February 20, 2019

Association for Truth in Pet Food (ATPF), a pet owner stakeholder association with worldwide membership, submits these comments regarding "*Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C.*"

Our first comment is regarding an edit change within the Guidance document as it contains a typo. Page 4, boxed content under title. Quoting, bold added for emphasis of typo, "*This guidance **represent** the current*…" We suggest the word "*represent*" be replaced with 'represents'.

As our members are specific to pet food consumers, the remainder of our comments will be in reference to pet products.

A significant concern we ask FDA to address is the need to prepare a second Guidance document specific to feed grade pet products (feed), as the language in this document refers to 'food'. FDA allows many materials into feed grade pet foods (feed) that the agency would never allow into 'food'. As example CPG Sec. 690.300 – "*Pet food consisting of material from diseased animals or animals which have died otherwise than by slaughter, which is in violation of 402(a)(5) will not ordinarily be actionable, if it is not otherwise in violation of the law. It will be considered fit for animal consumption*." Because this and other FDA Guidance documents clearly and distinctly separate feed and food, the same separation is requested here. Without such separation, the pet owning public is further confused by FDA's very different enforcement of law between 'food' and 'pet food/pet feed'.

On Page 6, under "III Discussion:" FDA states: "*The FDA's policy is to evaluate the particular circumstances of each individual recall in determining whether a public warning is needed in accordance with 21 CFR § 7.42(b)(2) as part of the recall strategy*."

We are confused to why FDA only addresses 21 CFR § 7.42(b)(2) in the Guidance document. We ask why 7.42(b)(1) is excluded? Further, specific to the pet owners ATPF represents, pet owners would certainly want notification of all 'depths of recall' to be public information. If a pet product is recalled at wholesale level, pet owners request that information to be provided to the public as well.

We are concerned with this statement within the Guidance document as it provides no legal clarification: "*The FDA may issue a public warning or notification before formally classifying a recall under 21 CFR § 7.41(b)*." As FDA has issued multiple public warnings regarding raw pet food (two during the recent government shutdown), we ask that FDA provide full disclosure in the Guidance document to the regulations that FDA must adhere to regarding all FDA issued public warnings. The disclosure to legal requirements FDA must adhere to regarding agency issued public warnings will benefit pet owners, and perhaps (if FDA is abiding by those federal regulations) begin to build pet owner trust in the agency.

Under the section "***1. Under what circumstances should firms issue public warnings?***" the Guidance document states "*The FDA will continue to assess the need for public warnings for voluntary recalls of FDA-regulated products based on the particular circumstances of the individual recall. The following recalls*

generally present examples of serious hazards to health such that a public warning may be warranted:…" One of the bullet points provided states:

> "*Recalls of food products initiated because of microbiological pathogen findings (e.g., Listeria monocytogenes, Salmonella, etc.) in environmental testing where direct food manufacturing contact surfaces are found to be contaminated*."

Again, this example provided in the document appears to be specific to 'food', not feed. FDA has historically shown complete disregard for pathogenic bacteria on "direct food manufacturing contact surfaces" within pet food (feed) manufacturing including taking no regulatory action (no public warning issued) of significant pest infestation in feed grade manufacturing facilities.

Evidence to this: "*Inspectional Observations*" stated in FDA EIR from Mars Petcare, Columbus, OH in 2017 found the pet feed manufacturer failed to 1) "*inspect, segregate, or otherwise handle raw materials and ingredients used in manufacturing under conditions that will protect the animal food against contamination and minimize deterioration*." And 2) Mars Petcare failed "*to take effective measures to exclude pests from your plant and protect against contamination of animal food by pests*." **No public warning was issued on these pet food (feed) products by the manufacturer or by FDA**. The double standard of regulation of pet feed products and 'food' products (even though the FD&C Act includes animal food under the legal definition of food) cause confusion with pet owning consumers buying pet products. Because of the distinctly different ways FDA regulates 'food' and 'feed', as exampled by this Mars Petcare EIR, we ask FDA to prepare a separate Guidance document specific to feed products.

Under "***2. Who prepares public warnings?***" The FDA states "*In some situations, the FDA may prepare and issue public warnings on its own initiative and in accordance with 21 CFR § 7.42(b)(2)*."

The full text of 21 CFR § 7.42(b)(2) FDA appears to be citing as foundation for agency issued warnings is as follows: "*(b) Elements of a recall strategy. A recall strategy will address the following elements regarding the conduct of the recall: (ii) Retail level, including any intermediate wholesale level; or*".

As evidenced by the full text, 21 CFR § 7.42(b)(2) makes no mention of FDA prepared and issued public warnings. We ask (again) that FDA provide the section number within CRF that provides authority to FDA for agency prepared and issued public warnings within the Guidance document. This legal validation supporting FDA actions is necessary for transparency to pet food consumers.

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