction programs; (4) provides technical assistance and monitors Navajo Area and Tribal facilities planning and construction programs; (5) coordinates interagency requirements for shared or cooperative projects with agencies such as Department of Defense, Department of Veterans Affairs, State, Tribal, and regional planning bodies; (6) provides technical assistance and consultation to the Tribal government to assist and brief those organizations on the progress of planning, design and construction projects; (7) ensures compliance with NEP A and other environmental regulations in planning, design and construction of health care facilities, support buildings, major renovations/expansion to existing facilities and staff quarters; (8) responsible for real property asset accountability of all IHS government property; and (9) responsible for budget accounting for all construction projects for all funding sources.

Division of Biomedical Engineering (GFJ35)

(1) Plans, develops, coordinates, appraises and evaluates Area-wide biomedical engineering programs; (2) assesses service unit biomedical engineering needs and develops appropriate action programs and modification to existing program functions; (3) coordinates staff assignments, designs medical equipment training and education

programs for hospital and clinical staff and career development activities for the NAIHS; (4) provides engineering and technical assistance and consultation on biomedical engineering and telemedicine equipment, purchases, modifications, installation and hospital renovation and construction projects; (5) coordinates safety and emergency response planning activities; (6) ensures compliance with regulatory requirements and agencies imposed on IHS such as National Fire Protection Agency, Association for the Advancement of Medical Instrumentation, JCAHO, Food and Drug Administration, etc.; (7) coordinates the modification, installation and design of medical, dental, and radiology equipment; (8) assesses and minimizes the clinical and physical risk of equipment use on patients and clinical staff through equipment maintenance, inspection, testing and quality assurance and risk management programs; (9) supports direct patient care programs by maintaining and certifying the operation and safety of all medical equipment; (10) provides specialized biomedical engineering equipment repair for all dental, medical, and radiology equipment; (11) coordinates and monitors complex medical and laboratory contracts Area-wide; (12) provides design and engineering of Picture Archiving and Communications System for radiology functions and recommends telemedicine applications for the applications for the clinical need and mission of IHS; and (13) specifies and designs telecommunications requirements for telemedicine to ensure sufficient bandwidth is available for the telemedicine programs.

Division of Occupational Health and Safety Management (GFJ36)

(1) Performs industrial hygiene activities including: Compliance surveys of radiographic equipment; assessment of radiation exposure to patients; quality assurance assessment of medical imaging processing; surveys of occupational exposure to nitrous oxide, ethylene oxide, anesthetic gases, mercury and other chemical hazards; evaluation of ventilation systems in negative pressure isolation rooms, operating rooms and dental operations; ergonomic analyses of workstations and high risk occupations; (2) coordinates safety and infection control program development and evaluation to include training and consultative assistance for safety officers and infection control practitioners; compliance reviews of existing policies and procedures; development of model policies and

procedures; safety and infection control program accreditation compliance reviews; occupational safety and infection control training for service unit staff; (3) coordinates environmental sampling to include sample collection and analysis of suspected asbestos-containing materials; sample collection and analysis of suspected lead-based paint; quantification of indoor air contaminants; (4) conducts environmental assessments which include surveys to determine service unit compliance with Federal, State and local environmental regulations; and (5) develops and coordinates facilities management to conduct life safety code (building fire safety component) surveys; conduct construction plan reviews for new construction and renovation and consult with and advocate for facility managers on life safety code compliance issues.

Office of Program Planning and Evaluation (GFJ4)

Serves as the Area's primary staff element and principal source of advice on program planning and evaluation activities to include: (1) Strategic planning coordination at the Area level, including planning, implementing, and monitoring progress on the achievement of the Area Strategic Plan; (2) facilities planning, including the development of program justification documents, program of requirements, quarters justifications, and other required facilities planning and construction documents; (3) staffing requirements and projections for service units, facilities projects, and other needs; (4) statistical and epidemiological reporting, analysis, and monitoring, and design/development to compile, analyze, report, and monitor health status, morbidity, mortality, patient care, health services, health systems, population, demographic, and other health related data for the Area, service units, Tribes, States, health programs, universities, researchers, and the general public and develop and implement data quality improvements and strategies; (5) resource allocation methodologies—updating and providing technical support for resource allocation to the OAD and the Navajo Area Management Council; (6) other program planning and health systems planning activities and technical support to the OAD—prepares briefings, issue papers, and other analyses for the OAD and assists local entities in health systems program development, implantation, and evaluation activities; (7) public affairs—coordinates media affairs and IRS clearance on media and publications; (8) urban coordination—

coordinates and serves as liaison between the local urban health program and the IRS HQ office and complying with requirements of the Indian Health Care Improvement Act provisions; (9) GPRA coordination—coordinates the implementation and reporting of Government Performance Results Act performance measurements in the Area; and (10) coordination of research and evaluation activities—including Institutional Review Board (IRB).

Office of Health Programs (GFJ5)

(1) Provides consultation and technical assistance to all operating and management levels of the NAIHS and Indian Tribes in the design and implementation of health management delivery system; (2) provides guidance and support to all field activities related to the day to day delivery of health care; (3) provides Area-wide leadership in health programs in relation to the IHS goals, objectives, policies, and priorities; (4) directs the development and implementation of health care administration and direct and contract health services, standards, quality control and quality assurance, operational planning activities and program reviews of health programs; and (5) provides leadership, guidance, and coordination of the health manpower and training programs.

Division of Clinical Services and Health Promotion (GFJ52)

(1) Provides direction for the operation of the health delivery activities of the NAIHS; (2) handles all logistics associated with the conduct of program reviews of service units; (3) advises on assessment findings for potential implications for NAIHS policy, plans, programs and operations; (4) develops quality of care evaluation criteria, standards of care, and guidance for the maintenance of the quality assurance programs of the NAIHS; and (5) conducts monitoring activities to assess the quality of care provided by the NAIHS.

Behavioral Health

(1) Plans, develops, and coordinates a comprehensive behavioral health program for the NAIHS in relation to stated goals and objectives and changing needs; (2) provides liaison with medical, alcohol, social services and other IHS disciplines regarding behavioral health issues; (3) provides technical consultation to Tribal and Urban groups and NAIHS staff; (4) coordinates and plans with service units, State, Federal, Tribal, professional, private and community organizations in identification,

development and use of alternate resources for services; and (5) is a central source of information and communication on behavioral health needs and services within the NAIHS; (6) plans, directs, and evaluates the effective implementation of Service Unit Alcohol and Substance Abuse Services; (7) assures service unit and all contracts or grants for alcohol/substance abuse services are responsive to and based on an assessment of Indian community needs (that meet the physical, emotional, and spiritual needs of the service population with optimal use of available resources); and (8) coordinates services with other IHS and Federal agencies, State, Tribal and community programs.

Dental Health and Performance Improvement

(1) Develops, coordinates, and evaluates oral health programs; (2) establishes standards for staffing, technical procedures, use of facilities, and dental contracts; (3) coordinates professional recruitment, assignment and development for the Area; and (4) improves quality and efficiency of the Dental Program.

Performance Improvement

(1) Plans, develops and coordinates the Navajo Area Performance Improvement Program; (2) assists in the promotion and maintenance of the quality of patient care and staff training to assure the application of appropriate standards for health care provided; and (3) advises service units on matters pertaining to accreditation, quality assurance and performance improvement programs.

Health Promotion Disease Prevention

(1) Plans, coordinates, and integrates Health Promotion and Disease Prevention Services with other NAIHS programs and services; (2) promotes community and preventive health services to improve the health and well being of beneficiaries with optimal use of available resources; (3) provides Area-wide leadership in preventive health services in relation to IHS goals, objectives, policies, and priorities; and (4) coordinates the development and implementation of preventive health services, standards, quality control and quality assurance; operational planning activities and program reviews of preventive health programs.

Health Informatics

(1) Plans, coordinates and assists in implementation of new software/hardware packages to support clinical

care. Assists in deployment of electronic health records and associated IT programs and systems will be an essential function; (2) provides a liaison function to promote communication and coordination between clinical staff, IT staff and administration; (3) analyzes and evaluates processes related to patient data flow, patient data quality and promotes changes for improved patient care; and (4) provides or acquires appropriate knowledge and training for both end users of clinical applications as well as IT and administrative staff.

Diabetes and Other Chronic Diseases Branch (GFJ521)

(1) Provides medical staff and other health professional/paraprofessionals state-of-the-art clinical care and treatment disease management guidelines emphasizing a team approach and comprehensive care; (2) provides materials and information on patient and family diabetes education and nutritional counseling; (3) provides technical assistance to Tribal and community based programs; (4) provides cultural and literacy appropriate diabetes education materials to community members and to staff; (5) conducts annual diabetes medical chart audit at ITV facilities; (6) networks with other Area and National Diabetes Program staff; (7) serves as project officer for IHS HQ awarded diabetes grant programs; (8) responsible for success of and reports on GPRA elements regarding outcomes of care relating to diabetes; and (9) responsible for taking best practice models for prevention and treatment of chronic diseases other than diabetes and fostering their application in health care settings where care is provided by the NAIHS.

Division of Nursing Services (GFJ54)

(1) Works with service unit Directors of Nurses to determine standards, develop, monitor, and evaluate nursing care services for the NAIHS; (2) provides professional guidance to service units and formulates guides, policies, and procedures; (3) coordinates nursing recruitment, assignments, and career development for the Navajo Area; and (4) assesses NAIHS professional staffing needs and provides consultation and technical assistance in the initiation of Area training programs for ancillary personnel and continuing education of paraprofessional and professional nursing staff members.

Hospital and Ambulatory Nursing (GFJ5)

(1) Coordinates the development and evaluation of ambulatory care activities; (2) coordinates professional staff recruitment, assignments, and development opportunities; (3) develops and disseminates appropriate standards for quality assurance; (4) collaborates with national health organizations, other IHS Areas, and service unit staff to promote and improve ambulatory care services; (5) coordinates the development and evaluation of inpatient care activities; (6) coordinates professional staff recruitment, assignments, and development opportunities; and (7) develops and disseminates appropriate standards for quality assurance.

Nurse Recruitment

(1) Collaborates with NAIHS managers to assess nursing manpower needs; (2) assesses the professional staffing needs; and (3) coordinates activities with NAIHS and HQ staff to recruit, assign and retain nursing care professionals.

Division of Professional Staff and Recruitment (GFJ55)

(1) Develops the NAIHS program to recruit, assign and retain health care professionals; (2) assesses the professional staffing needs and coordinates the development of strategies to satisfy these needs, and to increase the morale and retention of all professionals; (3) provides liaison with commissioned corps activities; and (4) maintains contact with related professional societies, educational institutions, and other Federal, State and local agencies.

Office of Indian Self-Determination (GFJ6)

(1) Plans, coordinates and implements all tasks relative to contracting activities pursuant to the Indian Self-Determination and Education Assistance Act, Pub. L. 93-638; (2) coordinates and effectuates respectful and positive relations with Tribal, State and Federal Governments and agencies, and intra-agency departments at local and national offices; (3) develops supportive relationships with local Tribal Governments and Tribal Organizations (contractors); (4) provides advice on the effect and impact of IHS policies, plans, programs and operations on Tribal operations and relationships; (5) advises on new methods and techniques for Indian community participation in, and management of their health programs; (6) provides technical assistance in such areas as

financial resource management (inter/intra-agency), health board and staff training; (7) organizes, collaborates, promotes and maintains effective Tribal consultation with NAIHS Health Boards, Tribal Government Programs, Tribal Organizations and Tribal Leaders; (8) coordinates activities with IHS HQ and NAIHS on relevant Tribal activities (9) coordinates, assists and monitors intergovernmental and legislative activity and functions; (10) monitors and provides liaison for the maintenance of an effective financial management system on all aspects of contract funding; (11) responsible for Contracting Officer's functions as it relates to Pub. L. 93-638 contract functions for NAIHS including contract development, execution, administration, and maintenance of contract files; (12) assists, establishes and maintains effective contract administration service policies and procedures, regulations for all Tribal contracts and grants under Pub. L. 93-638; (13) advises and reports pertinent data/information to the Area Director, Executive Committee, Pub. L. 93-638 Negotiation Team, service unit Chief Executive Officers, Tribal Governments, and Tribal Organizations relative to contracting activities; (14) compiles Area Director Report to Navajo Nation legislature on a quarterly basis; (15) collaborates with Area Program Offices, Pub. L. 93-638 contractors and IHS HQ on budget and program issues; (16) provides technical support to the Office of the General Counsel on Pub. L. 93-638 issues; (17) provides technical assistance and conducts monthly meeting on reconciliation and related tasks; and (18) assists with all administrative tasks in the operation of all Office of Indian Self-Determination programs, functions, services and activities.

Contracting Staff

(1) Assists, establishes and maintains effective contract administration service policies and procedures, regulations for all Tribal contracts and grants under Pub. L. 93-638; and (2) advises service units and the Tribe on matters pertaining to contracting under Pub. L. 93-638.

Project Management Staff

(1) Collaborates with Tribes and promotes effective Tribal consultation through liaison with NAIHS Health Boards, Tribal Government Programs, and Tribal Leaders; and (2) coordinates activities with NAIHS on all Tribal activities.

Finance and Budget Branch (GF)61

(1) Provides liaison for the maintenance of an effective financial management system on all aspects of Title I contract funding; and (2) provides technical assistance and consultation to Tribal programs on financial matters.

Navajo Area Office Service Units

Navajo Area Indian Health Service is the primary health care provider on the Navajo Indian reservation. The goal of the NAIHS health program is to provide for, and improve upon, the efficient delivery of high quality, comprehensive health care to the Navajo people. Comprehensive health care is provided through inpatient, outpatient and community health (preventive) programs centered around 6 hospitals, 7 health centers and 12 health stations and school clinics. The goal is to provide high quality, comprehensive preventive health care to the Navajo people, including prenatal care, immunizations, well-baby clinics, family planning, health education, and chronic disease follow-up. Service units in the NAIHS are as follows:

Chinle Service Unit (GFJA); Crownpoint Service Unit (GFJB); Fort Defiance Service Unit (GFJC); Gallup Indian Medical Center (GFJD); Kayenta Service Unit (GFJE); Shiprock Service Unit (GFJJ).

Dated: November 15, 2006.

Robert G. McSwain,

Deputy Director, Indian Health Service.

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BILLING CODE 4165-16-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; comment request; National Institute of Diabetes and Digestive and Kidney Diseases Information Clearinghouses Customer Satisfaction Survey

SUMMARY: Under the provisions of section 3507(a) (1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on August 14, 2006, page 46486 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: NIDDK Information Clearinghouses Customer Satisfaction Survey.

Type of Information Requested: Revision of a previously approved collection for which approval has expired. The OMB control number

0925-0480 will expire on November 30, 2006.

Need and Use of Information Collection: NIDDK is conducting a survey to assess the efficiency and effectiveness of services provided by NIDDK's three clearinghouses: the National Diabetes Information Clearinghouse (NIDC); the National Digestive Diseases Information Clearinghouse (NDDIC); and the National Kidney and Urologic Diseases Information Clearinghouse (NKUDIC). The survey responds to Executive Order 12821, "Setting Customer Service Standards," which requires agencies and departments to identify and survey their "customers to determine the kind and quality of service they want and their level of satisfaction with existing services."

Frequency of Response: On occasion.

Affected Public: Individuals or households; business and for profit organizations; not-for-profit agencies.

Type of Respondents: Physicians, health care professionals, patients, family and friends of patients.

The annual reporting burden is as follows:

Estimated Number of Respondents: 5,112.

Estimated Number of Responses per Respondent: 1.

Average Burden Hours per Response: 0.025.

Estimated Total Annual Burden Hours Requested: 128.

The annualized costs to respondents is estimated at \$6,400.00. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

BURDEN TABLE

Number of respondents	Frequency of response	Average time per response	Annual hour burden	Average hourly wage rate	Respondent cost
5,112	1.00	0.025	128	\$50.00	\$6,400.00

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the

information to be collected; and (4) Ways to minimize the burden of the collection of the information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: 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: Office of Management and Budget, Office of

Regulatory Affairs, New Executive Office Building, Room 10235, Washington DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection reports and instrument, contact Kathy Kranzfelder, Project Officer, NIDDK Information Clearinghouses, NID, Building 31, Room 9A04, MSC2560, Bethesda, MD 20852, or e-mail your request, including your address to: kranzfeldk@hq.nidDK.nih.gov.

Comments Due Date: Comments regarding this information collection are