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Dated: April 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0252]

Watson Laboratories, Inc.; Withdrawal of Approval of Bupropion Hydrochloride Extended-Release Tablets, 300 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of Bupropion Hydrochloride (HCl) Extended-Release (ER) Tablets, 300 Milligrams (mg) (Bupropion HCl ER Tablets, 300 mg), under abbreviated new drug application (ANDA) 77-715, held by Watson Laboratories, Inc. (Watson), 4955 Orange Dr., Fort Lauderdale, FL 33314. Watson has voluntarily requested that approval for this product be withdrawn and waived its opportunity for a hearing.

DATES: Effective April 9, 2014.

FOR FURTHER INFORMATION CONTACT:

Carolina M. Wirth, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6282, Silver Spring, MD 20993-0002, 301-796-3602.

SUPPLEMENTARY INFORMATION: FDA approved ANDA 77-715 for Bupropion HCl ER Tablets, 300 mg on June 13, 2007, under section 505(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(j)). Bupropion HCl ER Tablets, 300 mg was indicated for the treatment of major depressive disorder. On September 24, 2013, FDA requested that Watson voluntarily withdraw its Bupropion HCl ER Tablets, 300 mg from the market after results of a bioequivalence study conducted by Watson showed that the firm's Bupropion HCl ER Tablets, 300 mg are not therapeutically equivalent to the 300-mg strength of the reference listed

drug. In a letter dated September 30, 2013, Watson requested that FDA withdraw approval of the 300-mg strength of Bupropion HCl ER Tablets, approved under ANDA 77-715, under § 314.150(d) (21 CFR 314.150(d)). In that letter, Watson also waived its opportunity for a hearing. The Agency acknowledged Watson's requests in a letter dated October 4, 2013.

Therefore, under section 505(e) of the FD&C Act (21 U.S.C. 355(e)) and § 314.150(d), and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of the 300-mg strength of Bupropion HCl Extended-Release Tablets under ANDA 77-715 is withdrawn (see **DATES**). Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: April 3, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Organization, Functions, and Delegations of Authority

Part GFJ

Indian Health Service

Navajo Area Office

Part GFJ, of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), as amended at 52 FR 47053-67, December 11, 1987, as amended at 60 FR 56606, November 9, 1995, as amended at 61 FR 67048, December 19, 1996, as amended at 69 FR 41825, July 12, 2004, as amended at 70 FR 24087, May 6, 2005 70 FR 60350, October 17, 2005, and most recently amended at 71 FR 69570, December 1, 2006, is hereby amended to reflect a reorganization of the Navajo Area Indian Health Service (IHS). The purpose of this re-organization proposal is to update the current approved Navajo Area IHS organization structure due to the decrease in Area shares from Federal facilities transitioning to Public Law 93-638 Indian Self-Determination and Education Assistance Act facilities. Delete the functional statements for the Navajo Area IHS in their entirety and replace with the following:

Organizations and Functions

Department of Health and Human Services

Indian Health Service (G)

Navajo Area Indian Health Service (GFJ)

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).

Branch of Planning (GFJ1A)

Provides 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, reporting, and including monitoring 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; (5) developing and implementing data quality improvements and strategies; (6) ensuring resource allocation methodologies are current by updating and providing technical support for resource allocation to the Office of the Area Director (OAD) and the Navajo Area Management Council; (7) providing other program planning and health systems planning activities and technical support to the OAD by

preparing briefings, issue papers, and other analyses for the OAD and assisting local entities in health systems program development, implantation, and evaluation activities; (8) carrying out the functions of public affairs—by coordinating media affairs and IHS clearance on media and publications; (9) serving as coordinator for urban Indian health programs; (10) coordinating implementation and reporting of Government Performance Results Act performance measurements in the Area; and (11) coordinating research and evaluation activities including Institutional Review Board.

Branch of Indian Self-Determination (GFJ1B)

(1) Plans, coordinates and implements all tasks relative to contracting activities pursuant to the Indian Self-Determination and Education Assistance Act, Public Law 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 Headquarters (HQ) and NAIHS on relevant Tribal activities; (9) coordinates, assists and monitors inter-governmental 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 Public Law 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 Public Law 93–638; (13) advises and reports pertinent data/information to the Area Director, Executive Committee,

Public Law 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, Public Law 93–638 contractors and IHS HQ on budget and program issues; (16) provides technical support to the Office of the General Counsel on Public Law 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.

Equal Employment Opportunity Staff (GFJ1C)

(1) Advises the Area Director and other key management officials in the execution of their EEO 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.

Office of Administration and Management (GFJ2)

(1) Plans, directs, and coordinates NAIHS activities in the areas of policy, internal controls reviews, financial management, human resources management, third-party reimbursements, 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.

Division of Financial Management (GFJ2A)

(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, Public Health Service (PHS), Department of Health Human Services (HHS), OMB, and Congress as it relates 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.

Branch of Accounting (GFJ2A1)

(1) Provides advice and guidance to Area and Service Unit staff in the areas of Accounts Payable, Cash Management, Federal/Inter-agency Transactions, and Travel; (2) advises Area and Service Unit staff on the interpretation of accounting data and reports received from IHS HQ; (3) assures that accounting transactions are entered properly and prepares periodic or special purpose reports and financial statements for Area Divisions and Service Units; (4) provides interpretation and ensures 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; and (5) participates in reconciliations of all funding sources (Federal and Tribal) on a regular basis.

Branch of Budget (GFJ2A2)

(1) Ensures that accurate and current information is available at all times for the Navajo Area Executive Staff, Division Directors, and Service Unit management teams; (2) ensures that funds are allotted properly and accounted for in line with acceptable Federal accounting practices; (3) analyzes obligation trends and prepares periodic reports; and (4) assures that reconciliations of all funding sources (Federal and Tribal) are accomplished on a regular basis.

Branch of Third-Party (GFJ2A3)

(1) Establishes liaison and coordinates Medicare/Medicaid activities with State agencies; (2) plans and coordinates the third-party activities of NAIHS facilities; (3) develops policy pertaining to third-party activities, and coordinates and develops overall policy and plans for the implementation of, Indian Health Care Improvement Act, 25 U.S.C. 1601 *et seq.*; (4) provides technical assistance and guidance to Service Unit third-party staff; (5) provides advice and guidance to Area and Service Unit staff in the

areas of collection, accounts receivable, debt management and internal audit; (6) develops and implements Area-wide internal controls and ensures compliance with established policies, procedures and regulations; and (7) develops and implements Area-wide internal controls and ensures compliance with established policies, procedures and regulations.

Division of Administrative Services (GAJ2B)

(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; (5) organizes, maintains, monitors, evaluates, and reports on the acquisition, control, utilization, and disposition of personal property, (6) advises staff on the procedures for the development, revision, or cancellation of Area-issued directives and delegations; (7) ensures that Area and Service Unit personnel are afforded the opportunity to comment on draft IHS and NAIHS directives; (8) provides policy interpretation of Area-issued directives and delegations; and (9) maintains complete sets of IHS and NAIHS directives and delegations.

Branch of Property and Supply Management (GFJ2B1)

(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; (5) provides technical assistance Area-wide on property software packages, e.g. Sunflower

Assets; (6) provides overall management of Area Office expendable supplies to include reliability, timeliness, quality, service and cost effectiveness; (7) directs administrative and general supply items; (8) plans, develops, and manages the supply budget, operational stores; and (9) provides technical and staff assistance to Area and Service Units on matters related to the acquisition, utilization, disposition, and accountability of equipment.

Gallup Regional Supply Service Center (GFJ2B2)

(1) Responsible for the overall management of expendable supplies; (2) provides supply support directly to Service Units through management and operation of more than 2,000 pharmaceutical, laboratory, dental, medical, administrative, subsistence, and general supply items; (3) plans, develops, and manages supply budgets; and (4) provides technical and staff assistance to Service Units in matters related to the acquisition, utilization, disposition, and accountability of supplies.

Division of Acquisition Management and Contracts (GFJ2C)

Division of Acquisition Management and Contracts employees are located at each of the five Service Units. Positions located at the Service Units are considered Service Unit staff; however, due to the nature of the work, the line authority is with the Navajo Area Office.

(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) serves as the principle focus for liaison activities regarding the administrative aspects of procurements, intra/inter-agency agreements, collaborative agreements, Memorandum of Agreements (MOA) and Memorandum of Understanding (MOU), etc.; (4) determines and delegates procurement authority; and (5) administers the purchase card program.

Shared Services Center (GFJ2C1)

(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; (5)

evaluates and administers compliance and closeout of contracts; (6) plans, develops, and coordinates the execution of administrative systems, methods, and techniques for both Area Office and Service Unit procurement activities; (7) audits in-progress and completed work of Area Office and Service Units; (8) prepares and issues internal and field policies and guidance; (9) provides acquisition support through cost/price analysis and proposal and bid evaluation; (10) serves as NAIHS Ombudsman for development and fostering of contractual relationships; (11) reviews and processes other agreements, including intra/inter-agency agreements, collaborative agreements, MOAs, MOUs, etc.; and (12) provides technical assistance to non-acquisition personnel in the government and private sector.

Division of Information Technology (GFJ2D)

(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 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.

Branch of Systems Administration (GFJ2D1)

(1) Provides overall system administration support functions for the Navajo Area Office and Service Unit Resource and Patient Management System (RPMS), Microsoft® Windows®, 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.

Clinical Systems Staff (GFJ2D2)

(1) Plans, coordinates and assists in implementation of new software/hardware packages to support clinical care; (2) assists in deployment of electronic health records and associated Information Technology (IT) programs and systems as an essential function; (3) provides a liaison function to promote communication and coordination between clinical, IT staff and administrative staff; (4) analyzes and evaluates processes related to patient data flow, patient data quality and promotes changes for improved patient care; and (5) provides or acquires appropriate knowledge and training for both end users of clinical applications as well as IT and administrative staff.

Information Systems Security Staff (GFJ2D3)

(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 a wide area network and local area networks for optimum digital imaging/telehealth utilization and availability.

Policy, Planning, and Management Staff (GFJ2D4)

(1) Coordinates and promotes the NAIHS 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 (JC) or Centers for Medicare and Medicaid Services.

Office of Health Programs (GFJ3)

(1) Provides consultation and technical assistance to all operating and management levels of the NAIHS and Indian Tribes in the design and implementation of a 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, coordinates activities in Contract Health Services (CHS) funds, 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.

Branch of Clinical Services (GFJ3A)

(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.

Branch of Contract Health (GFJ3B)

(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; (3) coordinates and evaluates medical, preventive, and hospital services provided through formal contractual procedures; (4) implements and administers a CHS quality assurance program that is data based and verifiable for monitoring the quality of CHS; (5) establishes strategic CHS plans that are developed to support organizations, issues, or work processes; (6) coordinates and implements information resource related processes that integrates selected techniques/methods with CHS systems to solve processes/problems; and (7) coordinates and analyzes appeal cases, high cost care cases, and deferred CHS services.

Branch of Health Promotion and Disease Prevention (GFJ3C)

(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, quality assurance, operational planning activities and program reviews of preventive health programs.

Dental Health Staff (GFJ3D)

(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; (4) improves quality and efficiency of the Dental Program; (5) 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 is provided; and (6) advises Service Units on matters pertaining to accreditation, quality assurance, and performance improvement programs.

Nursing Services Staff (GFJ3E)

(1) Provides leadership, direction and consultation to Service Units in the overall development, planning, monitoring and evaluation of nursing care services; (2) works closely with the Service Unit Chief Nurse Executives to provide professional guidance in formulating policies, procedures and standards of care and practices; (3) coordinates nursing recruitment, assignments, retention and career development; (4) assesses NAIHS professional staffing needs, providing technical assistance and guidance in the initiation of Area training programs for ancillary nursing personnel and continuing education of paraprofessional and professional nursing staff; (5) provides advice and ensures Area-wide compliance with established policies, procedures and regulations; (6) establishes a liaison and provides guidance to Navajo Area Public Health Nursing programs; (7) collaborates and coordinates nursing activities with NAIHS and Headquarters; and (8) acts as a liaison with Tribal programs including the Community Health Program.

Professional Recruitment Staff (GFJ3G)

(1) Develops the NAIHS program to recruit, assign and retain health care professionals; (2) assesses the professional staffing needs, coordinates the development of strategies to satisfy these needs, and increase the morale and retention of all professionals; (3) provides liaison with Commissioned Corps activities; (4) maintains contact with related professional societies, educational institutions, and other Federal, State and local agencies; (5)

coordinates professional recruitment, assignment and development of Dental Officers for the Area; and (6) enhances partnerships with Tribal healthcare organizations that are administered by the Navajo Nation and its contractors by providing recruitment and retention activities for the organizations that have left Tribal shares at the Area Office for this purpose.

Navajo Human Resources Region (GALG4)

Navajo Human Resources Region employees are located at each of the five Service Units. Positions located at the Service Units are considered Service Unit staff; however, the line authority is with the Navajo Human Resources Region at Navajo Area Office.

(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, performance management, retirement, worker's compensation, and other Federal benefits services; (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 Public Law 93-638; (3) develops Area/Service Unit level training programs; (4) represents NAIHS in personnel management matters within and outside the Navajo Area; (5) implements personnel servicing responsibilities for the Public Law 93-638 human resources programs covered by the Area's appointing authority; (6) processes personnel actions and appointing of all civil service and Commissioned Corps employees; (7) implements the application of the principles, practices and techniques of personnel recruitment, examination, selection and/or placement; and (8) 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.

Division of Client Services

(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; (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; (5) establishes and maintains the Area Position Classification Program assuring positions are classified according to Office of Personnel Management classification standards, techniques, and guides; (6) conducts regulatory classification reviews and provides technical guidance and assistance on special position reviews for Service Unit managers; and (7) provides advice to managers on position management techniques and practices.

Division of Strategic Planning

(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 Public Law 93-437 scholarships and monitors student progress after scholarship award; and (5) evaluates training and career development activities throughout the Navajo Area.

Division of Workforce Relations

(1) Provides guidance, consultation, and assistance to management on employee relations matters (i.e., employee discipline, adverse actions, and appeals); (2) provides guidance, consultation, and assistance to management on labor relations matters, represents management in meetings with labor organizations, and before third-party officials; (3) provides guidance, consultation, and assistance to management on performance matters (i.e. employee performance plans and incentive awards); (4) provides assistance to employees on Federal retirement estimates and processing of retirement applications; (5) provides assistance to management and employees in the worker's compensation process in regards to employee injuries; and (6) provides assistance to employees regarding their Federal benefits including medical and life insurances, leave, and the processing of death benefits claims.

Office of Environmental Health And Engineering (GFJ4)

(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 construction 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; (6) allocates appropriation funds to all Office of Environmental Health and Engineering (OEHE) programs and projects; and (7) advises the Area on Public Law 93-638 as it relates to OEHE services and activities.

Division of Environmental Health Services (GFJ4A)

(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 Federal and State 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 (GFJ4B)

(1) Administers the Indian Sanitation Facilities Construction Program through Public Law 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; (4) provides technical liaison with other Governmental agencies, foundations and groups relative to public health engineering and environmental health; (5) provides personnel staffing, training, orientation, and development; (6)

ensures professional/technical/environmental standards compliance and support; (7) provides National Environmental Policy Act (NEPA) compliance documentation, approval, and support; (8) provides right-of-way easement documents, approval, and support; (9) provides specialty use/construction permits, approval, and support; (10) provides project funding document preparation, production, approval, and support; (11) coordinates multi-agency funded projects coordination, procurement, and task tracking; (12) provides procurement/warehousing/inventory of office and special order project materials/equipment/services; (13) provides project services, materials, equipment, and construction via Memorandum of Agreements and Public Law 93-638 contracts with Navajo Engineering Construction Authority and Navajo Tribal Utility Authority; (14) provides vehicle fleet maintenance, management, and support; (15) provides project electrical design, services, and support; (16) provides project accounting and payment services and/or support; (17) provides project final inspection/transfer process documentation, tracking, approval, and support; (18) provides technical support for writing, completion, and distribution of project final reports; and (19) coordinates feasibility studies related to Tribal, Tribal Chapter, and other outside agency requests.

Division of Facilities Management (GFJ4C)

(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; (3) develops and coordinates facility construction programs; (4) provides technical assistance and monitors Navajo Area and Tribal facilities planning and construction programs; (5) coordinates inter-agency 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 NEPA and other environmental regulations in planning, design and construction of health care facilities, support buildings, major renovations/expansions to existing facilities and staff

quarters; (8) responsible for real property asset accountability of all IHS government property; (9) responsible for budget accounting for all construction projects for all funding sources; and (10) advises the NAIHS on Public Law 93-638 as it relates to OEHE services and activities.

Division of Biomedical Engineering (GFJ4D)

(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, JC, 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 (GFJ4E)

(1) Performs industrial hygiene activities including compliance surveys of radiographic equipment; (2) assesses radiation exposure to patients; (3) provides quality assurance assessment of medical imaging processing; (4) provides surveys of occupational exposure to nitrous oxide, ethylene oxide, anesthetic gases, mercury and other chemical hazards; (5) evaluates ventilation systems in negative pressure isolation rooms, operating rooms and dental operations; (6) provides ergonomic analyses of workstations and high risk occupations; (7) provides safety and infection control program development and evaluation including training and consultative assistance for safety officers and infection control practitioners; (8) provides compliance reviews of existing policies and procedures; (9) develops model policies and procedures; (10) provides safety and infection control program accreditation compliance reviews; (11) provides occupational safety and infection control training for Service Unit staff; (12) provides environmental sampling to include sample collection and analysis of suspected asbestos-containing materials, lead-based paint and quantification of indoor air contaminants; (13) performs environmental assessments which include surveys to determine Service Unit compliance with Federal, State and local environmental regulations; (14) coordinates facilities management to conducts life safety code (building fire safety component) surveys; (15) conducts construction plan reviews for new construction and renovation; (16) consults with and advocates for facility managers on life safety code compliance issues; (17) coordinates Navajo Area emergency management planning, exercises and response; and (18) provides management training and consultation.

Division of Administrative Support (GFJ4G)

(1) Provides administrative direction and guidance to the operational Divisions within the NAIHS OEHE, including guidance provided to Area, District, and Field Offices located throughout the NAIHS; (2) performs accounting services for the OEHE Divisions, including planning and implementation of annual OEHE program budgets; (3) maintains annual OEHE budget commitment registers; (3) receives and approves vendor invoices; (4) provides certification of funds available within appropriate electronic

financial management and government travel systems; (5) ensures proper obligation and expenditure of program and project funds; (6) provides overall internal coordination with the NAIHS Divisions of Financial Management and the Division of Acquisition Management and Contracts, ensures appropriate financial transactions, documentation and reporting; (7) advises the OEHE Director on NAIHS OEHE IT needs and requirements, including computer equipment, computer networking, electronic mail, internet connectivity, new technologies, information system security awareness and compliance, and information system continuity of operations plans; (8) provides technical consultation and direct assistance to OEHE staff stationed at Area, District, and Field Offices concerning hardware and software installation, configuration, maintenance and repair; (9) assesses and monitors OEHE professional staffing needs; (10) coordinates with Division Directors to develop strategies to meet the needs and increase the morale and retention of OEHE staff; (11) works with Human Resources to prepare vacancy announcements and process personnel orders for civil servants and Commissioned Corps Officers; (12) encourages full program support and compliance concerning Indian preference and EEO requirements in hiring and managing staff; (13) oversees the OEHE staff professional development program; (14) receives, reviews, and processes OEHE training authorization documents to support continuing education and improved competencies among OEHE staff; (15) supports staff individual development plans (IDPs) and ensures training requests are consistent with established IDPs; (16) provides program management of OEHE personal property in terms of accountability, utilization, control, and disposal; (17) provides guidance on OEHE property management procedures including property accounting and reporting instructions; (18) documents all transactions affecting OEHE personal property; (19) assists the OEHE Director with Public Law 93–638 issues; (20) participates in formal Public Law 93–638 negotiations with the Navajo Nation and Tribal Organizations authorized by Navajo Nation to contract pursuant to Public Law 93–638; and (21) serves as members of the NAIHS Incident Response Team.

Navajo Area Service Units

Navajo Area IHS continues to be the primary health care provider for the Navajo Nation and San Juan Southern Paiute Tribe. The goal of the NAIHS is

to provide for, and improve upon, the efficient delivery of high quality, comprehensive health care to the Navajo Nation, San Juan Southern Paiutes and all IHS beneficiaries served at NAIHS facilities. Comprehensive health care is provided through inpatient, outpatient and community health (preventive) programs. The goal is to provide high quality, comprehensive preventive health care to the Navajo Nation, San Juan Southern Paiutes and all IHS beneficiaries served at NAIHS facilities, 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)
- Gallup Service Unit (GFJD)
- Kayenta Service Unit (GFJE)
- Shiprock Service Unit (GFJJ)

Dated: March 28, 2014.

Yvette Roubideaux,

Acting Director, Indian Health Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Division of Cancer Epidemiology and Genetics (DCEG) Fellowship Program and Summer Student Applications (NCI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

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 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.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Jackie Lavigne, Office of Education, Division of Cancer Epidemiology and Genetics, 9609 Medical Center Drive, MSC 9776, Bethesda, MD 20892–9776 or call non-toll-free number 240–376–7237 or Email your request, including your address to: lavignej@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Division of Cancer Epidemiology and Genetics (DCEG) Fellowship Program and Summer Student Applications (NCI), Existing Collection in Use without OMB Control Number, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Division of Cancer Epidemiology and Genetics (DCEG) Office of Education (OE) administers a variety of programs and initiatives to recruit pre-college through post-doctoral educational level individuals into the Intramural Research Program to facilitate their development into future biomedical scientists. DCEG trains post-doctoral, doctoral candidates, graduate and baccalaureate students, through full time fellowships, summer fellowships, and internships in preparation for research careers in cancer epidemiology and genetics. The proposed information collection involves brief online applications completed by applicants to the full time and the summer fellowship programs. Full-time fellowships include: Full-time Equivalents (FTE) and non-FTE fellowships for US citizens, permanent residents and international fellows. These applications are essential to the administration of these training programs as they enable OE to determine the eligibility and quality of potential awardees; to assess their potential as future scientists; to determine where mutual research interests exist; and to make decisions regarding which applicants will be proposed and approved for traineeship awards. In each case, completing the application is voluntary, but in order to