(b) In each case the consent shall be in writing and shall specify the individual, organizational unit, or class of individuals or organizational units to whom the record may be disclosed, which record may be disclosed, and, if applicable, for what time period. A blanket consent to release all of an individual's records to unspecified individuals or organizational units will not be honored. Verification of the identity of the individual and, where applicable, of the person to whom the record is to be disclosed shall be made in accordance with §21.44. Consent documents shall be retained for a period of at least 2 years. If such documents are used as a means of accounting for the disclosure, they shall be retained as provided in §21.71(e)(2).

§21.73 Accuracy, completeness, timeliness, and relevance of records disclosed from Privacy Act Record Systems.

(a) The Food and Drug Administration shall make reasonable efforts to assure that a record about an individual in a Privacy Act Record System is accurate, relevant to a Food and Drug Administration purpose, timely, and complete before such record is disclosed under §21.71.

(b) Paragraph (a) of this section shall not apply to disclosures that are required under part 20 of this chapter (the public information regulations) or made to other Federal Government departments and agencies. Where appropriate, the letter disclosing the information shall indicate that the Food and Drug Administration has not reviewed the record to assure that it is accurate, relevant, timely, and complete.

§21.74 Providing notice that a record is disputed.

Whenever an individual has filed a statement of disagreement with the Food and Drug Administration concerning a refusal to amend a record under §21.51(a)(2) or with another agency that provides the record to the Food and Drug Administration, the Food and Drug Administration shall in any subsequent disclosure under this subpart provide a copy of the statement of disagreement and a concise statement by the agency, if one has been prepared, of the reasons for not making the amendment(s) requested.

§21.75 Rights of legal guardians.

For the purposes of this part, the parent of any individual who is a minor or the legal guardian of any individual who has been declared to be incompetent due to physical or mental incapacity or age by a court of competent jurisdiction may act on behalf of the individual.

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

Subpart A—General Provisions

Sec.

Subpart B—Agency Actions Requiring Environmental Consideration

Subpart C—Categorical Exclusions

Subpart D—Preparation of Environmental Documents

Subpart E—Public Participation and Notification of Environmental Documents