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).

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[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).

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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.