approval of five new animal drug applications (NADA's), one held by Pfizer, Inc., and four NADA's held by Premiere Agri Technologies, Inc. Pfizer, Inc., notified FDA that its oxytetracycline soluble powder is no longer marketed. Premiere Agri Technologies, Inc., notified FDA that its approved NADA's are no longer required to manufacture Type B medicated feeds containing tylosin or virginiamycin. For these reasons, both sponsors requested that approval of the applications be withdrawn. In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the regulations by removing the entries which reflect approval of the NADA's.

EFFECTIVE DATE: February 27, 1995.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1722.

SUPPLEMENTARY INFORMATION: FDA has been informed by : (1) Pfizer, Inc., that it is no longer manufacturing or marketing its oxytetracycline soluble powder, and (2) Premiere Agri Technologies, Inc., that approval of its NADA's listed in the table is no longer required to manufacture Type B medicated feeds containing tylosin or virginiamycin (Type A medicated articles containing tylosin are covered by another NADA). Accordingly, both firms requested in writing that FDA withdraw approval of the applications.

NADA No.	Drug name	Sponsor name and address
10–661	Oxytetracycline soluble powder (Terramycin® Egg Formula).	Pfizer, Inc., 235 East 42d St., New York, NY 10017
45–690	Tylosin Type B medicated feeds and Type A medicated article.	Premiere Agri Technologies, Inc., P.O. Box 2508, Fort Wayne, IN 46801–2508 (former sponsor Henwood Feed Additives)
97–289	Tylosin Type B medicated feeds and Type A medicated article.	Do. (Former sponsor Feed Specialties Co., Inc.)
133–361	Virginiamycin Type B medicated feed.	Do. (Former sponsor Feed Specialties Co., Inc.)
133–839	Virginiamycin Type B medicated feed.	Do. (Former sponsor MAC-PAGE, Inc.)

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA's 10–661, 45–690, 97–289, 133–361, and 133–839 and all supplements and amendments thereto is hereby withdrawn, effective February 27, 1995.

In a final rule published elsewhere in this issue of the **Federal Register**, FDA is: (1) Amending 21 CFR 558.625 by removing and reserving paragraphs (b)(11) and (b)(15) to reflect the withdrawal of approval of NADA's 45–690 and 97–289 and (2) amending 21 CFR 558.635(b)(2) to reflect the withdrawal of approval of NADA's 133–361 and 133–839. It is unnecessary to amend the regulations to reflect withdrawal of approval of NADA 10–661 because it is not codified.

Dated: January 6, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–3801 Filed 2–14–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0024]

Somatic Cell and Gene Therapy Manufacturing Issues; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), is announcing a public meeting to discuss somatic cell and gene therapy production issues. The meeting is designed to discuss several issues related to the limited access to ancillary components on the development of somatic cell and gene therapies and to solicit public testimony regarding these issues.

DATES: The public meeting will be held on Monday, March 6, 1995, from 6 p.m. to 7:30 p.m., immediately following the National Institutes of Health, Recombinant DNA Advisory Committee meeting. Submit written requests for participation and written copies or summaries of oral presentations, or any written comments for possible discussion at the meeting by February 27, 1995. Written comments may also be submitted after the meeting to the Dockets Management Branch (address below).

ADDRESSES: The public meeting will be held at the National Institutes of Health, Bldg. 31C, 9000 Rockville Pike, conference room 6, Bethesda, MD. No registration is required to attend the meeting. Submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, written requests for participation and written copies or summaries of oral presentations, or any written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For information regarding the meeting: John G. Bishop, Center for Biologics Evaluation and Research (HFM–515), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–402–1336, FAX 301–496–7027.

For information regarding this notice: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: The field of gene and somatic cell therapy is rapidly evolving. FDA is interested in exploring approaches to overcome barriers to the development of novel and useful therapeutics for a variety of human diseases without diminishing patient safety. To facilitate this process, FDA is holding a public meeting to discuss practical concerns relating to gene therapy vector production and somatic cell production.

In recent months, FDA has been asked by several sponsors of clinical investigations conducted under investigational new drug applications to allow modifications to gene therapy protocols, due to limited access to critical reagents and products, e.g., growth factors used in the expansion of cells for somatic cell and gene therapies. Limited access to ancillary components could potentially lead to the adoption of suboptimal somatic cell and gene therapy procedures which might affect the investigation of the safety and

efficacy of somatic cell and gene therapy products. This limited access may, in the long term, unduly restrict progress in the field of somatic cell and gene therapy in the United States.

To obtain more information, FDA would like to discuss several issues related to the limited access to ancillary components on the development of somatic cell and gene therapies, including: (1) What are the ancillary components that are most critical to somatic cell and gene therapy trials? (2) What are the main reasons for the lack of availability of ancillary components? (3) Are there alternate suppliers of ancillary components? and (4) What is the impact of the limited supply of ancillary components on somatic cell and gene therapy development?

FDA is soliciting public testimony from biomedical researchers, university faculty and administrators, biotechnology associations, other Federal and government agencies, and other individuals and organizations with relevant information concerning limited access to critical ancillary componets for gene therapy and somatic cell therapy manufacturing. FDA also solicits testimony, in particular, from affected individuals and consumer organizations. All interested parties are invited to participate in the meeting.

Every effort will be made to accommodate each person who wants to participate in the public meeting. However, because presentations will be limited to the first 30 minutes of the meeting, the time allotted for each presentation will be restricted to 5 minutes. Due to the time limitations of the meeting, all requests may not be granted. Therefore, each person who wants to participate in the meeting is encouraged, by close of business on February 27, 1995, to do the following: (1) File a written request of participation containing the name, address, phone number, facsimile number, affiliation, if any, of the participant, and topic of the presentation, and (2) submit a copy or summary of their presentation. The requested information, including the written notice of participation, may be submitted to the Dockets Management Branch (address above). After the presentations, the remainder of the meeting will be used to allow for discussion.

Before the meeting, CBER will determine the schedule for the presenters. A schedule of the presenters will be filed with the Dockets Management Branch (address above) and mailed or FAX'ed to each participant before the meeting. Interested persons attending the meeting who did not request an opportunity to make a presentation or those who did request an opportunity to make a presentation but due to the time limitations were not granted the request will be given the opportunity to make an oral presentation at the conclusion the meeting, as time permits.

FDA will consider information presented and discussed at the meeting in the developing of future points to consider and regulatory and guidance documents, and in identifying topics for future discussion.

Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript of the public meeting and copies of information and comments submitted to the meeting record will be available for examination at the Dockets Management Branch (address above) approximately 15 working days after the meeting, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 10, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–3800 Filed 2–10–95; 3:00 pm]

BILLING CODE 4160–01–F

Indian Health Service

Health Professions Preparatory, Pregraduate and Indian Health Scholarship (Professions) Programs

AGENCY: Indian Health Service, HHS.

ACTION: Standing Notice of Availability of Funds for Health Professions Preparatory, Pregraduate and Indian Health Scholarship (Professions) Programs for Fiscal Years (FYs) 1995 and 1996.

SUMMARY: The Indian Health Service (IHS) announces the availability of approximately $3,578,200 to fund scholarships for the Health Professions Preparatory and Pregraduate Scholarship Programs for FY 1995 awards. Pending the availability of funds, a similar amount is anticipated in FY 1996. These programs are authorized by section 103 of the Indian health Care Improvement Act (IHCIA), Pub. L. 94–437, as amended by Pub. L. 100–713 and by Pub. L. 102–573.

The Indian Health Scholarship (Professions) Program, authorized by section 104 of the IHCIA, Pub. L. 94–437, as amended by Pub. L. 100–713 and by Pub. L. 102–573, has approximately $8,160,751 available for FY 1995 awards. Pending the availability of funds, a similar amount is anticipated in FY 1996.

Scholarships under the three programs will be awarded utilizing the Notice of Grant Award, form PHS–5152–1 (Rev. 7/92). For academic years 1995–1996 and 1996–1997, full-time and part-time scholarships will be funded for each of the three scholarship programs.

The Health Professions Preparatory Scholarship Program is listed as No. 93–123 in the Office of Management and Budget Catalog of Federal Domestic Assistance (CFDA). The Health Professions Pregraduate Scholarship Program is listed as No. 93.971, and the Indian Health Scholarship (Professions) Program is listed as No. 93.972 in the CFDA.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of *Healthy People 2000,* a PHS-led activity for setting priority areas. This program announcement is related to the priority area of Education and Community-Based programs. Potential applicants may obtain a copy of *Healthy People 2000*, (Full Report; Stock No. 017–001–00474–0) or *Healthy People 2000* (Summary Report; Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402–9325 (Telephone 202–783–3238).

DATES: The application deadline is April 1, 1995 and 1996. If April 1 falls on the week-end, the application will be due on the following Monday. Applications shall be considered as meeting the deadline if they are received by the appropriate Scholarship Coordinator on the deadline date or postmarked on or before the deadline date. (Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.) Applications received after the announced closing date will be returned to the applicant and will not be considered for funding.

ADDRESSES: Application packets may be obtained by calling or writing to the addresses listed below. The IHS Scholarship Program application forms include: IHS–856, 856–2 through 856–8, 815, 816, 818 and, F–01 through L–04 (approved under OMB No. 0917–0006, expires 12/31/97).