



## **FDA NON-DEBARMENT CERTIFICATION REQUIREMENTS**

(see form on reverse side)

The Generic Drug Enforcement Act of 1992 authorizes the Food and Drug Administration (FDA) to require applicants for (a) new drug applications (including supplements) and (b) abbreviated new drug applications (NDAs & ANDAs), to submit a certification of non-debarment, from any vendor, contractor, consultant, or investigator whose services/products may become part of an application for approval of a drug or biologic.

The FDA has the authority to prevent any individual or any organization convicted of certain crimes, or found to have engaged in certain types of conduct, that relate to the development or approval (or process thereof) of any drug, from providing services to an applicant for any type of NDA. (21 U.S.C. ?335[a]). Services include the development or submission of records or data that are (1) used to obtain approval of an application and (2) relate to the manufacturing, processing, or testing of the active ingredient(s) or the finished dosage forms(s).

The FDA can debar, permanently or for a set period of time, any individual whom the FDA finds has been convicted of committing conduct, or conspiring to conduct, or aiding or abetting conduct, which undermines the process for the regulation of drugs and such conduct served as the basis of conviction. Such conduct can also result in civil penalties of up to \$250,000 for each violation by an individual. The name of any person so debarred is published in the Federal Register along with the effective date and period of debarment. The FDA's Office of Regulatory Affairs also maintains a publicly available list with similar information about all debarred individuals and firms.

As this statute has become better known many pharmaceutical companies have begun to include contract terms which require MUOT to state that its employees are in compliance with the Act. Often they require that some sort of representation on non-debarment be signed by the principal investigator (and sometimes all project personnel.)

**In response, a Certification of Non-Debarment has been prepared by Research and Grants Administration (RGA) for use by MUOT employees. The unit administrator or project director is asked to obtain the signature of all MUOT employees who will participate in a particular clinical study. The completed Certification of Non-Debarment form should be returned to RGA where it will be retained internally by MUOT. Please keep a copy for your records. The signed form will not be provided to the sponsor.**

**Where a statement of compliance by MUOT is not required by a Sponsor, project personnel are not presently required to sign the MUOT certification form.**

**If you have any questions, please call Carol Reichenbach at ext. 4252.**

RGA Proposal # \_\_\_\_\_

**FDA CERTIFICATION OF NON-DEBARMENT**

**Protocol No.** \_\_\_\_\_

|                        |       |
|------------------------|-------|
| <b>Protocol Title:</b> | _____ |
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|-----------------|-------|---------------|-------|
| <b>Sponsor:</b> | _____ | <b>Dated:</b> | _____ |
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(See explanation on reverse side)

The prospective participant certifies to the best of his or her knowledge and belief that he or she:

- (a) is not presently debarred or convicted for a crime for which he or she can be debarred under the Generic Drug Enforcement Act of 1992 (21 U.S.C. 335[a]) (the "Act");
- (b) is not presently indicted or otherwise criminally or civilly charged by a government entity (Federal or state) with commission of the kinds of conduct for which he or she can be debarred under the Act;
- (c) will not knowingly employ or otherwise engage any individual who has been (i) debarred or (ii) convicted of a crime for which a person can be debarred under the Act, in any capacity in connection with the activities of developing or reporting data which may become part of an application for approval of a drug or biologic.

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