FDA likewise has determined that the drug component of the product (heparin) performs a secondary role by acting chemically to prevent thrombotic occlusions within the catheter.

Accordingly, to enhance consistency and efficiency in the regulation of these combination products by treating like products similarly, FDA is transferring primary review responsibility from CDER to CDRH for heparin catheter lock-flush solution products that have been regulated under the drug provisions of the act. The transferred products will be reviewed and regulated under the device provisions of the act. As with all combination products, CDRH will consult with CDER regarding the drug components of these products as appropriate. Catheter lock-flush solutions that contain only water or saline are considered devices rather than combination products and are regulated under the device provisions of the act.

The agency intends to assist manufacturers of currently marketed heparin catheter lock- flush solution products in the transition from approved new drug applications (NDAs) or approved abbreviated new drug applications (ANDAs) to 510(k) submissions under the device provisions of the act. Based upon the submissions made and the prior review of these products under the drug provisions of the act, FDA has determined that heparin catheter lock-flush solution products approved under these particular approved NDAs or ANDAs are substantially equivalent to heparin catheter lock-flush solution products cleared for marketing under section 510(k) of the act (21 U.S.C. 360(k)) and the approved NDAs or ANDAs will be considered cleared device premarket notifications (510(k) clearances) under section 510(k) when FDA has provided the sponsor written notification of the transfer and its effective date. No application user fees will be assessed for this administrative transfer. NDA and ANDA manufacturers that have previously notified FDA (i.e. before the date of this notice) that they have discontinued marketing their heparin catheter lock-flush solution products will be subject to review and clearance of a 510(k) submission prior to marketing their product again.

Heparin catheter lock-flush solution products are accessories to, and regulated along with, intravascular catheters as Class II devices (special controls). (See 21 CFR 880.5200.) Upon the effective date of the transfer, the transferred products will be subject to the provisions of section 510(k) of the act and its implementing regulations (part 807 (21 CFR part 807)). The transferred products will be subject to the general control provisions of section 513 of the act, including the Registration and Listing regulation (part 807), the Quality System Regulation (part 820 (21 CFR part 820)), and the Medical Device Reporting regulation (21 CFR part 803).

Manufacturers planning to change or modify the design, components, method of manufacture, or intended use of a transferred heparin catheter lock-flush solution product should evaluate whether a 510(k) submission is required for the change or modification as set forth in § 807.81(a)(3). If a 510(k) submission is required, the manufacturer should cite in its initial submission the NDA or ANDA number held for the product and include a copy of the letter sent from FDA notifying the sponsor of the transfer of review responsibility to CDRH.

FDA finds that there is a substantial likelihood that failure to comply with the Quality System Regulation (part 820) for this product will potentially present a serious risk to human health. Therefore, future 510(k) submissions for heparin catheter lock-flush solution products will be subject to pre-clearance inspections in accordance with section 513(f)(5) of the act (21 U.S.C. 360c).

FDA will contact applicants holding approved NDAs or ANDAs that it believes have products affected by this transfer. Holders of applications subject to transfer, holders of applications for discontinued heparin catheter lock-flush solutions products, or holders of applications for catheter lock-flush solution products with other ingredients who are uncertain as to which agency Center has primary jurisdiction, should contact James S. Cohen (see the **FOR FURTHER INFORMATION CONTACT** section).

Dated: August 9, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–13509 Filed 8–16–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0312]

Preparation for International Conference on Harmonization Meetings in Chicago, Illinois; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Preparation for ICH meetings in Chicago, Illinois'' to provide information and receive comments on the International Conference on Harmonization (ICH) as well as the upcoming meetings in Chicago, IL. The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Groups meetings in Chicago, IL, October 23 through 26, 2006, at which discussion of the topics underway and the future of ICH will continue.

Date and Time: The meeting will be held on Monday, October 2, 2006, from 1:30 p.m. to 4 p.m.

Location: The meeting will be held at 5600 Fishers Lane, 3d Fl., Conference Room G, Rockville, MD 20857. For security reasons, all attendees are asked to arrive no later than 1:25 p.m., as you will be escorted from the front entrance of 5600 Fishers Lane to Conference Room G.

Contact Person: Tammie Bell, Office of the Commissioner (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0919, e-mail: *Tammie.Bell2@fda.hhs.gov*, FAX: 301–480–0716.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), written material and requests to make oral presentations, to the contact person by September 25, 2006. If you need special accommodations due to a disability, please contact Tammie Bell at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The ICH was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical

requirements for medical product development among regulatory agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations. The ICH Steering Committee includes representatives from each of the ICH sponsors and Health Canada, the European Free Trade Area and the World Health Organization. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions.

The current ICH process and structure can be found at the following Web site: *http://www.ich.org*.

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Oral presentations from the public will be scheduled between approximately 3 p.m. and 4 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by September 25, 2006, and submit a brief statement of the general nature of the evidence or arguments they which to present, the names and addresses, phone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

The agenda for the public meeting will be made available on September 18, 2006, via the Internet at *http://www.fda.gov/cder/meeting/ICH_20061002.htm*.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: August 10, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–13505 Filed 8–16–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee for Pharmaceutical Science; 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: Advisory Committee for Pharmaceutical Science.

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 October 5 and 6, 2006, from 8:30 a.m. to 5 p.m.

Location: Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Mimi Phan, 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: 301–827–6801, e-mail: *mimi.phan@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572) in the Washington, DC area), code 3014512539. Please call the Information Line for up-to-date information on this meeting. The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm* under the heading ''Advisory Committee for Pharmaceutical Science.'' (Click on the year 2006 and scroll down to the above named committee meeting.)

Agenda: On October 5, 2006, the committee will: (1) Receive an update on the International Conference on Harmonization Quality Topics (Q8, Q9, Q10, Q4B, QOS) and discuss the impact on current regulatory direction, and (2) receive and discuss a series of presentations from the different offices within the Office of Pharmaceutical Science on progress being made on quality-by-design (QBD) initiatives, followed by presentations from the pharmaceutical industry trade associations (The Generic Pharmaceutical Association [GPhA] and The Pharmaceutical Research and Manufacturers of America [PhRMA]) on their QBD perspectives and issues. On October 6, 2006, the committee will: (1) Receive an awareness presentation on risk management for complex pharmaceuticals, (2) receive presentations and discuss bioequivalence issues pertaining to highly variable drugs, (3) discuss current thinking on issues and definitions pertaining to nanotechnology, (4) discuss implementation of definitions for topical dosage forms, and (5) receive an update and discuss current strategies and direction for the Critical Path Initiative.

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 September 21, 2006. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. each day. Time allotted for each presentation may be limited. 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 September 21, 2006.

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 Mimi Phan at least 7 days in advance of the meeting.

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

August 8, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E6–13506 Filed 8–16–06; 8:45 am]

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