food effect. In its February 15, 1994, letter accompanying NDA 50–711, Pfizer explained that the tablets are bioequivalent to the capsule formulation and ''* * * unlike the capsule, can be taken without regard to meals.'' After NDA 50–711 was approved, Pfizer decided not to market the capsule formulation and ZITHROMAX (azithromycin) 250-mg oral capsules were moved from the prescription drug product list to the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

In a citizen petition submitted under 21 CFR 10.30 dated May 4, 2004 (Docket No. 2004P–0220), as amended by a letter dated May 17, 2004, Wapner, Newman, Wigrizer & Brecher requested that FDA determine whether ZITHROMAX (azithromycin) 250-mg oral capsules were withdrawn from sale for reasons of safety or effectiveness. The agency has determined that ZITHROMAX (azithromycin) 250-mg oral capsules were not withdrawn from sale for reasons of safety or effectiveness. The petitioners identified no data or other information suggesting that ZITHROMAX (azithromycin) 250-mg oral capsules were withdrawn from sale as a result of safety or effectiveness concerns. FDA has independently evaluated relevant literature and data and has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records, FDA determines that, for the reasons outlined in this document, ZITHROMAX (azithromycin) 250-mg oral capsules, approved under NDA 50–670, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list ZITHROMAX (azithromycin) 250-mg oral capsules in the ''Discontinued Drug Product List'' section of the Orange Book. As a result, ANDAs that refer to ZITHROMAX (azithromycin) 250-mg oral capsules may be approved by the agency.

Dated: May 12, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–10032 Filed 5–19–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given that the following committee will convene its fiftieth meeting:

Name: National Advisory Committee on Rural Health and Human Services.

Dates and Times: June 12, 2005, 1:30 p.m.–5:15 p.m., June 13, 2005, 8:45 a.m.–5 p.m., June 14, 2005, 9 a.m.–10:45 a.m.

Place: Carnegie Hotel, 1216 W State of Franklin Road, Johnson City, TN 37604, Phone: 423–979–6400, Fax: 423–979–6424.

Status: The meeting will be open to the public.

Purpose: The National Advisory Committee on Rural Health and Human Services provides advice and recommendations to the Secretary with respect to the delivery, research, development, and administration of health and human services in rural areas.

Agenda: Sunday afternoon, June 12, at 1:30 p.m., the Chairperson, the Honorable David Beasley, will open the meeting and welcome the Committee. There will be a brief discussion of Committee business and updates by Federal staff. The first session will open with an overview of East Tennessee by Dr. Paul Stanton, President of East Tennessee State University. The remainder of the day's meeting will be devoted to panel discussions on the three topics for the 2006 workplan: Pharmacy Access, Health Information Technology (HIT), and Elderly Caregiver Support. The Sunday meeting will close at 5:15 p.m.

Monday morning, June 13, at 8:45 a.m., the Committee will break into Subcommittees and conduct site visits to local health and human services facilities. Transportation to these sites will not be provided to the general public. The Pharmacy Access Subcommittee will visit Wilson Pharmacy in Johnson City; the HIT Subcommittee will visit Central Appalachian Health Information Partnership in Mountain City; and the Elderly Caregiver Support Subcommittee will visit the Mountain Empire Older Citizens Area Agency on Aging in Big Stone Gap. The Subcommittees will reconvene at 1:45 p.m. at the Carnegie Hotel to continue discussions on the workplan. The Committee of the whole will reconvene at 4:30 p.m. for a brief discussion of the workplan. The Monday meeting will close at 5 p.m.

The final session will be convened Tuesday morning, June 14, at 9 a.m. The Committee will review the discussion of the 2006 Workplan and have updates on the Subcommittees site visits. The meeting will conclude with a discussion of the September meeting. The meeting will be adjourned at 10:45 a.m.

For Further Information Contact: Anyone requiring information regarding the Committee should contact Tom Morris, M.P.A., Executive Secretary, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 9A–55, 5600 Fishers Lane, Rockville, MD 20857, telephone (301) 443–0835, Fax (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Michele Pray-Gibson, Office of Rural Health Policy (ORHP), telephone (301) 443–0835. The Committee meeting agenda will be posted on ORHP's Web site *http://www.ruralhealth.hrsa.gov.*

Dated: May 13, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05–10098 Filed 5–19–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Opportunity for a Cooperative Research and Development Agreement (CRADA) for Research and Development of Vigabatrin as a Potential Pharmacotherapy for the Treatment of Cocaine and Methamphetamine Dependence

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The National Institute on Drug Abuse, a component of the National Institutes of Health, Department of Health and Human Services (DHHS) seeks an agreement with a pharmaceutical or biotechnology company to test the hypotheses that vigabatrin may be a safe and effective medication for the treatment of cocaine and methamphetamine dependence.

A body of literature relevant to preclinical studies of vigabatrin as a potential treatment agent for various types of substance dependence (including cocaine and methamphetamine) and a more limited body of literature concerning clinical results exists. As there are currently no medications approved by the U. S. Food and Drug Administration (FDA) for the treatment of cocaine and/or methamphetamine dependence, and cocaine and methamphetamine dependence have substantial negative public health impacts, the National Institute on Drug Abuse is interested in evaluating the safety and efficacy of vigabatrin for the treatment of cocaine and methamphetamine dependence.