

§ 1271.320

section and of the tracking system that you have established and are maintaining to comply with these requirements.

(g) *Requirements specific to dura mater donors.* You must archive appropriate specimens from each donor of dura mater, under appropriate storage conditions, and for the appropriate duration, to enable testing of the archived material for evidence of transmissible spongiform encephalopathy, and to enable appropriate disposition of any affected nonadministered dura mater tissue, if necessary.

[69 FR 68681, Nov. 24, 2004, as amended at 70 FR 29952, May 25, 2005]

§ 1271.320 Complaint file.

(a) *Procedures.* You must establish and maintain procedures for the review, evaluation, and documentation of complaints as defined in §1271.3(aa), relating to core current good tissue practice (CGTP) requirements, and the investigation of complaints as appropriate.

(b) *Complaint file.* You must maintain a record of complaints that you receive in a file designated for complaints. The complaint file must contain sufficient information about each complaint for proper review and evaluation of the complaint (including the distinct identification code of the HCT/P that is the subject of the complaint) and for determining whether the complaint is an isolated event or represents a trend. You must make the complaint file available for review and copying upon request from FDA.

(c) *Review and evaluation of complaints.* You must review and evaluate each complaint relating to core CGTP requirements to determine if the complaint is related to an HCT/P deviation or to an adverse reaction, and to determine if a report under §1271.350 or another applicable regulation is required. As soon as practical, you must review, evaluate, and investigate each complaint that represents an event required to be reported to FDA, as described in §1271.350. You must review and evaluate a complaint relating to core CGTP requirements that does not represent an event required to be reported to determine whether an investigation is necessary; an investigation

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may include referring a copy of the complaint to another establishment that performed manufacturing steps pertinent to the complaint. When no investigation is made, you must maintain a record that includes the reason no investigation was made, and the name of the individual(s) responsible for the decision not to investigate.

Subpart E—Additional Requirements for Establishments Described in § 1271.10

SOURCE: 69 FR 68686, Nov. 24, 2004, unless otherwise noted.

§ 1271.330 Applicability.

The provisions set forth in this subpart are being implemented for non-reproductive HCT/Ps described in §1271.10 and regulated solely under section 361 of the Public Health Service Act and the regulations in this part, and for the establishments that manufacture those HCT/Ps. HCT/Ps that are drugs or devices regulated under the act, or are biological products regulated under section 351 of the Public Health Service Act, are not subject to the regulations set forth in this subpart.

§ 1271.350 Reporting.

(a) *Adverse reaction reports.* (1) You must investigate any adverse reaction involving a communicable disease related to an HCT/P that you made available for distribution. You must report to FDA an adverse reaction involving a communicable disease if it:

- (i) Is fatal;
- (ii) Is life-threatening;
- (iii) Results in permanent impairment of a body function or permanent damage to body structure; or
- (iv) Necessitates medical or surgical intervention, including hospitalization.

(2) You must submit each report on a Form FDA-3500A to the address in paragraph (a)(5) of this section within 15 calendar days of initial receipt of the information.

(3) You must, as soon as practical, investigate all adverse reactions that are the subject of these 15-day reports and must submit followup reports within 15