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GENERAL REVIEW AND ENFORCEMENT POLICIES

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ANIMAL HEALTH HAZARD EVALUATION COMMITTEE

The Food and Drug Administration's recall policy (21 CFR Part 7) requires an evaluation be conducted of the health hazard (actual or potential) presented by a product being recalled or considered for recall. The regulations (21 CFR 7.41(a)) specify the factors to be considered, among others, by the Health Hazard Evaluation Committee in making the health hazard evaluation. The purpose of the health hazard evaluation, in general, is to identify and document:

- a. The population at risk;
- b. Conditions that may exacerbate or attenuate the risk and the probability of its occurrence;
- c. The risk associated with the product under conditions of use (as labeled); and
- d. The likelihood of the risk occurring in the future.

I. Purpose:

This document describes the organization of the CVM Health Hazard Evaluation Committee and the procedures to be followed when evaluating reports of products being recalled or considered for recall.

II. Committee Organization:

The Health Hazard Evaluation Committee will be composed of three members consisting of a chairperson and two Team Leaders. The individuals serving as committee members may change from one situation to another. The committee will be composed of the following individuals:

- A. The Director, Division of Surveillance, HFV-210, will serve as chairperson.
- B. One of the Team Leaders on the committee should be the supervisor of the individual performing the primary review. The other Team Leader will act as secondary member.

- C. The second Team Leader should be the one with the greatest secondary concern based on species (if immediately available); e.g., pet foods would normally be reviewed initially by the Team Leader of HFV-222 and secondly by the Team Leader of HFV-216.
- D. In the circumstance that none of the Team Leaders or the chairperson are available, persons acting in their behalf will serve on the committee.

III. Report Processing Procedures:

In order to meet the deadlines imposed by the Agency, it will be necessary to hand-carry health hazard evaluation files through each step of their review. As the reviews move up from the primary reviewer through the committee to the chairperson, it will be the responsibility of each person to insure that the file is either placed in the hands of the next reviewer or that the reviewer will be immediately available to perform the review and that the file is placed where it cannot be overlooked by the returning reviewer. Under no circumstances should a health hazard evaluation file be place in an in-basket with other work so that it may go unnoticed for hours (or longer.)