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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft guidance for industry (#136) entitled ''Protocols for the Conduct of Method Transfer Studies for Type C Medicated Feed Assay Methods.'' This draft guidance provides our recommendations for protocols for conducting the transfer study of a single-laboratory validated Type C medicated feed assay method to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DATES: Submit written or electronic comments on this draft guidance by January 29, 2007, to ensure their adequate consideration in preparation of the final document.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ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.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 Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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

Regulatory Program Standards'' (the Program Standards). The Program Standards are intended to help state, local, and tribal regulators design and manage a retail food regulatory program that is focused on the reduction of foodborne illness risk factors.

DATES: Submit written or electronic comments concerning the draft Program Standards document and its recommendations for collection of information by January 16, 2007.

ADDRESSES: Submit written requests for single copies of the draft Program Standards document to Glenda R. Lewis, Center for Food Safety and Applied Nutrition (HFS–626), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2150. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments concerning the draft Program Standards document and its recommendations for collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the draft Program Standards document and its recommendations for collection of information to *http://www.fda.gov/dockets/ecomments*. All comments should be identified with the docket number found in brackets in the heading of this document. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft manuals and received comments.

FOR FURTHER INFORMATION CONTACT: Glenda R. Lewis, Center for Food Safety and Applied Nutrition (HFS–626), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–2150.

SUPPLEMENTARY INFORMATION:

I. Background

While the responsibility for regulating retail and foodservice establishments lies primarily with state, local, and tribal jurisdictions, FDA provides assistance to these jurisdictions through multiple means including, but not limited to, training and technical assistance. Authority for providing such assistance is derived from section 311 of the Public Health Service Act (42 U.S.C. 243). In addition, FDA's mission under section 903(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(b)(2)(A)) includes ensuring that foods are safe, wholesome, and sanitary, and section 903(b)(4) of the act directs FDA to cooperate with food retailers, among others, in carrying out this part of its mission.

The Centers for Disease Control and Prevention has identified the major contributing factors associated with foodborne illness outbreaks. Five of these contributing factors directly relate to retail and foodservice establishments and are called ''foodborne illness risk factors'' by FDA. In an effort to assist state, local, and tribal regulators and the retail and food service entities they regulate, FDA developed draft Program Standards.

The Program Standards were developed to address the need for national uniformity among retail food regulatory programs, to promote uniform application of the FDA Food Code, and to reduce the occurrence of foodborne illness risk factors. The Program Standards were developed with extensive input from state, tribal, and local regulatory authorities. They capture the best management practices currently in use by those authorities and are intended to help those authorities design and manage a retail food regulatory program that is focused on the reduction of foodborne illness risk factors.

The incorporation of a risk-based methodology into regulatory inspection programs is an important element in reaching the goals established by the President's Council on Food Safety in the document entitled ''Food Safety Strategic Plan'' released in January 2001 (available at *http://www.foodsafety.gov/~fsg/cstrpl–4.html*) as well as FDA's food safety program goals.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 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: (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.

Title: Voluntary National Retail Food Regulatory Program Standards

In the **Federal Register** of May 9, 2001 (66 FR 23715), a 60-day notice was published soliciting comments on FDA's collection of information from local, state and tribal authorities concerning their use of or planned use of FDA's Program Standards. No comments were received in response to that notice. The agency has decided to reissue this 60-day notice for further comment because the Program Standards have been revised since the previous notice. The January 2005 revision of the Program Standards is available in draft for comment on FDA's Web site at *http://www.cfsan.fda.gov/~dms/ret3toc.html*.

The Program Standards define nine essential elements of an effective regulatory program for retail food establishments, establish basic quality control criteria for each element, and provide a means of recognition for those state, local, and tribal regulatory programs that meet the Program Standards. The program elements addressed by the Program Standards are as follows: (1) Regulatory foundation, (2) trained regulatory staff, (3) inspection program based on HACCP principles, (4) uniform inspection program, (5) foodborne illness and food security preparedness and response, (6) compliance and enforcement, (7) industry and community relations, (8) program support and resources, and (9) program assessment. Each standard includes a list of records needed to document compliance with the standard (referred to in the Program Standards document as ''quality records'') and has one or more corresponding appendices that contain forms and worksheets to facilitate the collection of information needed to assess a retail program under that standard. The respondents are State, local and tribal government agencies. Regulatory agencies may use existing, available records or may choose to develop and use alternate forms and worksheets that capture the same information.

In the course of their normal activities, state, local, and tribal

regulatory agencies already collect and keep on file many of the records needed as quality records to document compliance with the end of each Program Standard by jurisdictions that enroll. Although the detail and format in which this information is collected and recorded may vary by jurisdiction, records that are kept as a usual and customary part of normal agency activities include inspection records, written quality assurance procedures and records of quality assurance checks, staff training certificates and other training records, a log or database of food-related illness or injury complaints, records of investigations resulting from such complaints, an inventory of inspection equipment, records of outside audits, and records of outreach efforts (e.g., meeting agendas and minutes, documentation of food safety education activities). No new recordkeeping burden is associated with these existing records, which are already a part of usual and customary program recordkeeping activities by state, local, and tribal regulatory agencies, and which can serve as quality records under the Program Standards.

State, local, and tribal regulatory agencies that enroll in the Program Standards and seek listing in the FDA National Registry are required to report to FDA on the completion of the following three management tasks outlined in the Program Standards: (1) Conducting a program self assessment; (2) conducting a baseline survey of the regulated industry; and (3) obtaining an independent outside audit (verification audit). All three tasks must be completed within a 3-year time span. The results are reported to FDA on Form FDA 3519, ''FDA National Registry Report,'' and Form FDA 3520, ''Permission to Publish in National Registry.'' These forms are located in Appendix I of the Program Standards. If a regulatory agency follows all the recordkeeping recommendations in the individual standards and their appendices, it will have all the information needed to complete the forms. The time required to complete the forms is minimal.

Recordkeeping

FDA's recordkeeping burden estimate includes time required for a state, local, or tribal agency to review the instructions in the Program Standards, compile information from existing sources, and create any records recommended in the Program Standards that are not already kept in the normal course of the agency's usual and customary activities. Worksheets (Appendices) are provided to assist in this compilation. In estimating the time needed for the program self-assessment (Program Standards 1–8, shown in chart 1 of this document), FDA considered responses from four state and three local jurisdictions that participated in an FDA Program Standards Pilot study. Chart 2 of this document shows the estimated recordkeeping burden for the completion of the baseline data collection and chart 3 of this document shows the estimated recordkeeping burden for the verification audit. The overall program improvement cycle is a 3-year period for completion of all three management tasks.

CHART 1.—YEAR ONE—SELF ASSESSMENT

Standard	Recordkeeping Activity	Hours per Recordkeeper (Year One)
No. 1 Regulatory Foundation	Self Assessment: (Appendix A[1]) Completion of worksheet recording results of evaluations and comparison on worksheets	16
No. 2 Trained Regulatory Staff	Self Assessment: (Appendix B[1]) Completion of summary worksheet of each employee training records[2]	19
No. 3 HACCP Principles	Self Assessment: (Appendix C[1]) Completion of worksheet documentation	4
No. 4 Uniform Inspection Program	Self Assessment: (Appendix D[1]) Completion of worksheet documentation of jurisdiction's quality assurance procedures[2]	19
No. 5 Foodborne Illness and Food Security Preparedness and Response	Self Assessment: (Appendix E[1]) Completion of worksheet documentation	5
No. 6 Compliance Enforcement	Self Assessment: (Appendix F[1]) Selection and review of 20 to 70 establishment files @ 25 minutes per file. Estimate is based on a mean number of 45. Completion of worksheet	19
No. 7 Industry and Community Relations	Self Assessment: (Appendix G[1]) Completion of worksheet	2
No. 8 Program Support and Resources	Self Assessment: (Appendix H[1]) Selection and review of establishment files	8
Subtotal		92

[1]Or comparable documentation.

[2]Estimates will vary depending on the number of regulated food establishments and the number of inspectors employed by the jurisdiction.

CHART 2.—YEAR TWO—BASELINE DATA COLLECTION

Standard	Recordkeeping Activity	Hours Per Recordkeeper (Year Two)
No. 9 Program Assessment	Baseline Data Collection (Appendices I and J). Selection and inspection of randomly selected statistical sample of 9 to 87 establishments from each of 9 facility types[1]	333

[1]Calculation based on mean sample size of 39 and average FDA inspection time for each establishment type. Estimates will vary depending on the number of regulated food establishments within a jurisdiction and the number of inspectors employed by the jurisdiction.

CHART 3.—YEAR THREE—VERIFICATION AUDIT

Standard	Recordkeeping Activity	Hours per Recordkeeper (Year Three)
9	Verification Audit (Appendices I and J)[1]	46

[1]We estimate that no more than 50 percent of time spent to complete self assessment of all nine Standards is spent completing verification audit worksheets. Time will be considerably less if less than nine standards require verification audits.

FDA estimated the annual hours per recordkeeper (i.e., per enrolled jurisdiction) in table 1 of this document by adding the recordkeeping estimates for the management tasks of self assessment, baseline data collection, and verification audit (charts 1, 2, and 3 of this document) that enrolled jurisdictions must perform during a 3-year cycle, then dividing the total by three to obtain an annual average.

The estimates in tables 1 and 2 of this document are based on the estimated participation of 500 regulatory jurisdictions in the Program Standards. There are approximately 3,000 jurisdictions in the United States and its territories that have retail food regulatory programs. Enrollment in the Program Standards is voluntary, and therefore FDA does not expect all jurisdictions to participate in the near future. In its 2002 operational plan, the FDA National Retail Food Team established a goal of enrolling 15 percent of eligible agencies, or 450 programs, in the Program Standards by the year 2010. For purposes of this burden estimate, it is reasonable to take into account the possibility that this goal could be exceeded by approximately 10 percent, for a total of approximately 500 participating agencies.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

FDA Worksheets[2]	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Appendices A through J	500	1	500	157	78,500
Total Burden Hours					78,500

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

Reporting

Based on the number and nature of the items that need to be completed, FDA estimates a total of 12 minutes annually for each enrolled jurisdiction to complete both FDA Form 3519, ''FDA National Registry Report,'' and Form 3520, ''Permission to Publish in National Registry.'' Form 3519 requires the name and address of the jurisdiction; completion dates for the self assessment, baseline survey (original and update), and verification audit; names of the person(s) who completed the self-assessment, verification audit, baseline survey, baseline survey update, and action plan; signature of the program manager; and date the form was completed. Form 3520 requires the name of the jurisdiction, completion date of the self assessment, date of the verification audit report, name of the auditor, signature and title of the official completing the form, and date the form was completed. As explained previously in this document, FDA estimates that 500 regulatory jurisdictions will enroll in the Program Standards. The reporting burden in table 2 of this document includes only the time necessary to fill out and send the forms, as compiling the underlying information (including self-assessment reports, baseline surveys, outside audits, and supporting documentation) is accounted for under the recordkeeping estimates in table 1 of this document.

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

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Forms	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3519	500	1	500	6 min	50 hours
3520	500	1	500	6 min	50 hours

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

FDA Forms	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total Burden Hours					100 hours

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

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft Program Standards document and its recommendations for collection of information. 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. The draft Program Standards document and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft Program Standards document at *http://www.cfsan.fda.gov/~dms/ret3toc.html*.

Dated: October 31, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–19195 Filed 11–13–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[DHS–2006–0070]

Data Privacy and Integrity Advisory Committee

AGENCY: Office of the Secretary, Department of Homeland Security.

ACTION: Notice of Federal Advisory Committee Meeting.

SUMMARY: This notice announces the date, time, location, and agenda for the next meeting of the Department of Homeland Security Data Privacy and Integrity Advisory Committee. This meeting will be open to the public, with the exception of a one-hour administrative session.

DATES: The meeting will be held from 8 a.m. to 11:15 a.m. and 12:15 p.m. to 2:30 p.m. on Wednesday, December 6, 2006, in Miami Beach, Florida.

ADDRESSES: The Department of Homeland Security Data Privacy and Integrity Advisory Committee meeting will be held in the Key Biscayne A room of the Eden Roc Hotel, 4525 Collins Avenue, Miami Beach, Florida 33140. Persons wishing to make comments or who are unable to attend or speak at the meeting may submit comments at any time. All submissions received must include the docket number: DHS–2006–0070 and may be submitted by any one of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow instructions for submitting comments on the Web site.
- *E-mail: PrivacyCommittee@dhs.gov.* Include docket number in the subject line of the message.
- *Fax:* (571) 227–4171.
- *Mail:* Ms. Rebecca J. Richards, Executive Director, Data Privacy and Integrity Advisory Committee, Department of Homeland Security, Mail Stop D–3, Arlington, Virginia 22202.

Instructions: All submissions received must include the docket number: DHS–2006–0070. Comments received will also be posted without alteration at *www.regulations.gov*, including any personal information provided.

Docket: For access to the docket to read background documents or comments received by the DHS Data Privacy and Integrity Committee, go to *www.regulations.gov.* Comments received will be posted without alteration at *http://www.dhs.gov/privacy*, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Hugo Teufel III, Chief Privacy Officer, or Rebecca J. Richards, Executive Director, Data Privacy and Integrity Advisory Committee, Department of Homeland Security, Arlington, Virginia 22202, by telephone (571) 227–3813, by fax (571) 227–4171, or by e-mail *PrivacyCommittee@dhs.gov.*

SUPPLEMENTARY INFORMATION: The Data Privacy and Integrity Advisory Committee (''Privacy Advisory Committee'') will be meeting on Wednesday, December 6, 2006, in the Key Biscayne A room of the Eden Roc Hotel, 4525 Collins Avenue, Miami Beach, Florida 33140. The meeting will be held from 8 a.m. to 11:15 a.m. and 12:15 p.m. to 2:30 p.m.

During the meeting, the DHS Chief Privacy Officer will provide an update on the activities of the DHS Privacy Office. The Subcommittees will update the Committee on the work currently being conducted. In the morning and afternoon sessions, invited speakers will discuss data integrity and credentialing programs. A tentative agenda has been posted on the Privacy Advisory Committee Web site at *http://www.dhs.gov/privacy.*

Public comments will be accepted during the meeting between 2 p.m. and 2:30 p.m. All those who wish to make public comments during this time may register in advance or sign-up on the day of the meeting. In order to allow as many people as possible to testify, witnesses should limit their remarks to three minutes. For those wishing to make written comments, please follow the procedure noted above.

Public attendance is encouraged. Any member of the public who wishes to attend the public session is requested to provide his or her name and affiliation no later than 2 p.m. EST, Friday, December 1, 2006, to Rebecca J. Richards via e-mail at *PrivacyCommittee@dhs.gov*, or via telephone at (571) 227–3813. This will assist with the preparation of name badges, meeting materials and seating arrangements. Everyone who plans to attend is respectfully requested to be present and seated by 7:45 a.m. for the morning session and by 12 p.m. for the afternoon session.

Persons with disabilities who require special assistance should indicate this in their admittance request and are encouraged to identify anticipated special needs as early as possible.

Although every effort will be made to accommodate all members of the public, seating is limited and will be allocated on a first-come, first-served basis.

Hugo Teufel III,

Chief Privacy Officer.

[FR Doc. E6–19173 Filed 11–13–06; 8:45 am]

BILLING CODE 4410–10–P