# CPG Sec. 100.300 *Non-FDA Regulated Products Involving Communicable Disease Hazards*

BACKGROUND:

*Some time ago, an incident* occurred which involved plasma thawing during transit and leaking onto other commodities in the truck, including stepstools and printed material. The *Center for Biologics Evaluation and Research (CBER)* determined that this situation presented a potential health hazard to anyone handling the contaminated commodities, since intact and potentially infectious particles of the hepatitis B virus or other viruses might be present in the dried plasma on the contaminated articles.

There is no doubt that FDA has jurisdiction over the thawed plasma and would take whatever action was appropriate against the plasma and responsible individuals.

This policy guide addresses our authority with regard to the contamination of non-FDA regulated products.

In the above incident *CBER* recommended, for expediency and ease of handling, that the consignees be advised through local health authorities to disinfect or destroy the contaminated articles.

*In other incidents involving Anthrax on drum skins and saddle blankets, FDA has referred such problems to the Consumer Product Safety Commission and the Centers for Disease Control.*

POLICY:

*Such problems which are not specifically covered by the laws and/or regulations administered by FDA should be referred when we can identify a responsible agency at the federal, state, or local level that can expeditiously accomplish corrective action.

Sec. 361 of the Public Health Service Act is the source for authority to control the interstate movement of animals or articles found to be contaminated so as to be sources of dangerous infections to human beings. Such relevant regulations, 21 CFR Part 1210, may be utilized whenever necessary to protect the public health.*

*Material between asterisks is new or revised*

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