

APHIS Mandated Stop Distribution and Sale Procedures

1. CVB – IC concurrence

- a) Review 9 CFR 105.3. *Notices re: worthless, contaminated, dangerous or harmful biological products*
- b) Review VS Memorandum 800.53: Action to stop distribution and sale of product may be necessary to prevent risk to the health of animals, to the public health or well-being, or to the environment.
 - Note that 9 CFR105.3 (c)(2) requires notification to go to all persons known to have received the product. We execute regulatory flexibility based on the risk; not all notifications are required to go to the end person.
- c) Bring the issue to an IC Section Leader and evaluate the risk in relationship to the Virus-Serum-Toxin Act. For example,
 - Is the product worthless?
 - Potency test unsatisfactory?
 - Is the product contaminated?
 - Organic ?
 - Inorganic?
 - Is the product dangerous?
 - Safety issues?
 - Diagnosis incorrect?
 - Is the product harmful?
 - To the public interest?
 - Diagnosis may create economic harm?
- d) If future serials/subserials of a Product Code are in jeopardy, holds may be needed to be placed on the Product Code(s).
- e) Once agreement has been reached, as quickly as possible, schedule a time to contact the primary liaison of the firm for notification of the action.
- f) If primary liaison is not available; the alternate liaison can be notified. If alternate(s) liaison is not available check the APHIS Form 2001/2005 (on file) and you may notify a Principle Officer.
- g) Be prepared to describe why CVB is taking the action and why to the level determined. Determine if there is any needed documentation of (firm's) notification needed from the firm.

2. Notification to firm of APHIS Mandated Stop Distribution and Sale

- a) An IC Section Leader or Acting must be present during the telephone conversation of the notification. See **ICSOP0001**, *Delegation of Authority for Center for Veterinary Biologics-Inspection and Compliance*, for delegation of authority questions.
- b) Documentation of the telephone conversation is required.
- c) Notify liaison of the APHIS Mandated Stop Distribution and Sale. Be specific to Product Codes and/or Serials/Subserials.
- d) Notify liaison of the level of the action.
 - Licensed premises
 - Licensed distributors
 - All distributors known to have received the product

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- All persons known to have received the product
- e) Dependent upon circumstances, firm may be directed to account for the remaining quantity of each serial/subserial at each location (or specific location) in the distribution channel (9 CFR 105.3 (c)(3)).
- f) You may require the liaison to submit a complete and accurate report of all notifications concerning the stop distribution and sale action (9 CFR 105.3 (c)(4)).

3. Confirmation of Notification

- a) Confirm conversation by letter to primary liaison, the same day or next business day or as soon as possible depending on resources. Utilize template letter.
- b) See **ICSOP0016**, *Investigation and Processing of Alleged Violations of the Virus-Serum-Toxin Act*, if an investigation is involved.