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## Inspections, Compliance, Enforcement, and Criminal Investigations

### Double O Farms 07-Jun-06



Department of Health and Human Services

Public Health Service  
Food and Drug  
Administration

Cincinnati District Office  
Central Region  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
Telephone : (513) 679-2700  
FAX: (513) 679-2771

#### WARNING LETTER

June 7, 2006

CIN-06-29869-14

VIA FEDEX

Mr. Gary Oaks, Owner  
Double O Farms  
14340 Brown Road  
Verona, KY 41092

Dear Mr. Oaks:

A joint investigation by the U.S. Food & Drug Administration, the Ohio Department of Agriculture, and the Kentucky Department for Public Health, and a subsequent sample of your milk product, collected on 03/06/2006, has documented violations of the Public Health Service Act (PHS Act) and a Federal regulation promulgated under the PHS Act.

Our investigation determined that your firm distributes unpa.steurized milk in interstate commerce, in finished form for human consumption. Such distribution is a violation of the PHS Act, 42 U.S.C. § 271(a), and the regulation codified in Title 21, Code of Federal Regulations (CFR), section 1240.61(a). The regulation prohibits the delivery into interstate commerce of milk and milk products in final package form for direct human consumption unless they have been pasteurized. Your milk, shipped directly to customers for consumption, is in final package form for direct human consumption. For your information, we have enclosed a copy of the regulation as it was published in the Federal Register, 52 FR 29,509 (Aug 10, 1987).

The above observation is not intended to be an all-inclusive list of violations. It is your responsibility to ensure adherence with all requirements of the PHS Act and implementing regulations. You should take prompt action to correct this deviation and prevent any future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective actions can not be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

Your response should be sent to Charles S. Price, Compliance Officer, at the above letterhead address. If you have questions regarding any issue in this letter, please contact Mr. Price, at (513) 679-2700 x165.

Sincerely,

/s/

Carol A. Hepe  
District Director  
Cincinnati District

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