January 24, 2005

DIRECTIVE:	JOB CORPS PROGRAM INSTRUCTION NO. 04-11

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

FROM: GRACE A. KILBANE
National Director
Office of Job Corps

SUBJECT: Federal Drug Administration (FDA) Black Box Warning for Anti-Depressants

1. Purpose. To advise centers and health care providers on the latest FDA advisory regarding anti-depressants, and to suggest practices regarding prescribing and monitoring anti-depressant medications.

2. Background. On October 15, 2004, the FDA issued a Public Health Advisory (http://www.fda.gov/cder/drug/antidepressants/SSRIPHA200410.htm) announcing a multi-pronged strategy to warn the public about the increased risk of suicidal thoughts and behavior ("suicidality") in children and adolescents being treated with antidepressant medications. The agency is directing manufacturers to add a "black box" warning to the health professional labeling of all antidepressant medications describing this risk and emphasizing the need for close monitoring of patients started on these medications. The FDA has also determined that a Patient Medication Guide (MedGuide) advising patients receiving the drugs of the risks and precautions is appropriate, and is in the process of developing such a guide. It should be noted that the FDA's analyses indicate that only four percent of children and adolescents in the studies examined by the agency who were taking antidepressant medications experienced suicidality during the first few months of treatment. Therefore, 96 percent of children and adolescents in the studies who were taking such medications had no such reactions.

3. Action. Anti-depressant therapy in the under 18 age group should be undertaken after careful consideration of the risks and benefits, including a discussion of the recent FDA warning with the parents/guardians and the student. It is strongly recommended that centers and center health staff do the following:

- When possible, consult with, or refer to, child and adolescent psychiatry providers who specialize in caring for adolescents and young adults before initiating anti-depressant therapy.

- Inform parents/guardians and the student of indicators of a negative reaction to these medications; any suicidal thoughts or behaviors, an increase in agitation, restlessness, irritability, etc., that does not subside in a few days.

- Train all center staff on the possible negative reactions to anti-depressant medications and how to identify students at-risk for suicidal behavior. The center physician, center mental health consultant, or an outside community provider can conduct this training.

- Carefully document in the student's health record that informed consent was obtained, including a discussion of the risks and benefits of the treatment proposed, and alternatives to this treatment, including doing nothing; that questions were answered; that the student/parent/guardian agreed to go ahead with the proposed treatment; and the current assessment of suicidal risk.

- Once a student begins anti-depressant therapy, the FDA advocates at least weekly face-to-face contact with the student during the first four weeks of treatment, biweekly visits for the next four weeks, and as clinically indicated beyond 12 weeks. These visits should be documented in the student's health record.

- For students under the age of 18 already on anti-depressants:

    - A qualified center health professional should discuss the FDA findings with them and place a call to their parents as the student comes in for follow-up.

    - A joint decision about continuing or changing anti-depressant therapy should be made.

    - The decision should be documented in the chart along with the informed consent as outlined above.

Note that most students who respond positively to anti-depressant medications need to remain on the medication for at least 6 months before trying to go off the medication, or the depression symptoms may return.

Applicants and students of Job Corps who are taking anti-depressants should be dealt with on a case-by-case basis, relying in large part on the opinion of the prescribing physician or the wellness staff. If a student's individual circumstances or recent history indicate that he/she may not be a good candidate for anti-depressant therapy, but is in need of treatment, then a center may apply different or more restrictive actions than what are outlined in this Program Instruction. This might include a medical separation with reinstatement rights to begin anti-depressant therapy at home and return to the Job Corps Center once stable. Again, each student should be reviewed on a case-by-case basis.

4. Expiration Date. Until superseded.

5. Inquiries. Any inquiries should be directed to Barbara Grove, RN, at (202) 693-3116, or emailed to, grove.barbara@dol.gov.