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VIA FACSIMILE

FDA Dockets Management Branch
HFA-305
5630 Fisher Lane
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Rockville, MD 20852

Re: Docket No. 02N-0277

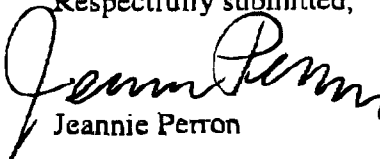
Dear Sir or Madam:

We hereby respectfully request that FDA provide clarification on an issue raised by the May 9, 2003 Proposed Rule Regarding Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Proposed 21 C.F.R. § 1.327(g) lists as excluded from the regulations of the subpart:

Persons who manufacture, process, pack, transport, distribute, receive, hold or import pet food who are not subject to the recordkeeping provisions of the animal proteins prohibited in ruminant feed regulation (§ 589.2000 of this chapter) are, with respect to pet food records, excluded from all the regulations in this subpart except for § 1.361 and § 1.363.

Pet food manufacturers who do not incorporate into their products protein derived from mammalian tissues, as that term is defined in 589.2000(a)(1), are not subject to the recordkeeping requirements of that rule. Those same manufacturers are therefore entitled to the exclusion of § 1.327(g). This section uses the term "persons" rather than either of the defined terms, "Domestic persons" or "Foreign facilities." We therefore assume that the exclusion in § 1.327(g) is intended to cover both foreign and domestic entities. Please clarify whether foreign manufacturers of pet food that does not contain protein derived from mammalian tissues and who export their products into this country also are entitled to the § 1.327(g) exclusion.

Respectfully submitted,


Jeannie Perron

02N-0277

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