



DEPARTMENT OF HEALTH & HUMAN SERVICES

94913d

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

August 5, 2004

WARNING LETTER NYK 2004-27

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Joel Newman, CEO/President
United Cooperative Farmers, Inc.
22 Kimball Place
Fitchburg, MA 01420

Dear Mr. Newman:

An inspection of your licensed medicated feed mill located at Building 16 Northeastern Industrial Park, Guilderland Center, NY was conducted by U.S. Food and Drug Administration Investigator Michael G. Sinkevich on April 13 & 15, 2004. That inspection revealed significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21 Code of Federal Regulations, Part 225). Such deviations cause feeds being manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

The deviations found include failure to conduct periodic potency assays during the calendar year on at least three representative samples of each feed required to be manufactured by a licensed medicated feed mill in accordance with 21 CFR 225.58(b)(1), failure to maintain an accurate daily inventory record for each drug used in accordance with 21 CFR 225.42(b)(6), and failure to accurately indicate the quantity and condition of drugs received on drug receipt records in accordance with 21 CFR 225.42(b)(5).

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. This may include seizure, injunction, or a notice of opportunity for a hearing on a proposal to withdraw your medicated feed mill license under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 515.22(c)(2).

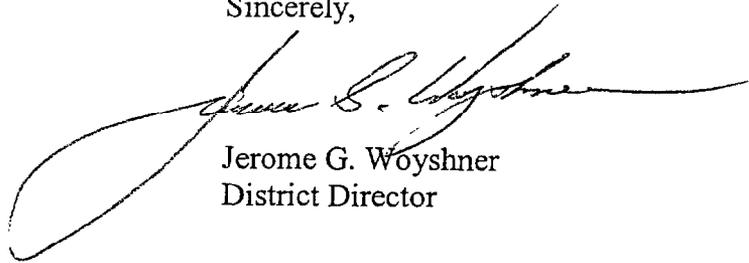
This letter is not intended to be an all-inclusive list of violations. As the Chief Executive Officer and President of this corporation, you are responsible for assuring that the operation of your Guilderland Center mill, as well as your mills at Fitchburg, MA and Auburn, ME, are operating in compliance with the law.

United Cooperative Farmers, Inc.

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Please notify this office in writing, within 15 days, of the steps you have taken to prevent a recurrence of similar violations. Your response should be directed to James M. Kewley, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Jerome G. Woyshner", with a large, sweeping flourish extending to the left.

Jerome G. Woyshner
District Director

cc: Mr. Mark K. Wagener, Plant Manager
United Cooperative Farmers, Inc.
Box 13, Bldg 16
Northeastern Industrial Park
Guilderland Center, NY 12085