

FDA attempted to conduct a reinspection of the firm on February 2, 1993, to, in part, determine the firm's status. During this inspection, it was observed that the donor chair had been removed and that no plasma had been collected since the inspection ending July 29, 1992. The inspection was terminated because a meaningful inspection could not be performed.

In a letter to FDA dated February 10, 1993, the firm requested voluntary revocation of its licenses and thereby waived its opportunity for a hearing under 21 CFR 601.5(a). The agency granted the licensee's request by letter dated August 24, 1993, which revoked the establishment license (U.S. License No. 314) and the product license for the manufacture of Source Plasma.

FDA has placed copies of the letters relevant to the license revocation on file under the docket number found in brackets in the heading of this document with the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. These documents include the following: FDA letters of September 3, 1991, May 20, 1992, and August 24, 1993; and the firm's letter of February 10, 1993. These documents are available in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m. Monday through Friday.

Accordingly, under section 351 of the Public Health Service Act (42 U.S.C. 262), 21 CFR 601.5, and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.68), the establishment license (U.S. License No. 314) and the product license issued to the North Carolina Memorial Hospital, doing business as the Clinical Coagulation Laboratory, for the manufacture of Source Plasma were revoked, effective August 24, 1993.

This notice is issued and published under 21 CFR 601.8 and the redelegation at 21 CFR 5.67.

Dated: June 27, 1994.

Michael G. Beatrice,
Deputy Director, Center for Biologics
Evaluation and Research.

[FR Doc. 94-16617 Filed 7-8-94; 8:45 am]

BILLING CODE 4160-01-F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public

advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

MEETING: The following advisory committee meeting is announced:

Joint Subcommittee Meeting of the Nonprescription Drugs Advisory Committee and Arthritis Advisory Committee on Over-the-Counter Internal Analgesic, Antipyretic, and Antirheumatic Drug Products

Date, time, and place. September 8 and 9, 1994, 8:30 a.m., Parklawn Bldg., conference rms. D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open committee discussion, September 8, 1994, 8:30 a.m. to 4 p.m.; open public hearing, 4 p.m. to 5 p.m., unless public participation does not last that long; open committee discussion, September 9, 1994, 8:30 a.m. to 4 p.m., open public hearing, 4 p.m. to 5 p.m., unless public participation does not last that long; Lee L. Zwanziger, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4695.

General function of the committees. The Nonprescription Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases. The Arthritis Advisory Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in arthritic conditions.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the joint subcommittee. Those desiring to make formal presentations should notify the contact person before August 15, 1994, and submit a brief statement of the general nature of the information or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their comments. In a subsequent issue of the Federal Register, FDA will publish a notice announcing the availability of background information.

Open committee discussion. On September 8 and 9, 1994, the joint subcommittee will discuss effectiveness data requirements and proposed

labeling indications for OTC analgesic drug products. The joint subcommittee will address topics such as: (1) Data requirements to support specific types of indications for OTC analgesic drug products; (2) recommendations for labeling indications for OTC analgesics; and (3) the current state of scientific knowledge in the areas of pain receptors, mechanism(s) of pain perception, and the basis for response to analgesic drug classes.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice: The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum for public participation; and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting, or in writing, prior to the meeting, a person attending the hearing who does not in advance of the meeting request an