9. Soltani, M., D. Beighton, J. Philpott-Howard, N. Woodford, ''Mechanisms of Resistance to Quinupristin-dalfopristin among Isolates of *Enterococcus Faecium* from Animals, Raw Meat, and Hospital Patients in Western Europe,'' *Antimicrobial Agents and Chemotherapy*, 44(2), pp. 433–436, 2000.

10. English, L. L., J. R. Hayes, D. G. White, S. W. Joseph, L. E. Carr, and D. D. Wagner, ''Antibiotic Susceptibility Profiles of *Enterococcus* Isolates from the Poultry Production Environment,'' Abstract J17, *2000 FDA Science Forum FDA and the Science of Safety: New Perspectives*, p. 73, 2000.

Dated: April 11, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–9696 Filed 4–14–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 00D–1086, 00D–1087, 00D–1088, 00D–1089, 00D–1090, and 00D–1091]

Guidance Documents for Premarket Notification (510(k)) Submissions for Six Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of six guidance documents. These six guidance documents are intended to serve as special controls for six devices that FDA has proposed previously to reclassify from class III (premarket approval) to class II (special controls). Elsewhere in this issue of the **Federal Register**, FDA is reopening the comment period on the proposed reclassification of the six devices and one other device. FDA is now inviting comment on these guidance documents because they were not available for comment at the time of the publication of the proposed reclassification (64 FR 12774, March 15, 1999).

DATES: Submit written comments by July 18, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number for the appropriate guidance document found in the **SUPPLEMENTARY INFORMATION** section. Submit written requests for single copies on a 3.5″ diskette of one or more of these guidance documents to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance documents.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2974.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 15, 1999, FDA published a proposed rule to reclassify 38 preamendments class III devices into class II and to establish special controls for these devices. FDA invited interested persons to comment on the proposed rule by June 14, 1999.

FDA received one request to reopen the comment period for six devices. The request noted that FDA had not made the guidance documents that were proposed as special controls for these six devices available for comment through FDA's Good Guidance Practices (GGP's) (62 FR 8961, February 27, 1997). The request further noted that it was impossible to comment on the proposed reclassification without the guidance documents being available. Therefore, the requester asked that FDA extend the comment period until at least 90 days after the guidance documents are publicly available. FDA agreed with the request. FDA also identified three additional devices for which the agency had not issued the guidance documents proposed as special controls in accordance with the GGP policy.

The agency is announcing the availability of the following six guidance documents (each with a separate docket number) for six of these nine devices. In the near future, FDA will announce the availability of two guidance documents that will address the other three devices.

The six guidance documents, with their docket numbers, and Facts-on-Demand (FOD) numbers are as follows:

Guidance document	Docket No.	FOD No.	21 CFR Section	Device name
Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions.	00D–1086	372	870.3260	Pacemaker lead adaptor.
Guidance Document for Vascular Prostheses 510(k) Submissions.	00D–1087	1357	870.3450	Vascular graft prosthesis of less than 6 millimeter diameter.
Guidance for Annuloplasty Rings 510(k) Submissions.	00D–1088	1358	870.3800	Annuloplasty ring.
Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions.	00D–1089	1632	870.4230	Cardiopulmonary bypass defoamer.
Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions.	00D–1090	1622	870.4260	Cardiopulmonary bypass arterial line blood filter.
Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions.	00D–1091	1361	870.4360	Cardiopulmonary bypass oxygenators.

These guidance documents represent the agency's current thinking on premarket notifications for these devices. These guidance documents do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both. Under FDA's GGP policy, each of these guidance documents is a Level 2 guidance.

II. Electronic Access

In order to receive these guidance documents via your fax machine, call the CDRH FOD system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system and enter the document number listed above followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of these guidance documents may do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes these guidance documents, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. These guidance documents are also available at http://www.fda.gov/cdrh/ODE.

III. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding these guidance documents by July 18, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number for each guidance document as listed in the table in the **SUPPLEMENTARY INFORMATION** section of this document. If you wish to comment on more than one guidance document, please submit your comments separately for each guidance document. The guidance documents and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 3, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–9710 Filed 4–18–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Industry Grassroots Meeting: Report on Partnership Activities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA), Office of Regulatory Affairs, San Francisco District Office is announcing the following meeting entitled ''Industry Grassroots Meeting: Report on Partnership Activities.'' The purpose of the meeting is to report the Partnership Among Industry and Regulators (PAIR) Committee activities and to solicit input from participants for future activities and projects for the PAIR Committee. The PAIR Committee was formed as a result of an action item coming out of a similar grassroots meeting held at the Oakland Federal Bldg. in January of 1997.

Date and Time: The meeting will be held on May 10, 2000, from 8 a.m. to 5 p.m.

Location: The meeting will be held at the Oakland Federal Bldg., North Tower, 3d Floor Auditorium, 1301 Clay St., Oakland, CA 94612.

Contact: Jake Pearson, San Francisco District Office (HFR–PA 160), 510–337–6877, FAX 510–337–6701, e-mail jpearson@ora.fda.gov, or Kathryn D. Macropol (HFR–PA 140), 510–337–6867, e-mail kmacropo@ora.fda.gov, Food and Drug Administration, 1431 Harbor Bay Pkwy., Alameda, CA 94502. Information is also available at the PAIR website at http://www.pair-ca.org.

Registration: There is no charge to attend the meeting; however, registration is required. The meeting is open to all interested in management and regulatory affairs activities of industries regulated by FDA. While attendance would most benefit those industries located in Northern California, all interested groups are encouraged to attend. You may register via the Internet at http://www.pair-ca.org and by completing the online registration form. Alternatively, you can register by sending your name, title, firm name, address, telephone, fax number, and e-mail address (if available) to the contacts listed above. Please include any topics of interest you would like to have included in the program.

If you need special accommodations due to a disability, please notify Jake Pearson at least 7 days in advance.

Dated: April 12, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–9712 Filed 4–18–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4201]

Guidance for Industry: Dioxin in Anti-caking Agents Used in Animal Feed and Feed Ingredients; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry (#98) entitled ''Dioxin in Anti-caking Agents Used in Animal Feed and Feed Ingredients.'' The guidance is intended to notify members of the feed industry of recent findings regarding the presence of dioxins congeners that may be present in anti-caking agents in animal feeds and to offer general advice regarding monitoring of these products. This guidance has been revised in response to comments.

DATES: Submit written comments at any time.

ADDRESSES: Submit written comments on this guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the guidance document entitled ''Dioxin in Anti-caking Agents Used in Animal Feed and Feed Ingredients'' may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm/fda/TOCs/guideline.html. Persons without Internet access may submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

FOR FURTHER INFORMATION CONTACT:

For general questions regarding the guidance document: Judy A. Gushee, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0150, e-mail: jgushee@cvm.fda.gov.

For scientific questions regarding the guidance document: Randall A.