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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

May 2, 2002

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

Ref. 2002-DAL-WL-16

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Michael D. Parker
President and CEO
Dow Chemical Company
2030 Dow Center
Midland, Michigan 48674

Dear Mr. Parker:

The U.S. Food and Drug Administration (FDA) inspected your vessel watering point facility, Dow North America Texas Operations, located at 2301 Brazosport Blvd., Freeport, Texas, on April 15, 2002. The observations made during the inspection are in violation of the Public Health Service Act and its implementing regulations for the Control of Communicable Diseases and Interstate Conveyance Sanitation found at Title 21, Code of Federal Regulations (CFR), Parts 1240 and 1250.

FDA's inspection revealed significant insanitary conditions, including:

1. Potable water outlets on docks A8 and A14 were not equipped with backflow prevention devices.
2. The check valve on the potable water outlet on dock A22 was not installed properly.
3. The potable water outlet on dock A22 was directed upward.
4. End caps and keeper chains were not provided for potable water outlets and were missing on all three docks.
5. Potable water outlets on docks A8 and A14 were on the same docks with non-potable outlets and were not identified.

Page 2 – Mr. Michael D. Parker, President and CEO
Dow Chemical Company
May 2, 2002

The list of inspectional observations, identified above, is not intended to be an all-inclusive list of the conditions at your vessel watering point. It is your responsibility to assure adherence to each requirement of the regulations. You should take prompt action to correct these deviations and ensure that future violations do not recur.

At the conclusion of FDA's inspection, a list of Inspectional Observations (FDA Form 483; copy enclosed) was issued to and discussed with Mr. Dennis R. Reiswig, Senior Quality Specialist. Please address each observation in your response letter.

Based on the inspectional observations, FDA is classifying your facility as "Provisional" for interstate carrier use for a period of thirty (30) days. A "Provisional" classification means that the facility may continue to operate; however, significant correction of violations must be made by the expiration date. On or about that date, a re-inspection of this facility will be conducted to assure that corrections meet FDA requirements. If significant corrections are not made at the time of the next inspection, the facility will be reclassified as "Not-approved" for carrier use.

You should notify this office in writing, within fifteen (15) days of receipt of this letter, of the specific steps you have taken to correct the aforementioned violations and to assure that such violations will not recur. If you cannot complete all corrections before you respond, please explain the reason for the delay and provide a deadline by which you will correct any remaining violations.

Your reply should be directed to Elvia Cervantes, Compliance Officer, at the above letterhead address. If you have any questions regarding your obligations under this letter, you may direct them to Ms. Cervantes at the above address or at (214) 253-5312.

Sincerely,



Michael A. Chappell
District Director

MAC:ejc

Enclosure

Cc: Mr. Tommy J. Block
Vice President, Texas Operations
Dow North America Texas Operations
2201 Brazosport Blvd.
Freeport, TX 77541