

§ 900.5

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initially accredited and at least annually when updated, in a manner and at a time specified by FDA.

(2) Accept applications containing the information required in 42 U.S.C. 263b(c)(2) for provisional certificates and in § 900.11(b)(3) for extension of provisional certificates, on behalf of FDA, and notify FDA of the receipt of such information;

(3) Submit to FDA the name, identifying information, and other information relevant to 42 U.S.C. 263b and specified by FDA for any facility for which the accreditation body denies, suspends, or revokes accreditation, and the reason(s) for such action;

(4) Submit to FDA an annual report summarizing all serious complaints received during the previous calendar year, their resolution status, and any actions taken in response to them;

(5) Provide to FDA other information relevant to 42 U.S.C. 263b and required by FDA about any facility accredited or undergoing accreditation by the body.

(i) *Fees.* Fees charged to facilities for accreditation shall be reasonable. Costs of accreditation body activities that are not related to accreditation functions under 42 U.S.C. 263b are not recoverable through fees established for accreditation.

(1) The accreditation body shall make public its fee structure, including those factors, if any, contributing to variations in fees for different facilities.

(2) At FDA's request, accreditation bodies shall provide financial records or other material to assist FDA in assessing the reasonableness of accreditation body fees. Such material shall be provided to FDA in a manner and time period specified by the agency.

[62 FR 55976, Oct. 28, 1997; 62 FR 60614, Nov. 10, 1997, as amended at 64 FR 32407, June 17, 1999]

§ 900.5 Evaluation.

FDA shall evaluate annually the performance of each accreditation body. Such evaluation shall include an assessment of the reports of FDA or State inspections of facilities accredited by the body as well as any additional information deemed relevant by FDA that has been provided by the ac-

creditation body or other sources or has been required by FDA as part of its oversight initiatives. The evaluation shall include a determination of whether there are major deficiencies in the accreditation body's performance that, if not corrected, would warrant withdrawal of the approval of the accreditation body under the provisions of § 900.6.

§ 900.6 Withdrawal of approval.

If FDA determines, through the evaluation activities of § 900.5, or through other means, that an accreditation body is not in substantial compliance with this subpart, FDA may initiate the following actions:

(a) *Major deficiencies.* If FDA determines that an accreditation body has failed to perform a major accreditation function satisfactorily, has demonstrated willful disregard for public health, has violated the code of conduct, has committed fraud, or has submitted material false statements to the agency, FDA may withdraw its approval of that accreditation body.

(1) FDA shall notify the accreditation body of the agency's action and the grounds on which the approval was withdrawn.

(2) An accreditation body that has lost its approval shall notify facilities accredited or seeking accreditation by it that its approval has been withdrawn. Such notification shall be made within a time period and in a manner approved by FDA.

(b) *Minor deficiencies.* If FDA determines that an accreditation body has demonstrated deficiencies in performing accreditation functions and responsibilities that are less serious or more limited than the deficiencies in paragraph (a) of this section, FDA shall notify the body that it has a specified period of time to take particular corrective measures directed by FDA or to submit to FDA for approval the body's own plan of corrective action addressing the minor deficiencies. FDA may place the body on probationary status for a period of time determined by FDA, or may withdraw approval of the body as an accreditation body if corrective action is not taken.

(1) If FDA places an accreditation body on probationary status, the body