the Evaluation of Proprietary Names.'' In performance goals agreed to under the September 27, 2007, reauthorization of the Prescription Drug User Fee Act (PDUFA IV), FDA agreed to implement various measures to reduce medication errors related to look-alike and sound-alike proprietary names, unclear label abbreviations, acronyms, dose designations, and error-prone label and packaging designs. Among these measures, FDA agreed to publish guidance on the contents of a complete submission package for a proposed proprietary name for a drug/biological product. FDA also agreed to performance goals for review of proprietary names submitted during the investigational new drug application (IND) phase or with a new drug application (NDA) or biologics license application (BLA); the goals stipulate that a complete submission is required to begin the review clock. (See section IX.A at *http://www.fda.gov/oc/pdufa4/pdufa4goals.html*).

This draft guidance, when finalized, is intended to promote prevention of medication errors by assisting industry in the submission of complete product information that will help FDA to evaluate the safety of proposed proprietary drug and biological product names, taking into account other factors that, in association with the name, can contribute to medication errors. In addition, FDA intends to use this information in the assessment of promotional aspects of proposed proprietary names.

This draft guidance applies to prescription drug products, including biologics, that are the subject of an IND, NDA, or abbreviated new drug application (ANDA); nonprescription drug products that are the subject of an NDA or ANDA; and biological products that are the subject of a BLA.

The draft guidance does not address other performance goals under PDUFA IV, including developing FDA internal policies and procedures to ensure that proprietary name review goals are met; developing guidance on best practices for naming, labeling, and packaging drugs and biologics to reduce medication errors; guidance on proprietary name evaluation best practices; and developing and implementing a pilot program for evaluating proposed proprietary names.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the contents of a complete submission for the evaluation of proprietary names. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 and FDA Form 1571 have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 and FDA Form 356h have been approved under OMB control number 0910–0338.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.regulations.gov*.

Dated: November 17, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–27896 Filed 11–21–08; 8:45 am]

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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 56605–56606 as amended November 6, 1995; and as amended at 61 FR 65063, December 10, 1996; and last amended at 72 FR 33099, June 11, 2008.)

This notice reflects organizational changes in the Health Resources and Services Administration, Office of Rural Health Policy (RH). Specifically, this notice updates the functional statement of the Office of the Associate Administrator (RH), and creates the following components: Hospital-State Division (RH1), Community-Based Division (RH2), and the Border Health Division (RH3).

Chapter RH, Office of Rural Health Policy

Section RH, 00 Mission

Delete in its entirety and replace with the following:

The Office of Rural Health Policy serves as a focal point within the Department and as a principal source of advice to the Administrator and Secretary for coordinating efforts to strengthen and improve the delivery of health services to populations in the Nation's rural areas and border areas, providing leadership and interacting with stakeholders in the delivery of health care to underserved and at risk populations.

Section RH–10, Organization

Delete in its entirety and replace with the following:

The Office of Rural Health Policy (RH) is headed by the Associate Administrator who reports directly to the Administrator, Health Resources and Services Administration. The Office of Rural Health Policy includes the following components:

(1) Office of the Associate Administrator (RH);

(2) Hospital State Division (RH1);

(3) Community Based Division (RH2); and

(4) Border Health Division (RH3).

Section RH–20, Functions

Delete the functional statement for the Office of the Associate Administrator (RH) and replace in its entirety.

Office of the Associate Administrator (RH)

The Office of the Administrator is headed by the Associate Administrator who, in conjunction with other management officials within HRSA, is responsible for the overall leadership and management of the Office of Rural Health Policy. The Office of Rural Health Policy serves as a focal point within the Department and as a principal source of advice to the Administrator and Secretary for coordinating efforts to strengthen and improve the delivery of health services to populations in the Nation's rural areas and border areas, providing leadership and interacting with stakeholders in the delivery of health care to underserved and at risk populations. Specifically, the Office of Rural Health Policy is organized around the following primary issue areas:

Delivery of Health Services: (1) Collects and analyzes information regarding the special problems of rural health care providers and populations; (2) works with States, State hospital associations, private associations, foundations, and other organizations to focus attention on, and promote solutions to, problems related to the delivery of health services in rural communities; (3) provides staff support to the National Advisory Committee on Rural Health and Human Services; (4) stimulates and coordinates interaction on rural health activities and programs in the Agency, Department and with other Federal agencies; (5) supports rural health center research and keeps informed of research and demonstration projects funded by States and foundations in the field of rural health care delivery; (6) establishes and maintains a resource center for the collection and dissemination of the latest information and research findings related to the delivery of health services in rural areas; (7) coordinates congressional and private sector inquiries related to rural health; (8) advises the Agency, Administrator and Department on the effects of current policies and proposed statutory, regulatory, administrative, and budgetary changes in the programs established under titles XVIII and XIX of the Social Security Act on the financial viability of small rural hospitals, the ability of rural areas to attract and retain physicians and other health professionals; (9) oversees compliance by CMS with the requirement that rural hospital impact analyses are developed whenever proposed regulations might have a significant impact on a substantial number of small rural hospitals; (10) supports specialized rural programs on minority health, mental health, preventive health education, oral health, and occupational health and safety; (11) directs the management of a nationwide rural health grants program; (12) directs the management of a program of State grants which support collaboration within State offices of rural health; (13) funds radiation exposure screening and education programs that screen eligible individuals adversely affected by the mining, transport and processing of uranium and the testing of nuclear weapons for cancer and other diseases.

Intergovernmental Affairs: (1) Provides the Administrator with a single point of contact on all activities related to important State and local government, stakeholder association, and interest group activities; (2) coordinates Agency cross-Bureau cooperative agreements and activities with organizations such as the National Governors Association, National Conference of State Legislatures, Association of State and Territorial Health Officials, National Association of Counties, and National Association of County and City Health Officials; (3) interacts with various commissions such as the Delta Regional Authority, Appalachian Regional Commission, Denali Commission and the United States and Mexico Border Health Commission; and (4) serves as the primary liaison to Department intergovernmental staff.

Hospital State Division (RH1)

The Hospital State Division serves as the focal point within the Office of Rural Health Policy to support rural hospital and State grant programs focused on rural populations. Specifically, the Hospital State Division is organized around the following primary issue areas: (1) Plans and manages a program of State grants which support collaboration within State offices of rural health; (2) works with States, State hospital associations, private associations, foundations, and other organizations to focus attention on, and promote solutions to, problems related to the delivery of health services in rural communities; and (3) provides coordinated technical assistance to grantees and rural communities.

Community Based Division (RH2)

The Community Based Division serves as the focal point within the Office of Rural Health Policy to support rural community grant programs. Specifically, the Community Based Division is organized around the following primary issue areas: (1) Plans and manages several nationwide rural health grants programs; (2) supports programs on rural health, public health, and health status improvement; (3) funds public and private non-profit entities for the operation of clinics that provide diagnosis, treatment and rehabilitation of active and retired coal miners and others with respiratory ailments (black lung) and other occupational related respiratory disease impairments; (4) funds radiation exposure screening and education programs that screen eligible individuals adversely affected by the mining, transport and processing of uranium and the testing of nuclear weapons for cancer and other diseases; and (5) provides technical assistance to grantees and rural communities.

Border Health Division (RH3)

The Border Health Division provides leadership and direction to coordinate the Agency's assets in border regions. Specifically, the Border Health Division: (1) Assures that the Agency's engagement with regions of the border is strategic, performance based, builds partnerships and alliances, and maximizes utilization of Agency assets; (2) assures agency-wide coordination by establishing border health program policies and procedures including tracking mechanisms; (3) conducts management and evaluation studies to improve the health delivery system on the border; (4) serves as the secretariat and chair for the agency's Border Health Workgroup; (5) plans, directs, and coordinates the Agency's border health activities; and (6) plans, coordinates and facilitates the agency agreements activities with border health issues.

Section RH–30, Delegations of Authority

All delegations and re-delegations of authority made to HRSA officials and employees of affected organizational components will continue in them or their successors pending further re-delegations, provided they are consistent with this reorganization.

This reorganization is effective upon the date of signature.

Dated: October 28, 2008.

Elizabeth M. Duke,

Administrator.

[FR Doc. E8–27776 Filed 11–21–08; 8:45 am]

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