

acquire from any one person during any 18-month period more than five miles of gas gathering pipelines located within certain portions of the Oklahoma counties.

In a separate agreement with Phillips, the Commission expressed concern that it might not have an adequate legal remedy if the proposed acquisition were consummated prior to Commission action. Phillips has agreed to maintain the assets that are being divested in their current condition and provide gathering service at existing terms and conditions to customers under contract with ANR until the Schedule A assets are either sold or the Commission decides not to accept this order.

The purpose of this analysis is to invite public comment concerning the consent order. This analysis is not intended to constitute an official interpretation of the agreement and order or to modify their terms in any way.

Donald S. Clark,  
*Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Health Care Policy and Research

#### Notice of Meeting

In accordance with section 10(a) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2) announcement is made of the following special emphasis panel scheduled to meet during the month of February 1997:

*Name:* Health Care Policy and Research Special Emphasis Panel.

*Date and Time:* February 7, 1997, 8:00 a.m.

*Place:* Doubletree Hotel, 1750 Rockville Pike, Halpine Room, Rockville, Maryland 20852.

Open February 7, 1997, 8:00 a.m. to 8:15 a.m. Closed for remainder of meeting.

*Purpose:* This Panel is charged with conducting the initial review of grant applications requesting dissertation support for health services research undertaken as part of an academic program to qualify for a doctorate.

*Agenda:* The open session of the meeting on February 7 from 8:00 a.m. to 8:15 a.m., will be devoted to a business meeting covering administration matters. During the closed session, the panel will be reviewing and discussing grant applications dealing with health services research issues. In accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C., 552b(c)(6), the Administrator, AHCP, has made a formal determination that this latter session will be

closed because the discussions are likely to reveal personal information concerning individuals associated with the grant applications. This information is exempt from mandatory disclosure.

Anyone wishing to obtain a roster of members or other relevant information should contact Carmen Johnson, Agency for Health Care Policy and Research, Suite 400, 2101 East Jefferson Street, Rockville, Maryland 20852, Telephone (301) 594-1449 x1613.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: January 3, 1997.

Clifton R. Gaus,

*Administrator.*

[FR Doc. 97-654 Filed 1-9-97; 8:45 am]

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## Food and Drug Administration

[Docket No. 95N-0200]

### Guidance for the Submission of Chemistry, Manufacturing, and Controls Information and Establishment Description for Autologous Somatic Cell Therapy Products; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Guidance for the Submission of Chemistry, Manufacturing, and Controls Information and Establishment Description for Autologous Somatic Cell Therapy Products." This guidance, prepared by the Center for Biologics Evaluation and Research (CBER) in consultation with the Center for Devices and Radiological Health, is intended to assist applicants in the preparation of the chemistry, manufacturing, and controls (CMC) section and the establishment description section of a biologics license application (BLA) or in the preparation of a product license application (PLA) and establishment license application (ELA) for all autologous somatic cell therapy products. This guidance may assist in complying with certain requirements in the Code of Federal Regulations.

**DATES:** Written comments may be submitted at any time; however, comments submitted by April 10, 1997, will be considered for the next revision.

**ADDRESSES:** Submit written requests for single copies of the guidance entitled, "Guidance for the Submission of Chemistry, Manufacturing, and Controls Information and Establishment Description for Autologous Somatic Cell

Therapy Products" to the Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. The document may also be obtained by mail or by calling the CBER Voice Information System at 1-800-835-4709, or 301-827-1800, or FAX at 1-800-CBER-FAX, or 301-827-3844.

Persons with access to the Internet may obtain the document in several ways. Users of "Web Browser" software, such as Mosaic, Netscape, or Microsoft Internet Explorer may obtain this document via the World Wide Web by using the following Uniform Resource Locators:

<http://www.fda.gov/cber/cberftp.html>  
<ftp://ftp.fda.gov/CBER/>

The document may also be obtained via File Transfer Protocol (FTP). Requests should connect to the FDA's FTP Server, FTP.FDA.GOV(192.73.61.21). CBER documents are maintained in a subdirectory called "CBER" on the server. Logins with the user name of anonymous are permitted, and the user's e-mail address should be sent as the password. The "READ.ME" file in that subdirectory describes the available documents which may be available as an ASCII text file (\*.TXT), or a Word Perfect 5.1 or 6.x document (\*.w51.wp6), or both. Finally, the guidance can be obtained by "bounce-back e-mail". A message should be sent to: "XVCMC@al.cber.fda.gov".

Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM-630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-3074.

#### SUPPLEMENTARY INFORMATION:

Over the last several years, FDA has worked to clarify its approach to the