Dated: July 13, 1999.

Laura M. Tarantino,

Deputy Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–20256 Filed 8–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Amoxicillin Injection for Sheep; Availability of Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of effectiveness, target animal safety, and human food safety data that may be used in support of a new animal drug application (NADA) or supplemental NADA for veterinary prescription use of amoxicillin injection for treatment of bacterial pneumonia in sheep. The data, contained in Public Master File (PMF) 5433, were compiled under National Research Support Project-7 (NRSP–7), a national agricultural research program for obtaining clearances for use of new drugs in minor animal species and for special uses.

ADDRESSES: Submit NADA's or supplemental NADA's to the Document Control Unit (HFV–199), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7569.

SUPPLEMENTARY INFORMATION: Amoxicillin injection, used for the treatment of sheep for bacterial pneumonia due to *Pasteurella* spp. and *Haemophilis* spp., is a new animal drug under section 201(v) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(v)). As a new animal drug, amoxicillin is subject to section 512 of the act (21 U.S.C. 360b), requiring that its uses in sheep be the subject of an approved NADA or supplemental NADA. Sheep are a minor species under § 514.1(d)(1)(ii) (21 CFR 514.1(d)(1)(ii)).

The NRSP–7 Project, Western Region, University of California, Davis, CA 95616, has provided target animal safety, effectiveness, and human food safety data for veterinary prescription use of amoxicillin injection in sheep for treatment of bacterial pneumonia due to *Pasteurella* spp. and *Haemophilis* spp. NRSP–7 did not provide information concerning potential environmental impacts of the manufacturing process. Such information is required upon submission of an application relying on this file to support approval.

Data and information on safety and effectiveness are contained in PMF 5433. Sponsors of NADA's or supplemental NADA's may, without further authorization, reference the PMF to support approval of an application filed under § 514.1(d). An NADA or supplemental NADA must include, in addition to reference to the PMF, animal drug labeling and other information needed for approval, such as data supporting extrapolation from a major species in which the drug is currently approved or authorized reference to such data, data concerning manufacturing methods, facilities, and controls, and information addressing potential environmental impacts of the manufacturing process. Persons desiring more information concerning the PMF or requirements for approval of an NADA or supplement may contact Naba K. Das (address above).

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information provided in this PMF to support approval of an application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 29, 1999.

George A. Mitchell,

Acting Deputy Director, Center for Veterinary Medicine.

[FR Doc. 99–20255 Filed 8–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel MSCDA (U10) NETWORK APPLICATIONS.

Date: August 6, 1999.

Time: 12:30 PM to 2:00 PM.

Agenda: To review and evaluate grant applications.

Place: 6100 Executive Blvd. 5th Floor, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Gopal M. Bhatnagar, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, National Institutes of Health, PHS, DHHS, 9000 Rockville Pike, 6100 Bldg., Room 5E01, Bethesda, MD 20892, (301) 496–1485.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.209, Contraception and infertility Loan Repayment Program; 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research, National Institutes of Health, HHS)

Dated: August 2, 1999.

Anna Snouffer,

Acting Committee Management Officer, NIH

[FR Doc. 99–20286 Filed 8–5–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which