

NDA No.	Drug	Applicant
8-306	PHENERGAN VC with Codeine (codeine phosphate; phenylephrine HCl; promethazine HCl) Syrup, 5 mg/5 mL; 6.25 mg/5 mL; 10 mg/5 mL	Do.
8-381	PHENERGAN FORTIS (promethazine HCl) Syrup, 25 mg/5 mL	Do.
8-381	PHENERGAN Plain (promethazine HCl) Syrup, 6.25 mg/5 mL	Do.
8-604	PHENERGAN VC (phenylephrine HCl; promethazine HCl) Syrup, 5 mg/5 mL; 6.25 mg/5 mL	Do.
9-000	CAFERGOT (caffeine; ergotamine tartrate) Suppository, 100 mg/2 mg	Novartis Pharmaceuticals Corp., One Health Plaza, East Hanover, NJ 07936-1080
9-509	ARAMINE (metaraminol bitartrate) Injection, equivalent to (EQ) 10 mg base/mL	Merck & Co., Inc., 770 Sumneytown Pike, BLA-20, P.O. Box 4, West Point, PA 19486
11-265	PHENERGAN with Dextromethorphan (dextromethorphan hydrobromide; promethazine HCl) Syrup, 6.25 mg/5 mL; 15 mg/5 mL	ANI
11-459	VISTARIL (hydroxyzine pamoate EQ hydroxyzine HCl) Capsules, 100 mg	Pfizer, Inc., 235 East 42 nd St., New York, NY 10017
11-689	PHENERGAN (promethazine HCl) Suppository, 50 mg	Wyeth
12-125	CARBOCAINE (mepivacaine HCl) Injection, 3 % (30 mg/mL/1.8 mL cartridge)	Eastman Kodak Co., Dental Products, 343 State St., Rochester, NY 14612-1122
18-062	PROVENTIL (albuterol sulfate) Syrup, EQ 2 mg base/5mL	Schering Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033
18-152	ESKALITH CR (lithium carbonate) Extended Release Tablets, 450 mg	GlaxoSmithKline, One Franklin Plaza, P.O. Box 7929, Philadelphia, PA 19101-7929
18-200	MIDAMOR (amiloride HCl) Tablets, 5 mg	Merck
18-201	MODURETIC 5-50 (amiloride HCl; hydrochlorothiazide) Tablets, 5 mg/50 mg	Merck
18-754	ORUDIS (ketoprofen) Capsules, 25 mg, 50 mg, and 75 mg	Wyeth
20-460	CYTOVENE (ganciclovir) Capsules, 250 mg and 500 mg	Roche Laboratories, Inc., 340 Kingsland St., Nutley, NJ 07110-1199

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list the drug products listed in this document in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs for the products may also be approved by the agency if they comply with relevant

legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: April 18, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 73 FR 12742-12744 dated March 10, 2008).

This notice reflects organizational changes in the Health Resources and Services Administration. Specifically, this notice moves the Office of Management (RS) under the Immediate

Office of the Administrator (RA) and transfers the Division of Procurement Management (RS4) from the Office of Management (RS) to the Office of Financial Management (RB). The notice also creates the Office of Commissioned Corps Affairs (RAH2) within the Office of International Health Affairs (RAH).

Chapter RA—Office of the Administrator

Section RA–10, Organization

Delete in its entirety and replace with the following:

The Office of the Administrator (RA) is headed by the Administrator, Health Resources and Services Administration, who reports directly to the Secretary. The OA includes the following components:

- (1) Immediate Office of the Administrator (RA);
- (2) Office of Equal Opportunity and Civil Rights (RA2);
- (3) Office of Planning and Evaluation (RA5);
- (4) Office of Communications (RA6);
- (5) Office of Minority Health and Health Disparities (RA9);
- (6) Office of Legislation (RAE);
- (7) Office of Information Technology (RAG);
- (8) Office of International Health Affairs (RAH); and
- (9) Office of Management (RAM).

Section RA–20, Functions

(1) Delete the functional statement for the Division of Procurement Management (RS4) and transfer the function to the Office of Financial Management (RB); (2) delete the functional statement for the Office of International Health Affairs and replace in its entirety; and (3) delete the functional statement for the Office of Management (RS) and replace in its entirety.

Office of International Health Affairs (RAH)

(1) Provides leadership, coordination, and advancement of international health activities relating to health care services for vulnerable and at-risk populations and for training programs for health professionals; (2) provides leadership within HRSA for the support for international health and coordinates policy development with the Office of Global Health Affairs (OGHA) and other Departmental agencies; (3) serves as a focal point within HRSA for the implementation of the Secretary's vision for a transformed commissioned corps and will ensure that HRSA's current and future force is better-equipped to meet the public health needs and necessities for the future; and (4) oversees the day-

to-day management and administration of HRSA's commissioned corps activities.

Office of Commissioned Corps Affairs (RAH2)

The Office carries out the following functions to the extent authorized by laws within the authority of HRSA. Specifically, the OCCA: (1) Oversees the day-to-day management and administration of HRSA's commissioned corps operational functions; (2) ensures HRSA's commissioned corps is ready to respond to public health challenges and emergencies identified by the Secretary; (3) in conjunction with the Office of Force Readiness and Deployment, ensures the readiness and deployment capability of officers assigned to HRSA; (4) in partnership with the Office of the Surgeon General (OSG), Office of Commissioned Corps Force Management (OCCFM), and the Office of Commissioned Corps Operations (OCCO) serves on inter-agency work groups and on government and non-government work groups and programs designed to further the goals of transformation; and (5) advises the HRSA Administrator on strategies to maximize the participation of the Agency and its components in transformation programs and activities.

Office of Management (RAM)

Provides Agency-wide leadership, program direction, and coordination to all phases of administrative management. Specifically, the Office of Management: (1) Provides management expertise and staff advice and support to the Administrator in program and policy formulation and execution; (2) provides administrative management services including human resources, procurement, property, space planning, safety, physical security, and general administrative services; (3) conducts Agency-wide workforce analysis studies and surveys; (4) plans, directs, and coordinates the Agency's activities in the areas of human resources management, including labor relations, personnel security, performance and alternative dispute resolution; (5) coordinates the development of policy and regulations; (6) oversees the development of annual operating objectives and coordinates HRSA work planning and appraisals; (7) directs and coordinates the Agency's organization, functions and delegations of authority programs; (8) manages the Continuity of Operations (COOP) program for the Offices supported by the Office of Management; (9) administers the Agency's Executive Secretariat and

committee management functions; (10) provides staff support to the Agency Chief Travel Official; and (11) provides staff support to the Deputy Ethics Counselor.

Division of Management Services (RAM1)

(1) Provides administrative management services including procurement, property, space planning, safety, physical security, and general administrative services; (2) ensures implementation of statutes, Executive Orders, and regulations related to official travel, transportation, and relocation; (3) provides oversight for the HRSA travel management program involving use of travel management services/systems, passenger transportation, and travel charge cards; (4) provides planning, management and oversight of all interior design projects, move services and furniture requirements; (5) develops space and furniture standards and related policies; (6) provides analysis of office space requirements required in supporting decisions relating to the acquisition of commercial leases and manages the furniture inventory; (7) provides advice, counsel, direction, and support to employees to fulfill the Agency's primary safety responsibility of providing a workplace free from recognizable safety and health concerns; (8) manages, controls, and/or coordinates all matters relating to mail management within HRSA, including developing and implementing procedures for the receipt, delivery, collection, and dispatch of mail; (9) maintains overall responsibility for the HRSA Forms Management Program that includes establishing internal controls to assure conformity with Departmental policies and standards, including adequate systems for reviewing, clearing, costing, storing and controlling forms; and (10) manages the Continuity of Operations (COOP) program for the Offices supported by the Office of Management.

Division of Workforce Management (RAM2)

(1) Conducts Agency-wide workforce analysis studies and surveys; (2) develops comprehensive workforce strategies that meet the requirements of the President's Management Agenda, programmatic needs of HRSA, and the governance and management needs of HRSA leadership; (3) evaluates employee development practices to develop and enhance strategies to ensure HRSA retains a cadre of public health professionals and reduces risks associated with turnover in mission

critical positions; (4) provides advice and guidance for the establishment or modification of organization structures, functions, and delegations of authority; (5) manages ethics and personnel security programs; (6) administers the Agency's performance management programs, including the SES Performance Review Board; (7) manages quality of work life, flexiplace, and incentive and honor awards programs; (8) coordinates with the service provider the provision of human resources management, working with the service provider to communicate human resources requirements and monitor the provider's performance; (9) directs and serves as a focal point for the Agency's intern and mentoring programs; (10) manages the Alternative Dispute Resolution Program; and (11) provides support and guidance on human resources issues for the Offices supported by the Office of Management.

Division of Policy Review and Coordination (RAM3)

(1) Advises the Administrator and other key Agency officials on cross-cutting policy issues and assists in the identification and resolution of cross-cutting policy issues and problems; (2) establishes and maintains tracking systems that provide Agency-wide coordination and clearance of policies, regulations and guidelines; (3) plans, organizes and directs the Agency's Executive Secretariat with primary responsibility for preparation and management of written correspondence; (4) arranges briefings for Department officials on critical policy issues and oversees the development of necessary briefing documents; (5) administers administrative early alert system for the Agency to assure senior Agency officials are informed about administrative actions and opportunities; (6) coordinates the preparation of proposed rules and regulations relating to Agency programs and coordinates Agency review and comment on other Department regulations and policy directives that may affect the Agency's programs; (7) manages and maintains a records management program for the Agency; (8) oversees and coordinates the Agency's committee management activities; (9) coordinates the review and publication of Federal Register Notices; (10) provides advice and guidance for the establishment or modification of administrative delegations of authority; (11) contributes to the analysis, development and implementation of Agency-wide administrative policies through coordination with relevant Agency program components and other related sources; and (12) provides

advice and guidance for the establishment or modification of program delegations of authority.

Section RA-30, Delegations of Authority

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

Chapter RB—Office of Financial Management

Section RB-10, Organization

Delete in its entirety and replace with the following:

The Office of Financial Management (RB) is headed by the Chief Financial Officer who reports directly to the Administrator, Health Resources and Services Administration. The Office of Financial Management includes the following components:

- (1) Office of the Chief Financial Officer (RB);
- (2) Division of Budget (RB1);
- (3) Division of Financial Policy and Controls (RB2); and
- (4) Division of Procurement Management (RB3).

Section RB-20, Functions

Delete the functional statement for the Office of Financial Management and replace in its entirety.

Office of the Chief Financial Officer (RB)

(1) Provides leadership and coordination in the development and administration of the Health Resources and Services Administration's (HRSA) financial management policies; (2) develops budget submissions for HRSA; (3) collaborates with the HRSA Office of the Administrator (OA) in the development and implementation of long-range program and financing plans; (4) participates in budget reviews and hearings; (5) manages HRSA's system of internal budgetary planning and control of funds; (6) develops and implements HRSA-wide budgetary, financial systems and procedures; (7) conducts HRSA-wide FTE tracking; (8) prepares all applicable financial reports; (9) analyzes data and makes recommendations to assure effective safeguards are in place to prevent fraud, waste and abuse; (10) identifies or conducts special financial management training programs for OCFO and HRSA staff components; (11) plans, directs, and coordinates the Agency's activities in the areas of procurement management; (12) plans, directs and

coordinates the Agency's competitive sourcing program; (13) manages the intra- and interagency agreements process; and (14) maintains liaison with the Department of Health and Human Services (HHS), Office of Management and Budget, Appropriations Committees, and other Government organizations on financial management matters.

Division of Budget (RB1)

(1) Reviews funds control measures to assure that no program, project or activity of HRSA obligates or disburses funds in excess of appropriations or obligates funds in violation of authorized purposes; (2) provides advice and assistance to senior HRSA management to verify the accuracy, validity, and technical treatment of budgetary data in forms, schedules, and reports, or the legality and propriety of using funds for specific purposes; (3) maintains primary liaison to expedite the flow of financial management work and materials within the Agency and/or between Agency components and HHS, OMB, and congressional staff; (4) provides overall financial-based analyses and fiduciary review for senior HRSA management in order to assure appropriate workforce planning, funds control guidance, and analytical technical assistance in all phases of the budgetary process; and (5) develops the long-range program and financial plan for the Agency in collaboration with the Office of Planning and Evaluation, and other administrative Agency components.

Division of Financial Policy and Controls (RB2)

(1) Provides leadership to define the control environment with senior HRSA management to perform risk assessments identifying the most significant areas necessary for internal control placements; (2) maintains overall responsibility for policies, procedures, monitoring of internal controls and systems related to payment and disbursement activities; (3) coordinates the development and improvement of HRSA's financial systems with the UFMS; (4) samples obligation documents and payment requests from a variety of private sector and Government sources to determine the validity and legality of the requests; (5) compiles and submits a variety of cash management and travel reports required by the Department of the Treasury and various other outside agencies; (6) serves as liaison with all HRSA Bureau/Office components and outside customers to provide financial information, resolve problems, and

provide information on payment and disbursement issues; (7) analyzes internal reports to provide management information on special interest topics; (8) develops needs assessment for financial management training based on Government-Wide and HHS standards; and (9) assures Treasury requirements and OMB suggestions for best practices are implemented in training plan for Agency-wide use.

Division of Procurement Management (RB3)

(1) Provides leadership in the planning, development, and implementation of policies and procedures for contracts; (2) exercises the sole responsibility within HRSA for the award and management of contracts; (3) provides advice and consultation of interpretation and application of the Department of Health and Human Services policies and procedures governing contracts management; (4) develops operating procedures and policies for the Agency's contracts programs; (5) establishes standards and guides for and evaluates contracts operations throughout the Agency; (6) coordinates the Agency's positions and actions with respect to the audit of contracts; (7) maintains liaison directly with or through Agency Bureaus or Offices with contractors, other organizations, and various components of the Department; and (8) provides leadership, guidance, and advice on the promotion of the activities in HRSA relating to procurement and material management governed by the Small Business Act of 1958, Executive Order 11625, and other statutes and national policy directives for augmenting the role of private industry, and small and minority businesses as sources of supply to the Government and Government contractors.

Section RB-30, Delegations of Authority

All delegations of authority and re-delegations of authority made to HRSA

officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

This reorganization is effective upon the date of signature.

Dated: April 18, 2008.

Elizabeth M. Duke,
Administrator.

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BILLING CODE 4165-15-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice; 60-day notice and request for comments; Extension of a currently approved collection, OMB Number 1660-0061, No Forms.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the need to continue collecting information from individuals and States in order to provide and/or administer disaster assistance through the Federal Assistance to Individuals and Households Program (IHP).

SUPPLEMENTARY INFORMATION: Section 206(a) of the Disaster Mitigation Act of 2000 (DMA 2000) (Public Law 106-390) consolidated the "Temporary Housing

Assistance" and the "Individual and Family Grant Programs" into a single program called "Federal Assistance to Individuals and Households" (IHP) at section 408 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Pub. L. 93-288, as amended). To implement this consolidation, which is intended to streamline the provision of assistance to disaster victims, FEMA published an interim final rule (67 FR 61446) which became effective on September 30, 2002. Pursuant to this rule applicants are able to request approval of late registrations, request continued assistance, and appeal program decisions. Similarly, States can partner with FEMA for delivery of disaster assistance under the "Other Needs" provision of the IHP through Administrative Option Agreements and Administration Plans addressing the level of managerial and resource support necessary.

Collection of Information

Title: Federal Assistance to Individuals and Households Program (IHP).

Type of Information Collection: Extension of a currently approved collection.

OMB Number: 1660-0061.

Form Numbers: No Forms.

Abstract: The Federal Assistance to Individuals and Households Program (IHP) enhances applicants' ability to request approval of late applications, request continued assistance, and appeal program decisions. Similarly, it allows States to partner with FEMA for delivery of disaster assistance under the "Other Needs" provision of the IHP through Administrative Option Agreements and Administration Plans addressing the level of managerial and resource support necessary.

Affected Public: Individuals and Households; State, Local or Tribal Governments.

Estimated Total Annual Burden Hours: 29,716 hours.

ANNUAL BURDEN HOURS

Project/activity (survey, form(s), focus group, etc.)	Number of respondents (A)	Frequency of responses (B)	Burden hours per respondent (C)	Annual responses (D)= (A × B)	Total annual burden hours (C × D)
Individuals:					
Request for Approval of Late Registration	8,000	1	0.75	8,000	6,000
Request for Continued Assistance	2,000	1	0.5	2,000	1,000
Appeal of Program Decision (to include review and use of supplemental guidance	30,000	1	0.75	30,000	22,500
States:					
Review of Administrative Option Agreement for the Other Needs provision of IHP	56	1	3	56	168