



TITLE: Emergency Use of a Test Article – Post Review

PURPOSE: Communicate the review of notifications of emergency uses of test articles in a life-threatening situation

RESPONSIBILITIES: HSPB Staff
Designated Reviewer

PROCEDURES:

The Designated Reviewer reviews the information regarding the proposed or actual emergency use of a test article using “HRP-317 - WORKSHEET: Emergency Use of a Test Article” as outlined in SOP-051: Emergency Use of a Test Article Review.

Complete an HSPB Correspondence Form and send it to the investigator if the Designated Review indicates the following:

- the **proposed use will** follow FDA regulations
- the **proposed use will NOT** follow FDA regulations
- the **actual use followed** FDA regulations

If the Designated Reviewer indicates that the **proposed use did NOT follow** FDA regulations:

- Complete an HSPB Correspondence Form and send to the investigator.
- Manage under SOP-014: Reportable Items” as Non-Compliance.

MATERIALS:

- SOP-051: Emergency Use of a Test Article Review
- SOP-013: Reportable Items
- HSPB Correspondence Form
- HRP-317 - WORKSHEET: Emergency Use of a Test Article

REFERENCES:

- 21 CFR §50.23; 21 CFR §56.104(c).

REVIEW/REVISIONS: From 10/01/2010 version: Renumbered from P&P-027; References to P&P-023 and P&P-024 revised to SOP-051 and SOP-013, respectively, to reflect new numbering system