Public Health Service
Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

August 14, 2006

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
2006-DT-26

Mr. Steven L. VanderHoff, Member/Owner
Vreba-Hoff Dairy, LLC,
7601 Dillon Highway
Hudson, MI 49247-9514

Dear Mr. VanderHoff:

An inspection of your dairy operation located at 7601 Dillon Highway, Hudson, Michigan 49247-9514, conducted by a representative of the U.S. Food and Drug Administration (FDA) on April 24-26, 2006, confirmed that you offered an animal for sale for slaughter as food that was adulterated under sections 402(a)(2)(C)(ii) [21 U.S.C. § 342(a)(2)(C)(ii)] and 402(a)(4) [21 U.S.C. § 342(a)(4)] of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and its associated regulations on the Internet through links on the FDA's web page at www.fda.gov.

On December 14, 2005, you sold a dairy cow identified with ear tag no. **[redacted]** who in turn sold the animal to **[redacted]** where it was slaughtered for human food use on December 15, 2005. The United States Dept. of Agriculture/Food Safety Inspection Service (USDA/FSIS) analysis found **[redacted]** parts-per-million (ppm) penicillin in the kidney. A tolerance of **[redacted]** has been established for residues of penicillin in the uncooked edible tissues of cattle as codified in Title 21, Code of Federal Regulations, Section 556.510 (21 C.F.R. 556.510). The presence of this drug at the reported level in the. edible tissues of this animal causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) (21 U.S.C. § 342(a)(2)(C)(ii)] of the Act.

Our investigation also found that you hold animals under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. You lack an adequate system to ensure that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially

hazardous residues of drugs from edible tissues. For example, you failed to maintain complete treatment records including the dose administered, the route of administration, or the name of all drugs administered. Food from animals held under such conditions is adulterated within the meaning of section 402(a)(4) [21 U.S.C. § 342(a)(4)] of the Act.

We note that this is not the first time that illegal residues have been found in animals from your farm. On June 17, 2005, you sold a dairy cow identified with ear tag no. **[redacted]**. This dairy cow was we note that this is not the first time that illegal residues have been found in animals from our farm. On June 17, 2005, you sold a dairy cow identified with ear **[redacted]**. This dairy cow was slaughtered for human food on June 22, 2005. The USDA/FSIS analyzed tissue samples collected from this animal and identified the presence of oxytetracycline in the liver at **[redacted]** parts per million (ppm) and in the muscle at **[redacted]**. The tolerance for oxytretracycline in cattle is **[redacted]** in the liver and **[redacted]** in the muscles (see 21 C.F.R. 556.500). In addition, in regard to this oxytetracycline residue, our investigator noted that you administered an approved animal drug via a route, intrauterine, which was not indicated in the labeling, without benefit of a valid veterinarian-client-patient relationship and that you failed to maintain adequate treatment records.

The above is not intended to be an all-inclusive list of violations. As a producer of dairy cows that are offered for use as food, you are responsible for ensuring that your overall operation and the food you distribute are in compliance with the law.

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 such as seizure and/or injunction.

You should notify this office in writing of the steps you have taken to bring your firm into compliance with the law within fifteen (15) working days of receiving this letter. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your written response should be sent to Ms. Judith Jankowski, Compliance Officer, U.S. Food and Drug Administration at the above address.

Sincerely,

/S/

Joann M. Givens
District Director
Detroit District Office