- The rate and extent of BPA release from devices under clinically relevant extraction conditions.
- What conditions affect the release and leaching of BPA?
- Estimates of patient exposure to BPA from use of the device.

FDA is interested in possible alternatives to BPA.

- Are you aware of available alternatives to the use of BPA in certain medical devices? Provide information concerning the alternative material and any associated risks.

FDA is interested in receiving information concerning devices that have been shown to release BPA, including cardiopulmonary bypass circuits, hemodialysis circuits and certain dental devices. For these devices provide the following information:

- Describe the device type and intended use.
- Describe how the device directly or indirectly contacts a patient.
- Describe whether, and how, the device is used in pediatric patients, and describe the pediatric population by age and gender.
- Identify and attach any study reports related to BPA release from this device type.

B. Human-Use Biological Products and Drugs (Including Protein Drugs)

For products that are: (1) Formulated with BPA-containing components or (2) liquid-based dosage forms [including solutions, suspensions, semisolids (cream, lotion, ointment, foam, gel etc.)] and packaged in plastic containers or in metal canisters with plastic lining or coating (e.g., epoxy) if either the container or the coating have been made by using BPA, please provide the following information:

- NDA/ANDA/BLA number.
- Drug product name, dosage form and route of administration.
- Components and composition of the formulation.
- Container closure system (CCS) and components in direct contact with the formulation.
- Drug Master File number(s) for the CCS, if applicable.
- Levels of BPA found either as an extractable (in model solvents from the CCS) or a leachable (in the formulation) through expiry, if known.
- Identify the analytical method(s) for quantitation of BPA.
- Acceptance criteria either as an extractable or leachable, if established.

Please also provide summary reports from any studies that you may have performed to evaluate the toxicity and to justify the safety of BPA in these products.

C. Other FDA-Regulated Products

We are also soliciting any relevant information on the use of, and potential exposure to, BPA from any other FDA-regulated products, including cosmetics, that have not been discussed in the above paragraphs.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and information. Submit a single copy of electronic comments and information or two paper copies of any mailed comments and information, except that individuals may submit one paper copy. Comments and information are to be identified with the name of the technology and the docket number found in brackets in the heading of this document. A copy of this notice and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 3, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–24506 Filed 10–14–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 18, 2008, from 8 a.m. to 5 p.m., November 19, 2008, from 8 a.m. to 5:30 p.m. and on November 20, 2008, from 8 a.m. to 12 noon.

Location: Holiday Inn/College Park, The Ballroom, 10000 Baltimore Ave., College Park, MD. The hotel telephone number is 301–345–6700.

Contact Person: Janie Kim, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *janie.kim@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138(301–443–0572 in the Washington, DC area), code 3014512530. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On November 18, 2008, the committee will discuss the justification of the non-inferiority margin for complicated skin and skin structure infections. On November 19, 2008, the committee will discuss: (1) New drug application (NDA) 022–110, telavancin powder for reconstitution and intravenous administration, Theravance, Inc., proposed for the treatment of complicated skin and skin structure infection, and (2) NDA 022–153, oritavancin, Targanta Therapeutics Corp., proposed for the treatment of complicated skin and skin structure infection. On November 20, 2008, the committee will discuss NDA 022–269, iclaprim, Arpida AG, proposed for the treatment of complicated skin and skin structure infection.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 4, 2008. Oral presentations from the public will be scheduled between approximately 1 p.m. to 1:15 p.m. on November 18, 2008, between approximately 11:30 a.m. to

11:45 a.m. and 4:15 p.m. to 4:30 p.m. on November 19, 2008, and between approximately 10:15 a.m. to 10:30 a.m. on November 20, 2008. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 24, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 28, 2008.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Janie Kim at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 6, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–24354 Filed 10–14–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Arthritis Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Arthritis Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 24, 2008, from 8:30 a.m. to 4:30 p.m.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301–589–5200.

Contact Person: Nicole Vesely, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–6793, FAX: 301–827–6776, e-mail: *nicole.vesely@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512532. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 21–856, ULORIC (febuxostat), Takeda Pharmaceuticals North America, Inc., for the proposed treatment of hyperuricemia in patients with gout.

FDA intends to make background material available to the public no later than 2 business day before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 7, 2008. Oral presentations from the public will be scheduled between approximately 2 p.m. and 3 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 30, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 31, 2008.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Nicole Vesely at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C.app. 2).

Dated: October 3, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–24355 Filed 10–14–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration