Respondents	No. of respondents	No. of responses/ Respondents	Avg. burden/ response (in hrs.)
State and large city health departments	60	12	0.583
State and large city health departments	60	2	3

The total annual burden is 1248. Send comments to Allison Eydt; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–2427 Filed 2–5–96; 8:45 am]

BILLING CODE 4163–18–P

[30DAY–03]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Office on (404) 639–3453.

The following requests have been submitted for review since the last publication date on January 23, 1996.

Proposed Project

1. An Assessment of The National Laboratory Training Network (NLTN)—(New)—The National Laboratory Training Network (NLTN) was established in 1989 to provide education and training to different levels of laboratory personnel in public health, private, independent laboratories and blood banks. Training in testing skills required to diagnose and monitor HIV infected individuals and AIDS-related diseases was the driving force behind its development. However, NLTN staff has responded to other emerging training needs such as those required to test for *Mycobacterium tuberculosis*, Hantaviruses, and other diseases.

The NLTN works primarily with the State Public Health Laboratories forming partnerships that facilitate laboratory training in most laboratory settings. This project is an evaluation of the effectiveness of the NLTN in meeting its goals and in satisfying the needs of its customers. Recipients of training and their supervisors will be the major sources of information. Some assessment of participants that have not attended NLTN courses will be necessary to use as a control group.

Surveys will be directed to all types of laboratories that perform diagnostic testing. Samples will be selected from local health department laboratories, state health department laboratories, microbiology course participants and physician office laboratories. The study was designed in FY 1994 and FY 1995. Data collection should begin late in FY 1995 and be completed in FY 1996.

Respondents	No, of respondents	No. of responses/ respondents	Avg. burden/ response
Laboratories	10,000	1	.5

The total annual burden is 5000. Send comments to Allison Eydt; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–2428 Filed 2–5–96; 8:45 am]

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Food and Drug Administration

[Docket No. 95N–0410]

Ivermectin Injection for American Buffalo; Availability of Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of target animal safety and effectiveness data and human food safety data to be used in support of a new animal drug application (NADA) or supplemental NADA for use of 1 percent ivermectin injection in American buffalo. The data, contained in Public Master File (PMF) 5059, were compiled under National Research Support Project No. 7 (NRSP–7), a national agricultural program for obtaining clearances for use of new drugs in minor animal species or in any animal species for the control of a disease that occurs infrequently or in limited geographical areas.

ADDRESSES: Submit NADA's or supplemental NADA's to the Document Control Unit (HFV–199), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–3125.

FOR FURTHER INFORMATION CONTACT: Jean M. Cooper, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1653.

SUPPLEMENTARY INFORMATION: Ivermectin injection for use in American buffalo is a new animal drug under section 201(w) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(w)). As a new animal drug, ivermectin is subject to section 512 of the act (21 U.S.C. 360b) which requires that its uses in American buffalo be the subject of an approved NADA or supplemental NADA. American buffalo are a minor species under § 514.1(d) (21 CFR 514.1(d)). The NRSP–7 Project, North Central Region, Michigan State University, East Lansing, MI 48824, has provided data and information that demonstrate human food safety and safety and effectiveness to American buffalo subcutaneously administered 1 percent ivermectin injection (200 micrograms of ivermectin per kilogram of body weight) for the treatment and control of hypodermosis caused by *Hypoderma bovis* (grubs).

The data and information are contained in PMF 5059. Sponsors of NADA's or supplemental NADA's may, without further authorization, refer to the PMF to support approval of an application filed under § 514.1(d). An NADA or supplemental NADA must include, in addition to a reference to the PMF, animal drug labeling and other data needed for approval, such as manufacturing methods, facilities and controls, data supporting extrapolation from a major species in which the drug is currently approved, or authorized reference to such data, and information addressing the potential environmental impacts (including occupational) of the manufacturing process and use of the drug product. Persons desiring more information concerning the PMF or requirements for approval of an NADA may contact Jean M. Cooper (address above).

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and 21 CFR 514.11(e)(2)(ii), a summary of target animal safety and effectiveness data and human food safety data submitted to support approval of an application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 25, 1996.
Stephen F. Sundlof,
Director, Center for Veterinary Medicine.
[FR Doc. 96–2371 Filed 2–5–96; 8:45 am]
BILLING CODE 4160–01–F

Health Care Financing Administration

Bureau of Program Operations, Statement of Organization, Functions, and Delegations of Authority

Part F of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Health Care Financing Administration (HCFA), (60 FR 42888, 42889, 42898, and 42899, Aug. 17, 1995) is amended to reflect a reorganization in the Bureau of Program Operations (BPO).

BPO is moving the Medicare Transaction System (MTS) functions from the MTS Initiative Task Force to the Office of Analysis and Systems (OAS). Expanding OAS's functions to include MTS is necessary because HCFA is transitioning to a new phase in the development of MTS. This phase requires a different management strategy to align the initial planning decisions with the organizational component that will bear responsibility for implementing MTS and ultimately strengthen the overall management of MTS.

The specific amendments to part F are described below:

Section F.10.D., Health Care Financing Administration, Associate Administrator for Operations and Resource Management (FL) (Organization), paragraph 4.b. is amended by adding subparagraphs (5) through (7). Paragraph 4.g. and all the associated subparagraphs are deleted in their entirety.

b. Office of Analysis and Systems (FLG1)

(5) Medicare Transaction System Quality Assurance (FLG15)

(6) Medicare Transaction System Development (FLG16)

(7) Medicare Transaction System Program Planning & Needs Analysis (FLG17)

Section F.20.D, Health Care Financing Administration Associate Administrator for Operations and Resource Management (FL) (Functions), paragraph 4.b. is deleted and replaced with the following new functional statement. In addition, paragraph 4.b. is further amended by adding subparagraphs (5) through (7). Paragraph 4.g. and subparagraphs (1) through (3) are deleted in their entirety.

b. Office of Analysis and Systems (FLG1)

- Provides requirements and specifications for the design, development, and maintenance of reporting and information management systems that generate data reflecting on Medicare program operations.
- Serves as the Agency focal point for the management and coordination of the Medicare Transaction System Initiative (MTSI). Represents HCFA to the Department, other Federal Agencies, and outside organizations.
- Provides direction and technical guidance for the design, development, implementation, verification and validation, and maintenance of the Medicare Transaction System (MTS) to integrate Medicare Part A and Part B claims processing systems.
- Identifies reporting and information needs for data relating to Medicare contractor operations and initiates appropriate action for establishing or modifying the reporting and information systems to satisfy these needs.
- Analyzes a broad range of information, including computer stored data, on operations performed in support of the Medicare program; prepares interpretive reports and recommendations on findings to internal bureau components for purposes of conducting program and performance evaluations.
- Provides overall support to other staff in analyzing and interpreting program and operational data to better understand the program.
- Provides requirements and specifications for the design, development, and management at the national level, activities required to enhance systems for improvement of the Medicare eligibility systems, Part A and Part B claims processing systems, and the Medicare program database.
- Provides direction and guidance to HCFA staff (central office and regional) on improving contractor systems.
- Prepares systems plans and develops policies for the design, implementation, and evaluation of shared systems and standardized modules for use by Medicare carriers, intermediaries, and hosts.
- Directs the design, development testing, and implementation of innovative system enhancements to the Common Working File (CWF) shared claims processing systems resulting in improvements to the national Medicare claims payment process.
- Provides requirements and specifications for the development, implementation, execution, and monitoring of a procedure to provide ongoing testing of national claims processing and information system to detect flaws in the operation of software, hardware, and related operations.
- Provides requirements and specifications for the development and implementation of systems that provide for the creation and maintenance of databases and test files that are required to conduct comprehensive system acceptance testing of a national claims processing and information system.

(5) Medicare Transaction System Quality Assurance (FLG15)

- Develops, implements, directs, and operates activities to assure the quality of Medicare Transaction System (MTS) development throughout the system development life cycle.
- Provides technical management, oversight, coordination and day-to-day monitoring of contract(s) for the independent verification and validation of MTS analysis, design, development, validation, implementation, and maintenance activities.
- Reviews and evaluates the effectiveness of the processes and procedures used to analyze, design, develop, implement, and maintain the MTS.
- Provides the documentation and analysis necessary to initiate and support corrective action resulting from findings of the MTS quality assurance activities.
- Reviews and evaluates quality assurance programs maintained by the MTS design contractor, the independent verification and validation contractor and HCFA to ensure integration of quality assurance activities throughout the MTS development process.
- Recommends alternatives to proposed methodologies for the analysis, design, development, validation, implementation and maintenance of the MTS.

(6) Medicare Transaction System Development (FLG16)

- Develops, implements, and directs activities to assure the development of the Medicare Transaction System (MTS) throughout the system development life cycle.
- Provides technical management, oversight and coordination and day-to-day monitoring of the contract(s) for performing the Medicare Transaction System (MTS) analysis, design, development, validation, implementation, and maintenance activities.
- Provides the inter- and intra-component coordination required to insure appropriate and timely review