April 5, 2007

DIRECTIVE: JOB CORPS INFORMATION NOTICE NO. 06-28

TO: ALL JOB CORPS NATIONAL OFFICE STAFF
    ALL JOB CORPS REGIONAL OFFICE STAFF
    ALL JOB CORPS CENTER DIRECTORS
    ALL JOB CORPS CENTER OPERATORS
    ALL NATIONAL TRAINING AND SUPPORT CONTRACTORS
    ALL OUTREACH, ADMISSIONS, AND CTS CONTRACTORS

FROM: ESTHER R. JOHNSON, Ed.D.
      National Director
      Office of Job Corps

SUBJECT: Food and Drug Administration Directive to Attention Deficit Hyperactivity Disorder Drug Manufacturers to Notify Patients Regarding Cardiovascular Adverse Events and Psychiatric Adverse Events

1. **Purpose.** To provide information on the Food and Drug Administration (FDA) directive released on February 21, 2007, instructing the manufacturers of all drug products approved for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) to develop Patient Medication Guides to alert patients to possible cardiovascular risks and risks of adverse psychiatric symptoms associated with the medicines, and to advise them of precautions that can be taken.

2. **Background.** In Job Corps, there are students receiving medications for ADHD. Consequently, it is important that the health and wellness program staff be knowledgeable of any current information that may impact the prescribing and monitoring of ADHD medications.

   An FDA review of reports of serious cardiovascular adverse events in patients taking usual doses of ADHD products revealed reports of sudden death in patients with underlying serious heart problems or defects, and reports of stroke and heart attack in adults with certain risk factors. Another FDA review of ADHD medicines revealed a slight increased risk (about 1 per 1,000) for drug-related psychiatric adverse events, such as hearing voices, becoming suspicious for no reason, or becoming manic, even in patients who did not have previous psychiatric problems. To help patients understand these risks, manufacturers are instructed to create a Patient Medication Guide for each individual product.
The FDA also recommends that children, adolescents, or adults who are being considered for treatment with ADHD drug products work with their physician or other health care professional to develop a treatment plan that includes a careful health history and evaluation of current status, particularly for cardiovascular and psychiatric problems (including assessment for a family history of such problems).

A complete list of the medicines that are the focus of the revised labeling and the draft Patient Medication Guides can be accessed at http://www.fda.gov/cder/drug/infopage/ADHD/default.htm. In addition, the FDA’s press release can be found on the Job Corps Health and Wellness Web site at http://jchealth.jobcorps.gov.

3. **Action.** Center Directors are to ensure that this Information Notice is distributed to all Job Corps center health and wellness staff, specifically the center physician, center mental health consultant, health and wellness manager, and center dentist. All other addressees are to ensure that this Information Notice is distributed to all appropriate staff.

4. **Expiration Date.** Until superseded.

5. **Inquiries.** Inquiries should be directed to either Barbara Grove, RN, at 202-693-3116 or grove.barbara@dol.gov, or Carol Abnathy at 202-693-3283 or abnathy.carol@dol.gov.