

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 For these reasons, both sponsors requested that approval of the applications be withdrawn.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 |
|----------|--------------------------------------|---|
| 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approval of NADA's 10-661, 45-690, 97-289, 133-361, and 133-839 and all supplements and amendments thereto is hereby withdrawn, effective February 27, 1995.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.

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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

| 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.) |

[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