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.

[FR Doc. 97–606 Filed 1–9–97; 8:45 am]

BILLING CODE 6750–01–M

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, AHCPR, 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]

BILLING CODE 4160–90–M

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 Managements 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

regulation of products that are comprised in whole or in part of living cellular materials. Recognizing that sponsors developing tissue and cell based therapies would soon want to make these products commercially available, FDA issued a notice in the Federal Register of October 14, 1993 (58 FR 53248), entitled ''Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Cell Therapy Products;'' this notice explained the regulatory framework for somatic cell and gene therapy products, but it did not provide detailed technical guidance. As announced in the Federal Register of July 18, 1995 (60 FR 36808), FDA held a public hearing on November 16 and 17, 1995, to solicit information on the nature and diversity of a subset of autologous somatic cell therapy products for structural repair or reconstruction called manipulated autologous structural cell products (MAS cell products) and to receive comments on the formulation and implementation of any new regulatory requirements. As announced in the Federal Register of March 7, 1996 (61 FR 9185), the agency held a Commissioner's roundtable public meeting on March 15, 1996, to present the elements of a planned regulatory framework intended to help ensure patient safety and confirmation of patient benefit, while accommodating the development of these therapies and the need for a flexible regulatory approach. Many of the concepts presented at the meetings were derived from ongoing FDA Reinventing Government initiatives. In the Federal Register of May 28, 1996 (61 FR 26523), FDA announced the availability of a guidance document entitled ''Guidance on Applications for Products Comprised of Living Autologous Cells Manipulated Ex Vivo and Intended for Structural Repair or Reconstruction.'' FDA now is providing the CMC guidance document that describes product characterization and establishment information for MAS cell products and other autologous somatic cell therapy products. This document is intended to assist manufacturers of all autologous somatic cell therapy products, whether used for structural repair or reconstruction, or for other purposes.

As outlined in the President's November 1995, National Performance Review, ''Reinventing the Regulation of Drugs Made From Biotechnology,'' and as part of FDA's continuing effort to reduce unnecessary burdens for industry without diminishing public health protection, FDA committed to using a standardized, single application format for drug and biological product approvals. An interim form for submission of the BLA, FDA Form 3439, is available from the Office of Communication, Training and Manufacturers Assistance (address above). Use of this form is voluntary. Establishments wishing to engage in clinical studies of autologous somatic cell therapy products, including MAS cell products, should submit an investigational new drug application (IND). Establishments seeking approval of autologous somatic cell therapy products for clinical use should either submit, as appropriate, a BLA or a product license application (PLA) and companion establishment license application (ELA).

The information FDA received at the public hearing of November 16 and 17, 1995, as well as comments received on the FDA Commissioner's roundtable meeting of March 15, 1996, were considered in developing the guidance for preparation of the CMC and establishment description sections of the BLA for autologous somatic cell therapy products.

The guidance document is divided into three parts. The general information section provides background information. Part 1, the CMC section, is divided into the following sections: (1) Introduction; (2) Biological Substance/Product, including discussions of Description and Characterization, Manufacturer(s), and Method(s) of Manufacture, Process Controls, Specifications/Analytical Methods, Container and Closure Systems/Shipping Containers, and Biological Substance Stability; (3) Biological Product, including discussions of Method(s) of Manufacture and Packaging, Specifications and Test Methods for Final Biological Product, Biological Product Stability, Container and Closure System, and Microbiology; (4) Environmental Assessment; and (5) Method Validation. Part 2, the establishment description section, provides a description of establishment information that should be submitted and related good manufacturing practice (GMP) controls for the manufacture of autologous somatic cell therapy products. Part 2 is divided into the following sections: (1) Introduction; (2) General Information; (3) Water Systems, including discussions of General Description of Water System, Validation Summary and Routine Monitoring; (4) Heating, Ventilation and Air Conditioning Systems; and (5) Contamination/Cross Contamination Issues, including discussions of Cleaning Procedures and Validation and Containment Features. This document provides guidance to manufacturers for providing the information describing establishment standards and GMP controls that would be submitted as part of the BLA or PLA and ELA.

As with other procedural guidance documents, FDA does not intend that this guidance would be all-inclusive. Alternative approaches could be warranted in specific situations, and certain aspects might not be applicable in all situations. If an applicant believed a procedure described in this guidance was inapplicable to a specific situation for a particular product, the applicant could provide, for CBER's consideration, information supporting an alternative process. If an applicant chooses to use alternative processes, the applicant may wish to discuss the matter further with the agency to prevent expenditure of money and resources on activities that later might be determined to be inappropriate by FDA. Additionally, FDA intends to further revise this guidance, as needed. FDA also encourages applicants who use the BLA to contact CBER to discuss use of the application further inasmuch as the agency's experience with its use will evolve. Although this guidance document does not create or confer any rights for or on any person, and does not operate to bind FDA or the public, it does represent the agency's current thinking on the CMC and establishment description sections of a BLA or PLA and ELA submitted for an autologous somatic cell therapy product.

Interested persons may, on or before April 10, 1997, submit written comments on the guidance document to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and information are to be identified with the

docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Written comments on this document will be considered in determining whether revisions to the guidance are warranted.

Dated: January 6, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–579 Filed 1–9–97; 8:45 am]

BILLING CODE 4160–01–F