The estimate of burden for FAPs and CAPs is based on the average number of new FAPs and CAPs received in calendar years 2000 through 2002 and the total hours expended in preparing the petitions. Although the burden varies with the type of petition submitted, an average FAP or CAP, or GRAS affirmation petition, involves analytical work and appropriate toxicological studies, as well as the work of drafting the petition itself. The burden varies depending on the complexity of the petition, including the amount and types of data needed for scientific analysis.

Electronic submissions of petitions contain the same petition information required for paper submission. The agency estimates that up to 30 percent of the petitioners for both food and color additives will take advantage of the electronic submission process. By using the guidelines and forms that FDA is providing, the petitioner will be able to organize the petition to focus on the information needed for FDA's safety review. Therefore, we estimate that petitioners will only need to spend approximately 1 hour completing the electronic submission application form (Form 3503 or 3504, as appropriate) because they will have already used the guidelines to organize the petition information needed for the submission.

The labeling requirements for food and color additives were designed to specify the minimum information needed for labeling in order that food and color manufacturers may comply with all applicable provisions of the act and other specific labeling acts administered by FDA. Label information does not require any additional information gathering beyond what is already required to assure conformance with all specifications and limitations in any given food or color additive regulation. Label information does not have any specific recordkeeping requirements unique to preparing the label. Therefore, because labeling requirements under § 70.25 for a particular color additive involve information required as part of the CAP safety review process, the estimate for number of respondents is the same for §§ 70.25 and 71.1, and the burden hours for labeling are included in the estimate for § 71.1. Also, because labeling requirements under parts 172, 173, 175 through 178, and 180 for particular food additives involve information required as part of the FAP safety review process under § 171.1, the burden hours for labeling are included in the estimate for § 171.1.

Dated: July 21, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–19075 Filed 7–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0034]

Agency Information Collection Activities; Announcement of OMB Approval; FDA Safety Alert/Public Health Advisory Readership Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''FDA Safety Alert/Public Health Advisory Readership Survey'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 13, 2003 (68 FR 25616), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0341. The approval expires on July 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: July 21, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–19076 Filed 7–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0312]

Discussion of Animal Feed Safety System: A Comprehensive Risk-Based Safety Program for the Manufacture and Distribution of Animal Feeds; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting to discuss the potential development of a comprehensive, risk-based animal feed safety system (AFSS) describing how animal feeds (individual ingredients and mixed feeds) should be manufactured and distributed to minimize risks to animals consuming the feed and people consuming food products from animals. We are informing you (consumers, animal feed processors, animal producers, State and local officials, and other interested persons) of this meeting in an effort to solicit comments and seek your assistance in our consideration of a safety program to effectively minimize the hazards to public health, both human and animal health, posed by animal feed products.

Date and Time: The public meeting will be held on Tuesday, September 23, 2003, from 1 p.m. to 5 p.m., and Wednesday, September 24, 2003, from 8 a.m. to 3 p.m. You may submit written or electronic comments at any time, but they would be most helpful if received either before or within 30 days after the close of the meeting.

Location: The meeting will be held at the Hyatt Dulles International Airport, 2300 Dulles Corner Blvd., Herndon, VA, 1–800–233–1234 or 703–713–1234.

Comments and Electronic Access: Interested persons may submit written or electronic comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Comments should be identified with docket number found in brackets in the heading of this document. A copy of the received comments will be available for public examination in the Dockets Management Division between 9 a.m.

and 4 p.m., Monday through Friday. You can view comments FDA has received on the Internet at *http://www.fda.gov/ohrms/dockets/*.

For General Information Contact: George Graber, Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6651; FAX 301–827–1484 or e-mail: *ggraber@cvm.fda.gov*.

For Information About Registration Contact: Linda Grassie, Center for Veterinary Medicine (HFV–12), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–3796; FAX 301–827–4065 or e-mail: *Linda.Grassie@fda.gov*.

Registration: There is no registration fee for the meeting, but registration is required. Limited space is available (maximum of 200), so early registration is encouraged. You may register by phone, Fax or e-mail (see *For Information About Registration Contact*). Registration forms are also available on the Division of Dockets Management Web site at *http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm*.

If you need special accommodations due to a disability, please contact Linda Grassie (see *For Information About Registration Contact*) at least 7 days in advance.

Transcripts: You may request a transcript of the meeting's general session in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857. The transcript will not include the individual breakout sessions, although their summaries will be included in the general session transcript. The transcript of the public meeting will be available after the meeting, at a cost of 10 cents per page. You may also examine the transcript of the meeting at the Division of Dockets Management (see *Comments and Electronic Access*) between 9 a.m. and 4 p.m., Monday through Friday and on the Center for Veterinary Medicine Web site at *http://www.fda.gov/cvm.*

SUPPLEMENTARY INFORMATION:

I. Background

The regulation of animal feed by FDA has focused on areas recognized as having an important impact on human health. Medicated feed good manufacturing practice regulations (GMPs) help prevent potentially unsafe drug residues in edible animal tissue. The regulation that prohibits the feeding of mammalian proteins to ruminant animals is intended to help prevent bovine spongiform encephalopathy in our cattle herd and the potential for variant Creutzfeldt-Jakob disease in humans. FDA believes it may be of value to develop a comprehensive preventive program for the manufacture and distribution of animal feed.

While emphasis for fostering safety has been placed on end product sampling, only a limited number of samples are tested for potential contaminants. More and more, industry is considering preventative, risk-based system controls to augment end product testing. We are exploring risk-based, preventative measures as an approach designed to help prevent feed-related hazards from occurring and to detect problems prior to distribution and sale of feed products. Control systems vary, but generally they have a number of common basic elements. These include the following elements: (1) A thorough analysis of manufacturing and distribution for each product, (2) identification of risks associated with the process and product, (3) identification and implementation of controls to effectively prevent identified risks, (4) employee training programs, (5) controls focused on critical steps, (6) assurances such steps are accurately and consistently performed, and (7) recordkeeping and validation of the system.

Although the purpose of an AFSS would be to reduce the risks associated with animal feeds, the design of a final program would consider costs, technological limitations, and other resource limitations. Some available approaches include hazard analysis and critical control points and GMPs, International Organization for Standardization procedures, statistical process controls, and standard sanitary operating procedures. These have been used by regulatory agencies and industry to help ensure the production and distribution of safe human foods.

II. Meeting

We are holding the meeting in an effort to gather information from you, our stakeholders, on the design of an effective, comprehensive, preventive, risk-based program to help minimize risks associated with animal feeds. Resources and costs are important considerations in any such undertaking, and we are receptive to suggestions about how these can be controlled or used most effectively (such as use of State inspections and self-inspections) while focusing preventive efforts on important known and emerging health risks associated with animal feeds.

The meeting will feature stakeholder and government speakers discussing safety measures currently in use and others which could be adapted to the feed industry. We plan several facilitated break-out discussion groups to explore topics such as the following:

1. What are the strengths of the current Federal and State regulatory programs for feed safety?
2. What are the weaknesses of the current Federal and State regulatory programs for feed safety?
3. What are the strengths and weaknesses of current industry feed safety programs?
4. What are the potential benefits of a comprehensive, risk-based Federal feed safety program?
5. What components should be included in an AFSS?
6. What is the potential burden (increased cost and manpower) of a comprehensive, risk-based Federal feed safety program, and what options are available to minimize the burden?

Dated: July 19, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–19030 Filed 7–25?–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0317]

Draft Guidance for Reviewers and Industry on Good Review Management Principles for Prescription Drug User Fee Act Products; 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 reviewers and industry entitled ''Good Review Management Principles for PDUFA Products.'' This is one in a series of guidance documents that FDA agreed to draft and implement in conjunction with the June 2002 reauthorization of the Prescription Drug User Fee Act of 1992 (PDUFA). The good review management principles (GRMPs) are intended to promote efficient and consistent management of application reviews. The GRMPs focus on the role of both reviewers and industry, emphasizing effective communication to enhance the drug development and review processes.

DATES: Submit written or electronic comments on the draft guidance by September 11, 2003. General comments on agency guidance documents are welcome at any time.