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HFE-3 7/28/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: CFN 1130786

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4012

July 28, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John R. Oakman, Jr., President
National Coach Works, Incorporated
10411 Hall Industries Drive
Fredericksburg, Virginia 22408-9406

Dear Mr. Oakman:

On July 23, 1997, a representative of the Food and Drug Administration conducted an inspection of your bus servicing facility at Fredericksburg, Virginia. This inspection was conducted under the authority of the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act.

The List of Observations (FDA-483) was issued to and discussed with Mr. Kevin Roberson, Environmental Control Officer. A copy of the FDA-483 is enclosed for your reference.

The inspection revealed a significant deviation from the Interstate Conveyance Regulations [21 CFR 1250], as follows:

- 1) There was no backflow prevention device upstream from the steam generator and sanitizer mixing valve.

As a result of this finding, this facility has been classified as "Provisional." A reinspection will be conducted on or about August 23, 1997, to determine if future classification will be "Approved" or "Not Approved." A "Not Approved" classification means you cannot provide water/sewage service to buses.

Please advise this office in writing, within 15 days of receipt of this letter, regarding actions taken to correct the deficiencies and to assure that such violative conditions will not recur.

Mr. John R. Oakman

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Your response should be directed to Wiley T. Williamson, III, Compliance Officer. Mr. Williamson can be reached at 410-962-4366, Extension 136.

Sincerely,



Elaine Knowles Cole
Baltimore District Director

Enclosure