TABLE 1—TOTAL ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Physician survey—pretest	100	1	100	.33	33
Physician survey—main study	600	1	600	.33	198
Consumer experiment—pretest	200	1	200	.25	50
Consumer experiment—main study	2,500	1	2,500	.25	625
Total					906

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

Dated: November 30, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–30385 Filed 12–2–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0597]

Agency Information Collection Activities; Proposed Collection; Comment Request; Index of Legally Marketed Unapproved New Animal Drugs for Minor Species

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the burden hours associated with indexing of legally marketed unapproved new animal drugs for minor species.

DATES: Submit either electronic or written comments on the collection of information by February 1, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Johnny Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *juanmanuel.vilela@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Index of Legally Marketed Unapproved New Animal Drugs for Minor Species—21 CFR Part 516 (OMB Control Number 0910–0620)—Extension

The Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to authorize FDA to establish new regulatory procedures intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species (species other than cattle, horses, swine, chickens, turkeys, dogs, and cats), as well as uncommon diseases in major animal species.

The MUMS Act added three new sections to the FD&C Act (sections 571, 572, and 573 (21 U.S.C. 360ccc, 360ccc–1, and 360ccc–2, respectively)). The final rule (72 FR 69108, December 6, 2007) implements section 572 of the FD&C Act, which provides for an index of legally marketed unapproved new animal drugs for minor species. Participation in any part of the MUMS program is optional so the associated paperwork only applies to those who choose to participate. The final rule specifies, among other things, the criteria and procedures for requesting eligibility for indexing and for requesting addition to the index as well as the annual reporting requirements for index holders.

Under the new subpart C of part 516 (21 CFR part 516, subpart C), § 516.119 provides requirements for naming a permanent-resident U.S. agent by foreign drug companies, and § 516.121 provides for informational meetings with FDA. Section 516.123 provides requirements for requesting informal conferences regarding agency administrative actions and § 516.125 provides for investigational use of new animal drugs intended for indexing. Provisions for requesting a determination of eligibility for indexing can be found under § 516.129 and provisions for subsequent requests for addition to the index can be found under § 516.145. A description of the

written report required in § 516.145 can be found under § 516.143. Under § 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 are able to modify their index listing under § 516.161 or change drug ownership under § 516.163. Requirements for records and reports are under § 516.165.

Description of Respondents: Pharmaceutical companies that sponsor new animal drugs.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number 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	1,200
516.141	20	1	20	16	320
516.143	20	1	20	120	2,400
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					4,872

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Annual frequency per recordkeeper	Total annual records	Hours per recordkeeper	Total hours
516.141	30	2	60	0.5	30
516.165	10	2	20	1	20
Total					50

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

Dated: November 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–30335 Filed 12–2–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0566]

Draft Guidance for Industry on Residual Solvents in Animal Drug Products; Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry #211 entitled "Residual Solvents in Animal Drug Products; Questions and Answers." The draft questions and answers (Q&A) guidance addresses the United States Pharmacopeia (USP) General Chapter <467> Residual Solvents that applies to both human and veterinary drugs and to compendial and non-compendial drug products. This document answers questions regarding CVM's implementation of USP <467> Residual Solvents.

DATES: Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by February 1, 2011.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sudesh Kamath, Center for Veterinary Medicine (HFV–145), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8260, e-mail: *sudesh.kamath@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On July 1, 2008, the USP implemented a requirement for the control of residual solvents in drug products marketed in the United States. Once implemented, the requirement, USP General Chapter <467> Residual Solvents, became a statutory requirement under section 501(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(b)).

FDA is announcing the availability of a draft guidance for industry #211 entitled "Residual Solvents in Animal