DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): NORA Exploratory/Development Grants Program (R21), RFA–OH–00–006

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): National Occupational Research Agenda Exploratory/Development Grants Program (R21), RFA–OH–00–006.

Times and Dates: Noon–12:30 p.m., July 11, 2000 (Open). 12:30 p.m.–5 p.m., July 11, 2000 (Closed). 8 a.m.–Noon, July 12, 2000 (Closed).

Place: Embassy Suites, 1900 Diagonal Road, Alexandria, Virginia 22314.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to RFA–OH–00–006.

This notice is published less than 15 days in advance of the meeting due to administrative delays.

Contact person for more Information: Michael J. Galvin, Jr., Ph.D., Health Science Administrator, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, 1600 Clifton Road, N.E., m/s D30 Atlanta, Georgia 30333. Telephone 404/639–3525, e-mail mtg3@cdc.gov.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: June 21, 2000.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention CDC.

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BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Ceftiofur Sodium Injection for Goats; 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 ceftiofur sodium injection for treatment of bacterial pneumonia in goats. The data, contained in Public Master File (PMF) 5671, 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: Ceftiofur sodium injection, used for the treatment of goats for bacterial pneumonia, 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, ceftiofur sodium is subject to section 512 of the act (21 U.S.C. 360b), requiring that its uses in goats be the subject of an approved NADA or supplemental NADA. Goats 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 ceftiofur sterile powder for reconstitution and injection in goats for treatment of bacterial pneumonia due to *Pasteurella* (*Mannheimia*) *haemolytica* and *P. multocida*. These data are contained in PMF 5671.

Under 21 CFR 25.15(d) and § 25.33(d)(4) (21 CFR 25.33(d)(4)), sponsors of NADA's and supplemental NADA's for drugs in minor species, including wildlife and endangered species, are categorically excluded from the requirement to prepare an environmental assessment or an environmental impact statement when the drug has been approved for use in another or the same species where similar animal management practices are used. The categorical exclusion applies unless, as in § 25.21 (21 CFR 25.21), extraordinary circumstances exist which indicate that the proposed action may significantly affect the quality of the human environment. Therefore, based upon information available, FDA agrees that when the application is submitted, the applicant may claim a categorical exclusion under § 25.33(d)(4) provided that the applicant can state that to the best of the applicant's knowledge, as in § 25.21, no extraordinary circumstances exist. It is assumed that the applicant has made a reasonable effort to determine that no extraordinary circumstances exist.

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 submitted to support approval of this 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 19, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00–16293 Filed 6–27–00; 8:45 am]

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