



January 16, 2001

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

Ref: KAN 2001-012

Dr. R. Hollis Klett, President
Xtra Factors
5626 West 19th Street
Greeley, CO 80634

Dear Dr. Klett:

Recently an inspection was made of your medicated feed mill operation located at 211 Pedigo Drive, Pratt, Kansas. This inspection was conducted on November 29, 2000, by an inspector with the Kansas Department of Agriculture, who documented significant deviations from Current Good Manufacturing Practice (CGMP) Regulations for Medicated Feeds (21 CFR, Part 225). Such deviations cause the medicated feeds manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Observations include failure to properly identify, store and control medicated articles to maintain their identity and integrity; failure to perform assays on medicated feeds as required; failure to document corrective actions when production record discrepancies are found.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. A copy of the Form FDA 483 is enclosed for your information.

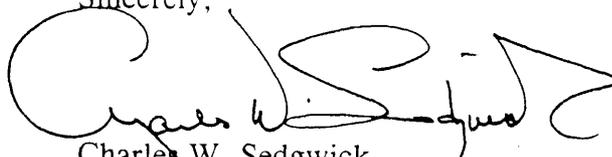
You should take prompt action to correct the noted violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction, and/or notice of opportunity for a hearing on a proposal to withdraw approval of your Medicated Feed Mill License, under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2). (This letter constitutes official notification under the law.) Based on the results of the November 29 inspection, evaluated together with the evidence before FDA when the Medicated Feed Mill License was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new

animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles W. Sedgwick", written over a large, stylized circular flourish.

Charles W. Sedgwick
District Director
Kansas City District

Enclosure - Form FDA 483

cc: Henry C. Bingaman
Plant Manager
Xtra Factors
211 Pedigo Drive
Pratt, KS 67124