whole, the agreement and such modification is documented and provided to the potential applicant as described in paragraph (f)(1) of this section; or

(2) FDA by written order determines that a substantiated scientific requirement essential to the determination of safety or effectiveness of the new animal drug appeared after the conference.

(h) *When the terms of a presubmission conference agreement are not valid* (1) A presubmission conference agreement will no longer be valid if:

(i) The potential applicant makes to FDA, before, during, or after the presubmission conference, any untrue statement of material fact; or

(ii) The potential applicant fails to follow any material term of the agreement; and

(2) A presubmission conference may no longer be valid if the potential applicant submits false or misleading data relating to a new animal drug to FDA.

(i) *Dispute resolution*. FDA is committed to resolving differences between a potential applicant and FDA reviewing divisions with respect to requirements for the investigation of new animal drugs and for NADAs, supplemental NADAs, and ANADAs as quickly and amicably as possible through a cooperative exchange of information and views. When administrative or procedural disputes arise, a potential applicant should first attempt to resolve the matter within the appropriate review division beginning with the individual(s) most directly assigned to the review of the application or investigational exemption. If the dispute cannot be resolved after such attempts, the dispute shall be evaluated and administered in accordance with applicable regulations (21 CFR 10.75). Dispute resolution procedures may be further explained by guidance available from the Center for Veterinary Medicine.

[69 FR 51170, Aug. 18, 2004]

§514.6 Amended applications.

The applicant may submit an amendment to an application that is pending, including changes that may alter the conditions of use, the labeling, safety, effectiveness, identity, strength, quality, or purity of the drug or the adequacy of the manufacturing methods, facilities, and controls to preserve them, in which case the unamended application may be considered as withdrawn and the amended application may be considered resubmitted on the date on which the amendment is received by the Food and Drug Administration. The applicant will be notified of such date.

§514.7 Withdrawal of applications without prejudice.

The sponsor may withdraw his pending application from consideration as a new animal drug application upon written notification to the Food and Drug Administration. Such withdrawal may be made without prejudice to a future filing. Upon resubmission, the time limitation will begin to run from the date the resubmission is received by the Food and Drug Administration. The original application will be retained by the Food and Drug Administration although it is considered withdrawn. The applicant shall be furnished a copy at cost on request.

§514.8 Supplements and other changes to an approved application.

(a) *Definitions*. (1) The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) apply to those terms when used in this part.

(2) The following definitions of terms apply to this part:

(i) *Assess the effects of the change* means to evaluate the effects of a manufacturing change on the identity, strength, quality, purity, and potency of a drug as these factors may relate to the safety or effectiveness of the drug.

(ii) *Drug substance* means an active ingredient as defined under §210.3(b)(7) of this chapter.

(iii) *Minor changes and stability report (MCSR)* means an annual report that is submitted to the application once each year within 60 days before or after the anniversary date of the application's original approval or on a mutually agreed upon date. The report must include minor manufacturing and control changes made according to §514.8(b)(4) or state that no changes were made;