Sec. 675.200 Diversion of Adulterated Food to Acceptable Animal Feed Use (CPG 7126.20)

BACKGROUND:

In the past, FDA has authorized the salvage of human or animal food considered to be adulterated for its intended use by diverting that food to an acceptable animal feed use. Most of these instances have involved, but have not been limited to, the interpretation of section 402(a)(3) and (4) of the Federal Food, Drug, and Cosmetic Act to allow different standards for foods intended for human use vs. food intended for animal use, e.g., defect action levels for filth in a food intended for human use but not for the same food intended for animal feed use. Diversion requests, however, have also included USDA detained meat and poultry products contaminated with drug or other chemical residues, as well as food and feed under voluntary industry recall or quarantine that may be considered adulterated for their intended use(s). To assist in handling certain specific types of diversion requests, the Agency has developed Compliance Policy Guide 7126.05. [Diversion (after heat treatment) of rodent, roach, or bird contaminated food for animal use.] No single set of criteria, however, can be prepared to cover diversion requests in all possible situations. This guide provides procedures for submitting requests to the agency for authorization to divert adulterated foods for which no criteria have been established.

To facilitate handling, requests for diversion should be submitted in writing to the appropriate FDA District Office. The District will transmit the requests to Division of Compliance, *Center for* Veterinary Medicine, HFV-230. Each request should include the following information.

a. Name and address of the requestor, and the name of the owner of the subject articles.

b. The precise physical location of the product.

c. A precise identification of the product (including lot numbers, amount of articles in each lot, etc.).

d. The reason(s) the articles are considered adulterated for their originally intended food uses.

e. The levels, on a lot-by-lot basis, of any adulterant; all analytical data regarding such levels of an adulterant, and the methodology used in determining the levels of the adulterant.

f. The cause of adulteration if known.

g. The name and address of the proposed consignee.

h. The reconditioning or denaturing procedure, if any.

i. The proposed labeling as well as written information or instruction to accompany the product.

j. All special restriction information, e.g., the product may be under detention by the United States Department of Agriculture and therefore require an official correspondence between agencies regarding approval of the diversion.

k. The intended use of the diverted food. This will include complete description of the class of animals involved, whether they are food or non-food producing, the part of the country in which the food will be used, and all assurances that have been secured that indeed the food will be used as agreed.

l. All available information from the firm proposing the diversion on the safety of the adulterant for the intended animal use and, where appropriate, for the consumption of the edible products of
the animals.

m. Information from the firm proposing the diversion, sufficient for a determination whether disposition of such article, including packaging material, will result in the release of a toxic substance into the environment [See 21 CFR 25.1(f)(9) and (g) and proposed 21 CFR 25.24(d)(4). An Environmental Impact Analysis Report under 21 CFR 25.1(j) or an Environmental Assessment under proposed 21 CFR 25.31 (44 FR 71747) is required if the proposed disposition fails to meet the above criterion for exclusion].

POLICY:

Diversion requests will be handled on an ad hoc basis. The *Center* will consider the requests for diversion of food considered adulterated for human use in all situations where the diverted food will be acceptable for its intended animal food use. Such situations may include:

a. Pesticide contamination in excess of the permitted tolerance or action level.

b. Pesticide contamination where the pesticide involved is unapproved for use on a food or feed commodity.

c. Contamination by industrial chemicals.

d. Contamination by natural toxicants.

e. Contamination by filth.

f. Microbiological contamination.

g. Over tolerance or unpermitted drug residues.

Some general policy issues to be considered while evaluating proposals for diversion of food considered to be adulterated to animal feed use are:

a. A seizure action and a voluntary request for diversion are two separate processes. A seizure action and a request for diversion cannot legally be processed simultaneously. No diversion request submitted under this guideline will be considered once a seizure recommendation has been forwarded to headquarters. If a seizure recommendation is withdrawn and if the requirements of this policy are met, a diversion request may be entertained. Naturally, a diversion-based means of reconditioning seized articles may be an appropriate means of meeting the requirements of a court-ordered consent decree arising from a seizure.

b. Diversion may only be allowed where there is a legally enforceable assurance that the subject foods will not be placed into interstate commerce before the request is approved and the products appropriately diverted (i.e., meats not under USDA detention but nevertheless containing illegal residues would be appropriate for seizure or state embargo but not for diversion if the meats were already shipped in interstate commerce). Accordingly, this policy will primarily apply to embargoed goods or bonded goods to assure adequate control of the adulterated goods.

c. Where diversion is legally appropriate, data are required to demonstrate that the diverted use poses no safety hazards to the animals consuming the diverted food and to the public who may be exposed to edible tissues of such animals.

d. The diversion policy does not sanction or authorize the blending of the adulterated foods, i.e., the policy does not authorize the diluting of an adulterated product to below a tolerance or action
level.

*Material between asterisks is new or revised*

Issued: 11/1/81
Revised: 3/95