OMB 0910-
SUPPORTING STATEMENT

INDEX OF LEGALLY MARKETED UNAPPROVED NEW ANIMAL DRUGS FOR MINOR SPECIES

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

This information collection approval request is for a Food and Drug Administration (FDA) proposed rule intended to implement section 572 of the Minor Use and Minor Species (MUMS) Animal Health Act of 2004. The MUMS Act is made up of three sections (571, 572, and 573) and it establishes new regulatory procedures intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species as well as uncommon diseases in major animal species. Section 572 of the legislation provides for a public index listing of legally-marketed unapproved new animal drugs for minor species of animals. The drugs in this index will only be indicated for use in non-food minor species or for use in early non-food life stages of food-producing minor species. This proposed rule will, among other things, specify the procedures for requesting eligibility and addition to the index as well as the annual reporting requirements for index holders.

The specific citations within 21 CFR 500 regarding information collection requirements for which we request OMB approval are:

Section 516.119: Permanent-resident U.S. agent for foreign requestor.

Section 516.121: Meetings.

Section 516.123: Informal conferences

Section 516.125: Investigational use of new animal drugs to support indexing.

Section 516.129: Content and format of a request for determination of eligibility for indexing.

Section 516.141: Qualified expert panels.

Section 516.143: Written report.

Section 516.145: Content and format of a request for addition to the index.

Section 516.161: Modifications to indexed drugs.

Section 516.163: Change in ownership of an indexed drug

Section 516.165: Records and Reports.

2. How, By Whom, Purpose of Collection

Foreign drug companies will provide the FDA with the name and address of a permanent U.S. resident agent to represent them at the time they establish their initial index file. Such information, or any changes in such information, will be submitted in writing to the FDA/Center for Veterinary Medicine (CVM), Office of Minor Use and Minor Species Animal Drug Development (OMUMS), as specified in section **516.119**.

Drug companies may request, in writing, a meeting with FDA to discuss the requirements for indexing under section **516.121** as well as an informal conference to dispute an action taken by FDA in regards to a request for indexing, as specified in section **516.123**.

Section 516.125 provides for investigational use of new animal drugs intended for indexing.

Requests for determination of index eligibility and, if determined eligible, subsequent requests for addition to the index, including a written report, will be prepared by drug companies and submitted to OMUMS, as specified in sections **516.129** and **516.145**. Based on the criteria provided in the MUMS Act and in this proposed rule, OMUMS will grant or deny such requests for each drug owner and their specific drug, dosage form, and intended use. These two collections of information from each drug owner are required only once for each specific drug/dosage form/intended use. A description of the written report required in section 516.145 can be found under section **516.143**.

Under section **516.141** are provisions for drug companies to nominate a qualified expert panel as well as the panel's recordkeeping requirements. This section also calls for the submission of a written conflict of interest statement to FDA by each proposed panel member.

Index holders may modify their index listing (section **516.161**) or change drug ownership (section **516.163**) by notifying OMUMS in writing.

Records and reports, as specified in section **516.165**, will be prepared by holders of indexed drugs and will be submitted to OMUMS. One of these requirements is an annual written drug experience report. These reports will be used by OMUMS to monitor possible drug-related adverse events.

All information collection specified in this proposed rule is new.

3. Consideration Given to Information Technology

We encourage the submission of data electronically, and will consider any such electronic submissions which will be more efficient for industry and facilitate review by the Agency.

4. Identification of Information

The information provided is unique to the particular product or application cited. There are no other regulations that require the submission of this same information.

5. Small Business

Because many new animal drugs for minor uses and minor species traditionally come from smaller drug companies, we expect the MUMS Act to have a beneficial impact on small business. The collection of information outlined in this proposed rule is commensurate with what is required by the MUMS Act and should pose no greater burden to small businesses than it does to large pharmaceutical firms. A small business coordinator has been established on the Commissioner's staff to ensure that small businesses have an adequate opportunity to express their concerns and to keep our management apprised of how its regulatory decisions may impact the small business community. Furthermore, we encourage sponsors, whether small or large businesses, to meet with us to discuss questions concerning submissions.

6. Less Frequent Information Collection

Periodic drug experience reports, as proposed in section 516.165, shall be submitted to OMUMS annually. This frequency is the same as is currently required for approved drugs under 21 CFR 514.80(b)(4). FDA will review the records and reports required in this section to facilitate a determination under section 572(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc-1) as to whether there may be grounds for removing a drug from the index.

7. Information Collection Circumstances

Required reports are consistent with 5 CFR 1320.5.

8. Consultations with Persons Outside FDA

In the FEDERAL REGISTER of August 22, 2006 (71 FR 48840), FDA invited public comment on the proposed rule. In response to that notice FDA received 2 comments concerning the estimated paperwork reporting burden. These 2 comments are summarized in the preamble to the final rule which published December 6, 2007 (72 FR 69108); part VI I "Paperwork Reduction Act of 1995 "section.

9. Payment or Gift

There are no provisions for payments or gifts to respondents under section 572 of the MUMS Act or under any part of this proposed rule.

10. Confidentiality Provisions

Confidentiality of data and information in an index file is provided for in section 516.171 of this proposed rule. In order to comply with the requirements of 21 CFR part 20 and sections 514.11 and 514.12, the Center exercises security precautions in the handling of documents. This same level of security will be provided for index files. A security controlled document file room, locked files, drawers and doors are required for in-house protection. Unused documents are destroyed by shredding. This protection is continued after a drug is added to the index.

The Center has a Freedom of Information Officer who is responsible for administering the policies relative to the release of information.

11. Privacy

There are no questions of a sensitive nature.

12. Burden of Information Collection

TABLE 1. ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. Of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
516.119	2	1	2	1	2
516.121	30	2	60	4	240
516.123	3	1	3	8	24
516.125	2	3	6	20	120
516.129	30	2	60	20	1200
516.141	20	1	20	16	320
516.143	20	1	20	120	2400
516.145	20	1	20	20	400
516.161	1	1	1	4	4
516.163	1	1	1	2	2
516.165	10	2	20	8	160
Total					4872

[1] There is no capital or operating and maintenance cost associated with this collection of information.

TABLE 2. ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	No. Of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
516.141	30	2	60	0.5	30
516.165	10	2	20	1	20
Total					50

[1] There is no capital or operating and maintenance cost associated with this collection of information.

The burden estimate for this reporting requirement was derived in our Office of Minor Use and Minor Species Animal Drug Development by extrapolating from relevant portions of the current INAD/NADA reporting requirements for similar actions by a similar segment of the regulated industry and from previous interactions with the minor use/minor species community.

13. Costs to Respondents

There are no capital costs or operating and maintenance costs associated with this collection.

14. Costs to the Federal Government

In the first year we estimate 1.0 FTE in OMUMS × 60% spent on paperwork × $115,000 per GS-14 FTE = $69,000.

In year ten we estimate that up to 4 full time equivalent employees (one GS-14 position, two GS-13 positions and one GS-11 position) would be needed to administer the program which will cost the government about $378,000.

15. Reason for Changes

This is a new program.

16. Statistical Reporting

There is no intent on the part of the Federal Government to publish this data, nor is any general statistical analysis by the Federal Government anticipated.