DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661 Industry Information: www.fda.gov/oc/industry	07/02/2012 - 07/06/2012* FEI NUMBER 3008472092

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Edinson Vergara, President

FIRM NAME	STREET ADDRESS
Mexicali Cheese Corp.	91-52 87th St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Woodhaven, NY 11421-2948	Ready-to-Eat Cheese Manufacturer and Distributor

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Deviation from the procedural requirements of a decree of injunction.

Specifically,

Your firm is bound to Consent Decree for Permanent Injunction, Civil Action #12-415, filed 05/01/12, which specifies in section 5 that you will not receive, prepare, process, pack, hold; or distribute any articles of food unless and until the procedural requirements of the Consent Decree are met; however it was determined that your firm has been receiving, manufacturing, holding, packaging and distributing articles of food, specifically ready-to-eat cheeses, since May 1st, 2012.

Your firm has not complied with the requirements identified in the Consent Decree prior to resuming ready-to-eat cheese manufacturing operations in that:

- Your firm did not cease operations after signing the Consent Decree and continued to manufacture ready-to-eat cheeses from May 1st, 2012 to the present without receiving written notice from the FDA that your firm appears to be in compliance with the requirements set forth in the Consent Decree.
- Your firm did not report to FDA in writing the actions that were taken to bring your operations into compliance with the Consent Decree, including documentation that you have cleaned and sanitized the facility and equipment therein and made improvements; documentation that you have conducted environmental testing in a manner acceptable to the FDA and received laboratory results showing that *L. mono* is no longer present in the facility; specific measures that you have taken to address each of the violations documented by FDA and NYSDAM since January 2009; and a copy of the Listeria Monitoring Program for FDA written approval prior to implementation.
- Your firm did not destroy within thirty (30) calendar days upon entry of the Consent Decree, under FDA's supervision, and according to a destruction plan submitted in writing and approved in writing by FDA prior to implementation, all in-process and finished articles of food in your custody, control, or possession.
- Your firm did not develop a written Listeria Monitoring Program that includes provisions for the following, but not limited to:
  - The written employee training program that you created is not provided in Spanish
  - Your firm has developed an environmental sampling program and conducted sampling, however the results of such sampling were not sent to the FDA within two (2) calendar days

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Valerie A. Potopsingh, Investigator Valerie A Potopsingh Amber D. Brodas, Investigator	07/06/2012