

## ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form No. and name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Medical/Clinical Laboratory Technologist .....	57.305: Hemovigilance Incident .....	500	12	10/60
Staff RN .....	57.400: Outpatient Procedure Component— Annual Facility Survey.	5,000	1	5/60
Staff RN .....	57.401: Outpatient Procedure Component— Monthly Reporting Plan.	5,000	12	15/60
Staff RN .....	57.402: Outpatient Procedure Component Event.	5,000	25	40/60
Staff RN .....	57.403: Outpatient Procedure Component— Monthly Denominators and Summary.	5,000	12	40/60
Registered Nurse (Infection Preventionist) ....	57.500: Outpatient Dialysis Center Practices Survey.	6,000	1	1.75
Staff RN .....	57.501: Dialysis Monthly Reporting Plan .....	6,000	12	5/60
Staff RN .....	57.502: Dialysis Event .....	6,000	60	13/60
Staff RN .....	57.503: Denominator for Outpatient Dialysis	6,000	12	6/60
Staff RN .....	57.504: Prevention Process Measures Monthly Monitoring for Dialysis.	600	12	30/60
Staff RN .....	57.505: Dialysis Patient Influenza Vaccina- tion.	250	75	10/60
Staff RN .....	57.506: Dialysis Patient Influenza Vaccina- tion Denominator.	250	5	10/60
Epidemiologist .....	57.600: State Health Department Validation Record.	152	50	15/60

**Kimberly S. Lane,**

*Deputy Director, Office of Scientific Integrity,  
Office of the Associate Director for Science,  
Office of the Director, Centers for Disease  
Control and Prevention.*

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**BILLING CODE 4163-18-P**

## 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.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0002]

#### Withdrawal of Approval of New Animal Drug Applications; Quali-Tech Products, Inc.; Bambermycins; Pyrantel; Tylosin; Virginiamycin

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**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](mailto: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 097-980 for Quali-Tech TYLAN-10 (tylosin phosphate) Premix, NADA 118-815 for Q.T. BAN-TECH (pyrantel tartrate), NADA 132-705 for FLAVOMYCIN (bambermycins), 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 097-980, 118-815, 132-705, and 133-335, and all supplements and