

Advertisements: Appropriate Language for Recruitment Material

When submitting advertisements and other recruitment material(s), consider the following items:

- 1. No claims should be made, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device.**

Such representation would not only be misleading to subjects but would also be a violation of the FDA's regulations concerning the promotion of investigational drugs [21 CFR 312.7(a)] and of investigational devices [21 CFR 812.7(d)].

- 2. Advertising for recruitment into investigational drug, biologic or device studies should not use terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational.**

A phrase such as "receive new treatments" leads study subjects to believe they will be receiving newly improved products of proven worth.

- 3. Advertisements should not promise "free medical treatment," when the intent is only to say subjects will not be charged for taking part in the investigation. Advertisements may state that subjects will be paid, but should not emphasize the payment or the amount to be paid, by such means as larger or bold type.**

- 4. Generally, advertisements to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest.**

When appropriately worded, the following items may be included in advertisements. It should be noted, however, that it is not required to include all of the listed items:

- (a) The name, phone number and address of the clinical investigator and/or research facility;
- (b) The condition under study and/or the purpose of the research;
- (c) In summary form, the criteria that will be used to determine eligibility for the study;
- (d) A brief list of participation benefits, if any (e.g., a no-cost health examination);
- (e) The time or other commitment required of the subjects; and
- (f) The location of the research and the person or office to contact for further information
- (g) Please include the following item on advertisements:
For general information about participant rights, contact 1-866-680-2906.

Adapted from the FDA Information Sheets - 1998 Updated