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drugs in the context of dog and cat foods (1) that provided nutrients in support of the animal's total required daily nutrient needs, (2) that were distributed only through licensed veterinarians and (3) with respect to which manufacturers restricted labeling claims. However, noting an increase in the number of dog and cat foods labeled as being intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease, and noting that animal health may suffer when such products are not subject to pre-market FDA approval and are provided in the absence of a valid veterinarian-client-patient relationship, the FDA recently issued a list of specific factors it will consider in determining whether to initiate enforcement action against products that satisfy the definitions of both an animal food and an animal drug, but which do not comply with the regulatory requirements applicable to animal drugs. We currently produce products, such as cat food with hairball management, that undergo FDA pre-market inspection. While we believe that we market our products in accordance with the applicable FDA regulatory requirements, the FDA may classify some of our products differently than we do and may impose more stringent regulations applicable to animal drugs, such as requirements for pre-market approval and compliance with GMPs for the manufacturing of pharmaceutical products. We intend to produce more products that we anticipate will be subject to FDA pre-market inspection, including new products to the Therapeutic market segment.

Under Section 423 of the FFDCA, the FDA may require the recall of an animal feed product if there is a reasonable probability that the product is adulterated or misbranded and the use of or exposure to the product will cause serious adverse health consequences or death. In addition, pet food manufacturers may voluntarily recall or withdraw their products from the market. In 2010, we voluntarily issued a recall of certain of our products due to possible excess Vitamin D present in specific production runs caused by an error occurring at a supplier.

Most states also enforce their own labeling regulations, many of which are based on model definitions and guidelines developed by AAFCO. AAFCO is a voluntary, non-governmental membership association of local, state and federal agencies that are charged with regulation of the sale and distribution of animal feed, including pet foods. The degree of oversight of the implementation of these regulations varies by state, but typically includes a state review and approval of each product label as a condition of sale in that state.

Most states require that pet foods distributed in the state be registered or licensed with the appropriate state regulatory agency. In addition, most facilities that manufacture, process, pack, or hold foods, including pet foods, must register with the FDA and must renew their registration every two years. This includes most foreign, as well as domestic facilities. Registration must occur before the facility begins its pet food manufacturing, processing, packing, or holding operations.

In 2011, the FSMA was enacted. The FSMA mandates, among other things, that the FDA adopt preventative controls to be implemented by pet food facilities in order to minimize or prevent hazards to food safety. In October 2013, the FDA issued a proposed rule entitled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals." An updated proposed rule was issued in September 2014. The proposed rule would establish GMPs in the manufacturing, processing, packing and holding of animal food. In addition, the proposed rule would require certain facilities to establish and implement hazard analysis and risk-based preventive controls for food for animals. Although these requirements are not yet in effect, we believe we are well-positioned for these changes.

We are also subject to the laws of Canada, Mexico and Japan, as well as provincial and local regulations, with regard to products exported to those jurisdictions. In Canada, we are subject to regulation and oversight by the Canadian Food Inspection Agency and other provincial and local agencies. In Mexico, we are subject to regulation and oversight by the Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA), the National Service of Health, Food Safety and Quality (SENASICA) which is an administrative body of SAGARPA and other state and local agencies. In Japan, we are subject to regulation and oversight by the Ministry of Agriculture, Forestry and Fisheries, the Ministry of the Environment and other local agencies. As we enter into new foreign markets, we will be subject to similar laws and regulation, and oversight by foreign governmental and regulatory agencies, in those jurisdictions.