

05n-0403-ereg005.txt

From: no-reply@erul emaki ng.net
Sent: Wednesday, January 24, 2007 6: 32 PM
To: Dockets, FDA
Subject: Public Submi ssi on

Please Do Not Reply Thi s Email .

Public Comments on Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Bi ologi cs License Appli cation, and Animal Drugs; Public Meeting; Extension of Comment Period: =====

Title: Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Bi ologi cs License Appli cation, and Animal Drugs; Public Meeting; Extension of Comment Period
FR Document Number: E6-18310
Legacy Document ID:
RIN: 0910-AA49
Publish Date: 10/31/2006 00: 00: 00
Submitter Info:

First Name: Pedro
Last Name: Aldahondo
Category: Private Industry - C0001
Organization Name: ALK-Abello, Inc.

Comment Info: =====

General Comment: ALK-Abell?, Inc. is a manufacturer of Allergenic Extracts for the veterinary and human market and a registered Drug Establishment. All Allergenic Extracts are marketed and sold to the Allergy Specialist, Veterinarians and General Practitioners directly. They are not sold through wholesaler or distribution channels. The client base of physicians is not set up to use the latest technology such as bar coding and NDC numbers since there is no benefit to be derived by employing such systems in their practice. This accounts for why the latest technology including bar coding and the NDC code system is not prevalent in this industry. Confirmation to this was evident when Allergenic Extract manufacturers argued against the bar coding requirements which led to their being exempt. Many of our products and those of our competitors are currently listed but they are identified under a general product category such as ?pollens?. To list every possible allergen, solutions, potency, vial size etc. as required under product listing will mean filing for over 8200 stock products and stock mixtures. In addition, in order to include all the prescriptions mixtures that can potentially be ordered, an extraordinary number of product listings will have to be filed (50,000 is a conservative estimate). Order patterns are varied and are as small as a single vial. As a manufacturer, developing and applying the technology to accommodate NDC numbers on product labels on such a vast product line will present an undue burden on our company and our industry. In many cases, the addition of an NDC number on the product label will not be possible on an already cluttered labeled that includes cautions, warnings, license numbers, company name and address and detailed product descriptions. Other than to benefit the FDA to administer their programs, none will be derived for our industry. We request exemption from the rule because it is burdensome to our company and industry and may not fulfill some of the FDA stated initiatives.