

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Experiment .....	900	1	900	0.17 (10 min.) .....	153
Total .....	.....	.....	.....	.....	216

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

## II. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Olsen, S., L. MacKinnon, J.S. Goulding, et al., "Surveillance for Foodborne Disease Outbreaks—United States, 1993 to 1997," *Morbidity and Mortality Weekly Report*, vol. 49, pp. 1–51, 2000.
2. "FDA 101: Product Recalls—From First Alert to Effectiveness Checks," (<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm>).
3. Calvin, L., "Outbreak Linked to Spinach Forces Reassessment of Food Safety Practices," *Amber Waves*, vol. 5, pp. 24–31, 2007.
4. Lucier, G. and R. Dettmann, "Vegetables and Melons Outlook: A Report From the United States Department of Agriculture, Economic Research Service," VGS-327, June 26, 2008.

Dated: October 4, 2011.

**David Dorsey,**

*Acting Associate Commissioner for Policy and Planning.*

[FR Doc. 2011-26131 Filed 10-7-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0509]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Appeals of Science-Based Decisions Above the Division Level at the Center for Veterinary Medicine

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. **DATES:** Fax written comments on the collection of information by November 10, 2011.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, *Fax:* 202-395-7285, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0566. Also include the FDA docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Juanmanuel 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](mailto:juanmanuel.vilela@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed

collection of information to OMB for review and clearance.

#### Appeals of Science-Based Decisions Above the Division Level at the Center for Veterinary Medicine—21 CFR Part 10.75 (OMB Control Number 0910-0566)—Extension

**Respondents:** Respondents to this collection of information are applicants that wish to submit a request for review of a scientific dispute.

The Center for Veterinary Medicine's Guidance for Industry #79 "Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine" describes the process by which the Center for Veterinary Medicine (CVM) formally resolves disputes relating to scientific controversies. A scientific controversy involves issues concerning a specific product regulated by CVM related to matters of technical expertise and requires specialized education, training, or experience to be understood and resolved. Further, the guidance details information on how the Agency intends to interpret and apply provisions of the existing regulations regarding internal Agency review of decisions. In addition, the guidance outlines the established procedures for persons who are sponsors, applicants, or manufacturers, for animal drugs or other products regulated by CVM, that wish to submit a request for review of a scientific dispute. When a sponsor, applicant, or manufacturer has a scientific disagreement with a written decision by CVM, they may submit a request for a review of that decision by following the established Agency channels of supervision for review.

In the **Federal Register** of July 13, 2011 (76 FR 41264), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
10.75 .....	1	3	3	10	30

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimated annual reporting burden is based on CVM's experience over the past 3 years in handling formal appeals for scientific disputes. The number of respondents multiplied by the number of responses per respondent equals the total annual responses. The average burden per response (in hours) is based on discussions with industry and may vary depending on the complexity of the issue(s) involved and the duration of the appeal process.

Dated: October 4, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-26132 Filed 10-7-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0281]

#### Pilot Program To Evaluate Proposed Proprietary Name Submissions; Public Meeting on Pilot Program Results Will Not Be Held

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that it will not hold a public meeting to discuss the results of a 2-year voluntary pilot program that enabled participating pharmaceutical firms to evaluate proposed proprietary names and submit the data generated from those evaluations for FDA to review. FDA anticipated holding a public meeting at the end of fiscal year 2011 to discuss the results of the pilot program, but the Agency did not receive sufficient pilot submissions to form a basis for discussion. Interested parties may submit to the docket any additional comments on the pilot program. As previously announced, FDA plans to publish a draft guidance describing the best test methods for proprietary name evaluation.

**DATES:** Submit either electronic or written comments by November 10, 2011.

**ADDRESSES:** Submit electronic comments on the pilot program or this document 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. Identify comments with the docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

*Regarding human drug products:* Carol Holquist, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4416, Silver Spring, MD 20993-0002.

*Regarding human biological products:* Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration (HFM-17), 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In Title I of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85), Congress reauthorized and expanded the Prescription Drug User Fee program for fiscal years 2008 to 2012 (PDUFA IV). In performance goals agreed to in conjunction with the reauthorization of PDUFA IV, FDA agreed to publish a concept paper on and implement a pilot program to enable pharmaceutical firms to evaluate proposed proprietary names and submit the data generated from those evaluations to FDA for review. (See IX.B at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm>).

In June 2008, FDA held a public technical meeting (see 73 FR 27001, May 12, 2008) to discuss a draft concept paper describing the pilot program and FDA's thinking about how pharmaceutical firms could participate in the pilot program to evaluate proposed proprietary names and submit the data generated to FDA for review. After considering comments from the meeting and the public docket, FDA announced the availability of the concept paper entitled "PDUFA Pilot Project Proprietary Name Review" in the **Federal Register** of October 7, 2008

(73 FR 58604). As stated in the concept paper, the goals of the pilot program were to minimize the use of names that are misleading or that are likely to lead to medication errors, to make FDA's application review more efficient, and to make regulatory decisions more transparent.

In the **Federal Register** of October 1, 2009 (74 FR 50806), FDA announced the opportunity for firms to register for and submit data to the voluntary pilot program. FDA stated that at the end of fiscal year 2011, or after accruing 2 years experience with pilot program submissions, the Agency would evaluate the results to determine whether the model of industry conducting reviews, submitting the results to FDA, and FDA reviewing the data is feasible and whether it is a better model than FDA conducting de novo reviews of proprietary names. FDA planned to hold a public meeting to discuss the results of the pilot program and recommended additions and/or changes to methods based on the report results. FDA also stated that, following the meeting, FDA would publish draft guidance on best test practices for proprietary name review.

FDA began accepting requests to participate in the pilot program on October 1, 2009, and the pilot program ended on September 30, 2011. Although three applicants registered to participate during the 2-year period, FDA received only one complete submission for pilot program review, which is not a sufficient number to assess the feasibility of industry conducting reviews of proposed proprietary names. Therefore, the public meeting that was anticipated to occur at the end of fiscal year 2011 to assess the pilot program for evaluation of proposed proprietary names will not be held because of insufficient participation. The pilot program docket (docket number FDA-2008-N-0281) has remained open for comment during the 2-year pilot program, and FDA has invited comments on human factor testing. In lieu of a public meeting, interested persons may submit any additional comments to the docket. After the close of the public comment period, FDA intends to publish a draft guidance