meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: November 6, 2006.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E6–19151 Filed 11–13–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0329]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medicated Feed Mill License Application

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 December 14, 2006

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: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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.

Medicated Feed Mill Licensing Application—21 CFR Part 515 (OMB Control No. 0910–0337)—Extension

The Animal Drug Availability Act (ADAA) of October 9, 1996, amended section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) to replace the system for the approval of specific medicated feed with a general licensing system for feed mills. Before passage of the ADAA, medicated feed manufacturers were required to obtain approval of Medicated Feed Applications (MFAs) in order to manufacture certain types of medicated feeds. An individual approved MFA was required for each and every applicable medicated feed. The ADAA streamlined the paperwork process for gaining approval to manufacture medicated feeds by replacing the MFA system with a facility license for each medicated feed manufacturing facility. Implementing regulations are at part 515 (21 CFR part 515).

In the **Federal Register** of August 25, 2006 (71 FR 50433), FDA solicited comments on the information collection provisions of this proposed collection. In response to that request, FDA received no comments.

Description of Respondents: Medicated feed manufacturers.

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

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
515.10(b)	7	1	7	0.25	1.75
515.11(b)	100	1	100	0.25	25
515.23	25	1	25	0.25	6.25
515.30(c)	0.15	1	0.15	24	3.6
Total					36.6

[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	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
510.305	1,070	1	1,070	0.03	32.10

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

The estimated annual reporting burden on industry is 36.6 hours as shown in table 1 of this document. Industry estimates it takes about 1/4 hour to submit the application. We estimate 132 original and supplemental applications, and voluntary revocations for a total of 33 hours (132 submissions x 1/4 hour). An additional 3.6 hours is added for the rare notice of opportunity for a hearing to not approve or revoke an application. Finally, we estimate 36 hours for maintaining and retrieving labels as required by 21 CFR 510.305. We estimated .03 hours for each of approximately 1,070 licensees. Thus, the total burden for recordkeeping requirements is 32.10 hours (1,070 x 0.03).

Dated: November 7, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–19152 Filed 11–13–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0441]

Draft Guidance for Industry: Protocols for the Conduct of Method Transfer Studies for Type C Medicated Feed Assay Methods; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft guidance for industry (#136) entitled ''Protocols for the Conduct of Method Transfer Studies for Type C Medicated Feed Assay Methods.'' This draft guidance provides our recommendations for protocols for conducting the transfer study of a single-laboratory validated Type C medicated feed assay method to laboratories that have no experience with the test method.

DATES: Submit written or electronic comments on this draft guidance by January 29, 2007, to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft 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.

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Rebecca L. Owen, Center for Veterinary Medicine (HFV–141), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–9842, e-mail: *rebecca.owen@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 512(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) establishes the requirements for a new animal drug approval. FDA regulations specify the information you (the sponsor) must submit as part of your new animal drug application (NADA) and the proper format for the NADA submission (§ 514.1 (21 CFR 514.1)). As part of your NADA submission, you must describe analytical procedures capable of determining the active component(s) of the new animal drug within a reasonable degree of accuracy and of assuring the identity of such components (21 CFR 514.1(b)(5)(vii)). This includes a description of practicable methods of analysis (assay methods) that have adequate sensitivity to determine the amount of the new animal drug in the final dosage form (21 CFR 514.1(b)(5)(vii)(a)). In the case of a Type A medicated article, the Type C medicated feed is a final dosage form used to treat the animal. Thus as part of the NADA review process, FDA looks at assay methods for determining the amount of a new animal drug in Type C medicated feed.

This draft guidance provides our (the Office of New Animal Drug Evaluation or ONADE) recommendations for protocols for conducting the transfer study of a single-laboratory validated Type C medicated feed assay method to laboratories that have no experience with the test method. Many testing laboratories, including state feed laboratories and contract laboratories, use Type C medicated feed assay methods to determine whether the drug in a medicated feed is within the assay limits. The term ''assay limits'' refers to the amount of the drug detected when a Type B/C feed is assayed. The limit is a range that is codified at 21 CFR 558.4(d). When feed assay values fall within this range, it indicates that the feed has been prepared with the correct amount of Type A medicated article. Because many different laboratories use medicated feed assays, it is important that the assay methods are reproducible. Sponsors should conduct method transfer studies to evaluate reproducibility. A method transfer study is part of the evaluation process for a Type C medicated feed assay method and demonstrates the transferability of the feed assay method among different laboratories by comparing the results each laboratory obtains when using the method to analyze a specific set of feed samples. Sponsors may expand the method transfer study to include other medicated feed products, such as Top Dress Type C, Free-Choice Type C, and Type B medicated feeds.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in § 514.1 have been approved under OMB control nos. 0910–0032 and 0910–0154.

III. Significance of Guidance

This draft level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

This draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this draft guidance document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Electronic comments may be submitted on the Internet at *http://www.fda.gov/dockets/ecomments*. Copies of the draft guidance document entitled ''Protocols for the Conduct of Method Transfer Studies for Type C Medicated Feed Assay Methods'' may be obtained from the CVM Home Page (*http://www.fda.gov/cvm*) and from the Division of Dockets Management Web site (*http://www.fda.gov/ohrms/dockets/default.htm*).

Dated: November 7, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–19204 Filed 11–13–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0419]

Draft Voluntary National Retail Food Regulatory Program Standards; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Voluntary National Retail Food