

(d) If the application is deficient, FDA will identify its shortcomings and advise the applicant so it may submit additional information within the designated time period. FDA may deem the application incomplete and deny the request for accreditation if the applicant fails to respond to a request for additional information in a timely manner. All information submitted to FDA in response to any requests for additional information should be received no later than September 25, 2003.

(e) If the application is adequate, FDA will file it for full review, rating and ranking by the TPRB. A rating criteria checklist will be used to assess the relevant qualifications and competence of persons applying to become APs. The agency has assigned a weight (5, 15 or 20) to each of eight elements. The eight elements are addressed in section II.B.6 of this document, Contents of an AP Application. The weight of the element is based on how essential the information is in determining if the applicant is suitable to perform Quality System / Good Manufacturing Practices (QS/GMP) inspections on behalf of FDA. Each member of the TPRB will assess each of the eight elements and will vote a "quality level" score from 0 to 4 (0 = Unsatisfactory, 2 = Satisfactory, 4 = Exceeds) for each element. The final Quality Level Score will be determined by a majority vote of the TPRB. Quality Level Score x Weight = Element Score. The eight element scores will be totaled to yield an "Application Rating" (maximum rating attainable is 400). The TPRB will then rank the applications (highest application rating first).

(f) If more than 15 applicants seeking accreditation satisfy the minimum requirements, FDA will accredit the 15 applicants that have the highest scores. If fewer than 15 persons are initially accredited, additional applications will be considered during the 12 months that follow the publication of this guidance. Persons seeking accreditation that are not among the 15 highest ranking applications can reapply 12 months after the publication of this guidance and persons who did not previously apply may also apply 12 months after publication of this guidance.

(g) FDA may deny the request for accreditation if we determine that the application does not meet the criteria established for APs or scores lower than the 15 highest rated applications received by August 25, 2003.

(h) FDA will stop accepting applications on August 25, 2003. FDA plans to publish on its Web site the List of Persons Accredited for Inspections on or before October 26, 2003.

6. Contents of an AP Application

Applicants should include the information described as follows:

- (a) Administrative Information
 - Application in English;
 - Name and address of the organization seeking accreditation;
 - Telephone number and e-mail address of the contact person. The contact person should be the individual to whom questions about the content of the application may be addressed and to whom a letter of determination and general correspondence will be directed;
 - Name and title of the most responsible individual at the AP. Foreign applicants may wish to identify an authorized representative located within the United States who will serve as the AP's contact with FDA;
 - Name and title of the most responsible individual at the parent organization, if applicable;
 - Brief description of the applicant, including: type of organization (e.g., not-for-profit institution, commercial business, other type of organization); size of organization (number of employees); organizational charts showing the relationship of the organization involved in the AP inspection program and its relationship with parent or affiliate companies; number of years in operation; nature of work (e.g., conformity assessment testing or certification laboratory); and sufficient information regarding ownership, operation, and control of the organization to assess its degree of independence from manufacturers and distributors of products regulated under the act. Please include your annual report or, if it is available electronically on the Internet, please include the appropriate Web site address. If the applicant's organization has offices in numerous locations, please be specific and name all locations that you plan to participate in the AP inspection process for your firm. Applicants may include all locations under one application if they will operate under the same processes and procedures for AP inspections. Include curriculum vitae (CVs) for all supervisory personnel and explain where supervisory oversight will be located;
 - List countries that have certified, accredited or recognized the applicant for quality system or GMP inspections/auditing and the date of such certification, accreditation, or recognition;
 - Specify any accreditation for assessment of quality systems that you may have, such as accreditation to ISO/IEC Guide 62. If you are accredited to standards other than Guide 62, please

provide copies of the standards in English.

- Activities for which the AP seeks accreditation. This includes a list identifying the devices the applicant seeks to inspect. Applicants may simply state "all devices" or identify the devices they wish removed from their scope of work by classification panel or by classification name (e.g., except cardiovascular devices under 21 CFR part 870 or except 21 CFR 870.3620, 870.3630, 870.3640, and 870.3670).

(b) Prevention of Conflict of Interest

The applicant should submit a copy of the written policies, procedures and sample certification/compliance statements established to prevent conflicts of interest. MDUFMA requires that the AP and its employees (including contract employees) involved in the performance of inspections and the preparation and approval of reports be free from conflicts of interest and the appearance of conflicts of interest that might affect the inspection process. No personnel of an AP involved in inspections, nor their spouses or minor children, may have ownership of or other financial interest in any product regulated under the act. In accordance with section 704(g)(3)(E) of the act, APs will annually make available to the public the extent to which the AP complies with conflict of interest requirements.

(c) Technical Competence

FDA will consider several factors with respect to personnel qualifications and the preparedness of the applicant to conduct technically competent inspections. The applicant should document these factors in its application and include:

- The written policies and procedures established to ensure that manufacturers are inspected by qualified personnel;
- The written instructions for the duties and responsibilities of personnel, including inspectors, with respect to the inspection of device manufacturing facilities;
- The written personnel qualification standards established to ensure that inspectors and other designated personnel are qualified in all of the regulatory and technical disciplines needed to effectively inspect for compliance with FDA's regulatory requirements for medical devices;
- The documentation (e.g., CVs) to establish that the inspectors and other involved non-supervisory personnel meet the established criteria for qualified personnel. This includes documentation of knowledge, education, training, skills, abilities and experience, including specialized education and experience needed for