DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Impact of Japanese Encephalitis Vaccination in Cambodia, Funding Opportunity Announcement (FOA) CK14–001, initial review.

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 aforementioned meeting:

Time and Date: 1:00 p.m.–3:00 p.m., October 17, 2013 (Closed).
Place: Teleconference.
Status: 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 Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to “Impact of Japanese Encephalitis Vaccination in Cambodia, FOA CK14–001”.

Contact Person for More Information: Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road NE., Mailstop E60, Atlanta, Georgia 30333, Telephone: (404) 718–8833.

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.

Elaine L. Baker,
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of four new animal drug applications (NADAs) held by Quali-Tech Products, Inc., at the sponsor’s request because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective September 3, 2013.

FOR FURTHER INFORMATION CONTACT: David Alterman, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855; 240–453–6843; email: david.alterman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Quali-Tech Products, Inc., has requested that FDA withdraw approval of the following four NADAs because the products, used to manufacture Type C medicated feeds, are no longer manufactured or marketed: NADA 980 for FLAVOMYCIN (tylosin phosphate) Premix, NADA 118–815 for Quali-Tech TYLAN–10 (tylosin phosphate) Premix, NADA 132–705 for FLAVOMYCIN (bambermycin), and NADA 133–335 for STAFAC (virginiamycin) Swine Pak 10.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 Notice of withdrawal of approval of application (21 CFR 514.116), notice is given that approval of NADAs 980–980, 118–815, 132–705, and 133–335, and all supplements and
amendments thereto, is hereby withdrawn.

Elsewhere in this issue of the Federal Register, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: August 20, 2013.

Bernadette Dunham, Director, Center for Veterinary Medicine.

FOR FURTHER INFORMATION CONTACT:

DATES:

ACTION:

Penicillin; Roxarsone

Diethylcarbamazine; Nicarbazin;

Drug Applications;

Withdrawal of Approval of New Animal

[FR Doc. 2013–20615 Filed 8–22–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0835]

Withdrawal of Approval of New Animal Drug Applications; Diethylcarbamazine; Nicarbazin; Penicillin; Roxarsone

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of three new animal drug applications (NADAs) at the sponsors’ request because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective September 3, 2013.

FOR FURTHER INFORMATION CONTACT:

David Alterman, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20857. Email: david.alterman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Phibro Animal Health Corp., 65 Challenger Rd., 3d Floor, Ridgefield Park, NJ 07660 has requested that FDA withdraw approval of NADA 098–371 for use of nicarbazin, penicillin, and roxarsone in 3-way, combination drug Type C medicated feeds for broiler chickens and NADA 098–374 for use of nicarbazin and penicillin in 2-way, combination drug Type C medicated feeds for broiler chickens because the products are no longer manufactured or marketed.

R. P. Scherer North America, P.O. Box 5600, Clearwater, FL 33518 has requested that FDA withdraw approval of NADA 123–116 for Diethylcarbamazine Citrate Capsules used in dogs for the prevention of heartworm disease because the product is no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 Notice of withdrawal of approval of application (21 CFR 514.116), notice is given that approval of NADA 098–371, NADA 098–374, and NADA 123–116, and all supplements and amendments thereto, is hereby withdrawn.

Elsewhere in this issue of the Federal Register, FDA is amending the animal drug regulations to reflect the withdrawal of approval of these applications.

Dated: August 19, 2013.

Bernadette Dunham, Director, Center for Veterinary Medicine.

FOR FURTHER INFORMATION CONTACT:

Information Collection Request Title: Combating Autism Act Initiative Evaluation (OMB No. 0915–0335 [Revision]

Abstract: In response to the growing need for research and resources devoted to autism spectrum disorders (ASD) and other developmental disabilities (DD), the U.S. Congress passed the Combating Autism Act (CAA) in 2006. The Act included funding for the U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) to increase awareness, reduce barriers to screening and diagnosis, promote evidence-based interventions, train health care professionals to screen for, diagnose or rule out, and provide evidence-based interventions for ASD and other DD. In 2011, the Combating Autism Reauthorization Act (CARA) was signed into law, reauthorizing funding for the CAA’s programs for an additional 3 years at the existing funding levels. Through the CARA, HRSA is tasked with increasing awareness of ASD and other DD, reducing barriers to screening and diagnosis, promoting evidence-based interventions, and training health care professionals in the use of valid and reliable screening and diagnostic tools.

Need and Proposed Use of the Information: HRSA’s activities under the CARA legislation are delegated to the Maternal and Child Health Bureau (MCHB), which is implementing the Combating Autism Act Initiative (CAAI) in response to the legislative mandate. The purpose of this evaluation is to design and implement an evaluation to assess the effectiveness of MCHB’s activities in meeting the goals and objectives of the CAAI, and to provide sufficient data to inform MCHB and the Congress as to the utility of the grant programs funded under the Initiative. The evaluation will focus on indicators related to: (1) Increasing awareness of ASD and other DD among health care providers, other MCH professionals, and the general public; (2) reducing barriers to screening and diagnosis; (3) supporting research on evidence-based interventions; (4) promoting the development of evidence-based guidelines and tested/validated intervention tools; (5) training professionals; and (6) building capacity for systems of services in states.

Likely Respondents: Grantees funded by HRSA under the CAAI will be the respondents for this data collection activity. The programs to be evaluated are listed below.