

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

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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.

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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.