authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director of CBER (21 CFR 5.67).

Dated: March 27, 1997.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 97–8987 Filed 4–8–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

Part D, Chapter DB (Office of Operations) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, and 60 FR 56605, November 9, 1995, and in pertinent part at 56 FR 50126, October 3, 1991) is amended to reflect the reorganization of the Center for Veterinary Medicine (CVM), Office of Operations, in the Food and Drug Administration (FDA).

The Center for Veterinary Medicine will continue to develop and recommend the veterinary medical policy of the Agency with respect to the safety and effectiveness of animal drugs, feeds, feed additives, veterinary medical devices (medical devices for animal use), and other veterinary medical products. The restructuring of the Center is proposed to strengthen the delivery of services to our constituents and customer groups by streamlining the organization through delayering lines of authority and responsibility, and improving channels of communications at all levels within the Center.

1. Delete *Office of the Center Director (HFV1)*, Center for Veterinary Medicine (HFV), in its entirety and replace with the following:

Office of the Center Director (DBVA). Directs overall Center activities and coordinates and establishes Center policy in the areas of research, management, scientific evaluation, compliance and surveillance.

Approves new animal drug applications and issues notices of withdrawal of new animal drug approvals when the opportunity for a hearing has been waived.

Authorizes for use as edible products animals treated with investigational drugs and terminates exemptions for investigational trials. In conjunction with appropriate agency officials in the foods area, provides FDA policy development and direction on environmental impact matters.

Serves as focal point for operational review and compliance activity policy and legislative matters; serves as focal point for international harmonization and trade issues related to animal drugs and feeds; leads and provides oversight of research animal issues for FDA.

Plans, develops and implements the Center's Equal Employment Opportunity and Affirmative Action Program.

Develops, reviews, and coordinates all **Federal Register** publications pertaining to Center functions and coordinates requests and activities pertaining to the Regulatory Flexibility Act, Executive Orders on Regulations, Paperwork Reduction Act, and regulations planning and implementation.

2. Delete the *Office of Management (HFV1A)*, Center for Veterinary Medicine (HFV), in its entirety and replace with the following:

Office of Management and Communications (DBVB). Provides guidance and leadership in the analysis, planning, coordination and evaluation of administrative management activities including: personnel; employee orientation and development; procurement; travel; facilities; property; security; records management; performance management; awards; budget formulation and execution; information resources management; program analysis; and management analysis. Provides administrative assistance and support to the Veterinary Medicine Advisory Committee (VMAC) Executive Secretary.

Plans, develops, and implements Center management policies. Provides leadership and direction for the management and administrative interface with the Agency, the Department and other Federal agencies.

Serves as Center interface with the Agency and Department on budget issue resolutions.

Performs analysis, program assessments, or special studies of key issues relative to policy review and oversight. Directs a variety of short-range and long-range special projects or assignments of substantial significant to the Center.

Implements Internal Control Reviews in accordance with the Office of Management and Budget, Department and Agency guidelines. Provides direction in the preparation of responses to the Office of Inspector General and the General Accounting Office regarding audits and investigation.

Directs the Center's outreach efforts to consumers, professionals and the industry in communicating the program goals and priorities of the Center. Maintains the CVM Home Page on the World Wide Web. Provides automated scientific literature searches and retrieval support. Supports public and consumer affairs, including freedom of information.

Directs the Center's Strategic Plan and the efforts of Strategic Implementation Groups (SIG) to effectively accomplish Center goals and objectives. Facilitates implementation of SIG recommendations.

3. Insert *Administrative Staff (DBVB–1),* under the Office of Management and Communications (DBVB), reading as follows:

Administrative Staff (DBVB–1). Serves as the focal point in the Center for administrative management activities. Coordinates the administrative management activities in the Offices with designated Administrative Officers, i.e., personnel management, property acquisition and surplus, inventory, procurement, travel services, security procedures, records management, performance management, conflict of interest, special government employees, and telecommunications. Safeguards the administrative management services against waste, fraud and abuse.

Manages the Center's award systems through the Strategic Plan Awards Committee and the CVM Incentive Awards Committee. Manages CVM's participation in the Agency's Honor Award process, including the first and second tier ceremonies.

Provides budget execution and fiscal accounting services for the Center. Monitors and provides officials with continual awareness of obligated commitments and status of funds.

Directs, develops and implements the Center's overall professional, scientific, technical, clerical, and management training programs; formal career development programs and New Employee Orientation Program. Coordinates all Special training programs from the Agency and Department.

4. Insert *Communications Staff (DBVB–2),* under the Office of Management and Communications (DBVB), reading as follows:

Communications Staff (DBVB–2). Plans, produces, and publishes a bimonthly subscription newsletter entitled the *FDA VETERINARIAN* and other publications such as CVM UPDATES and consumer fliers.

Supports FDA public affairs/ consumer affairs initiatives, including

supporting the efforts of CVM's Press Officer and FDA Public Affairs Specialists in headquarters and the field.

Develops, prepares, and coordinates the Center's responses to requests for information through the Freedom of Information Act (FOIA).

Provides automated, scientific literature search capabilities and retrieval support to CVM. Keeps the Center current on improvements to these systems.

Delivers the Center's message to our customers, both inside and outside government, through the most effective and up-to-date medial technologies available, including the World Wide Web, the Internet, etc.

Establishes and coordinates industry/producer group outreach initiatives.

Responds to inquiries to the Center, including letters and telephone inquiries from consumers, industry representatives, government officials, health professionals and academics.

5. Insert *Program Planning and Evaluation Staff (DBVB–3),* under the Office of Management and Communications (DBVB), reading as follows:

Program Planning and Evaluation Staff (DBVB–3). Prepares the Agency annual budget estimates. This includes all phases of budget analysis and formulation and presentation. Assists staff in justifying budgets for anticipated needs.

Conducts management and program analysis studies and participates in the program planning process to identify operational goals and evaluation methods. Designs and recommends systems and procedures and develops policy recommendations to implement study conclusions.

Provides management and consulting services, including policy development and analysis of proposed policy changes. Assists Center managers in assessing management problems and designs and recommends systems and procedures; develops and recommends policy to implement study conclusions.

Conducts Internal Control Reviews in accordance with instructions and guidelines provided by Agency and OMB. Conducts analysis and presents summary of findings to management officials. Assists in the coordination and preparation of responses to the Office of the Inspector General and the General Accounting Office regarding audits and investigations.

6. Insert *Information Resources Management Staff (DBVB–4),* under the Office of Management and Communications (DBVB), reading as follows:

Information Resources Management Staff (DBVB–4). Implements information resources management functions for the Center including systems development, systems management, telecommunications plan and ADP security.

Provides systems analysis and programming support for the Center. Directs the utilization of the Center's central computer system and the internal network of personal computers and video display terminals.

Provides user support for all functions involving the CVM local area network and wide area network.

Provides support and training on ADP security including implementation of the FDA and DHHS security requirements.

7. Delete *Office of New Animal Drug Evaluation (HFVT),* Center for Veterinary Medicine (HFV), in its entirety and replace with the following:

Office of New Animal Drug Evaluation (DBVC). Evaluates for animal safety and effectiveness new animal drugs in pharmaceutical dosage forms or for use in animal feed, and the safety aspects of drug and food additive residues remaining in food produced for human consumption from animals, intentionally or otherwise, administered drugs or food additives.

Reviews and determines the adequacy of information submitted in support of proposed use of investigational new animal drugs, and recommends to the Center Director appropriate action on new animal drug applications and acts on investigational new animal drug (INAD) notices of exemption and authorization requests.

Evaluates manufacturing methods and procedures for new animal drug products.

Coordinates the development and implementation of regulations and policies pertaining to new drugs intended for animal use.

Evaluates office activities to ensure compliance with the National Environmental Policy Act (NEPA).

Provides technical support and expert testimony in legal proceedings relative to the approval of new animal drugs.

Participates in international activities designed to harmonize the drug approval process.

8. Delete the *Office of Surveillance and Compliance (HFVU),* Center for Veterinary Medicine (HFV), in its entirety and replace with the following:

Office of Surveillance and Compliance (DBVD). Advises the Center Director on surveillance and compliance policy concerning FDA regulatory responsibility with respect to animal drugs, feeds, feed additives, veterinary medical devices, and other veterinary medical products.

Develops and evaluates surveillance and monitoring programs to ensure the safety and effectiveness of animal drugs and to detect emerging resistance to antimicrobials among zoonotic enteric pathogens.

Plans, develops, monitors, and evaluates Center surveillance and compliance programs and coordinates their field implementation to ensure the safety and effectiveness of marketed animal drugs, feeds, feed additives, veterinary medical devices, and other veterinary medical products.

Directs and coordinates the development of scientific evidence supporting Formal Evidentiary Hearings requested by the Center.

Recommends to the Center Director the amendment or withdrawal of approved new animal drugs applications.

Develops, coordinates, and directs the Center's Bioresearch Monitoring Program to ensure reliability of information on which to base new animal drug and food additive approvals.

Provides epidemiology expertise to the Center as needed.

9. Delete the *Office of Science (HFVV1),* Center for Veterinary Medicine (HFV), in its entirety and replace with the following:

Office of Research (DBVE). Advises and assists the Center Director and other officials on research matters which affect Center policy direction and long-range goals.

Provides focal point for all research activities in the Center, serves as the liaison for intramural and extramural research.

Provides scientific review, guidance, and support for research activities (extramural research, training, and fellowship activities); serves as the Center focal point for pre-award coordination.

Evaluates and reviews the adequacy of research resources; appraises the technical aspects and contributions of Center science programs.

Initiates, manages, and reviews Center contracts, grants, cooperative agreements, and interagency agreements with regard to enhancing the Center research and science program activities.

Evaluates and interprets results of scientific research; initiates and recommends action as appropriate to implement policy changes.

10. Delete *Administrative Staff (HFVV2),* under the Office of Science (HFVV1), in its entirety and replace with the following:

Administrative Staff (DBVE–1). Manages budget, property, space, and acquisition of equipment and services for intramural research programs.

Responsible for the maintenance, repair, and construction of grounds, buildings, and equipment, as applicable, in support of intramural research programs.

Develops and manages health, safety, and chemical disposal required for intramural research programs.

Produces, reviews, and tracks correspondence, reports, and manuscripts for the intramural research program.

11. **Prior Delegations of Authority**. Pending further delegations, directives, or orders by the Commissioner of Food and Drugs, all delegations of authority to positions of the affected organizations in effect prior to this date shall continue in effect in them or their successors.

Dated: January 23, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–9053 Filed 4–8–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–R–207]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New Collection; *Title of Information Collection:* Evaluation of Five State Health Care Reform Demonstrations and the Evaluation of the Medicaid State Health Reform Demonstrations; *Form No.:* HCFA–R–207; *Use:* These evaluations will investigate health care reform in ten states that will implement or have implemented demonstration programs using Medicaid Section 1115 waivers. The surveys will gather information to answer questions regarding access to health care, quality of care delivered, satisfaction with health services, and the use and cost of health services. The surveys will be administered to Medicaid eligible and newly covered enrollees and eligible and near-eligible non-enrollees. A subsample of survey respondents will be SSI recipients and other disabled people who have participated in demonstrations for at least a year. Quality of care surveys will be administered to Medicaid enrollees who have diabetes and to parents of children in the Medicaid program who have pediatric asthma. *Frequency:* (Other) one time for most respondents; *Affected Public:* Individuals or Households; *Number of Respondents:* 60,483; *Total Annual Responses:* 60,691; *Total Annual Hours:* 18,267.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov/regs/prdact95.htm, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Analysis and Planning Staff, Attention: John Rudolph, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: April 1, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources.

[FR Doc. 97–9082 Filed 4–8–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Drug Rebate Program—Manufacturers; *Form No.:* HCFA–367, 367 a, b, and c; *Use:* Section 1927 requires drug manufacturers to enter into and have in effect a rebate agreement with the Federal Government for States to receive funding for drugs dispensed to Medicaid recipients; *Frequency:* Quarterly; *Affected Public:* Business or other for-profit; *Number of Respondents:* 520; *Total Annual Responses:* 2,080; *Total Annual Hours:* 49,480.

2. *Type of Request:* Extension of a currently approved collection; *Title of Information Collection:* State Drug Rebate (Medicaid); *Form No.:* HCFA–368 and HCFA-R–144; *Use:* Section 1927 requires State Medicaid agencies to report to drug manufacturers and HCFA on the drug utilization for their State and the amount of rebate to be paid by the manufacturers; *Frequency:* Quarterly; *Affected Public:* State, local, or tribal government; *Number of Respondents:* 51; *Total Annual Responses:* 204; *Total Annual Hours:* 6,125.

To request copies of the proposed paperwork collection referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410)