DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
New England District Office 1 Montvale Ave, Stoneham, MA 02180 Tel: (781) 587-7500 Industry Information: www.fda.gov/oc/industry	10/19/12, 11/7/12 and 11/16/12
	FEI NUMBER 3008170448

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Gregory Conigliaro, General Manager

FIRM NAME	STREET ADDRESS
Alaunus Pharmaceutical LLC.	687 Waverly Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Framingham, MA 01702	API Repacker

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 I OBSERVED:

1. The firm repacks Fentanyl, Morphine Sulfate, Methadone, Hydromorphone, and Bupivicaine bulk API into (b) (4) containers. The firm has not performed any testing to assure that the (b) (4) containers are not reactive, additive, or absorptive when used to hold the individual API's.

2. The stability program for the repackaged Fentanyl, Morphine Sulfate, Methadone, Hydromorphone, and Bupivicaine bulk API's is deficient in that:

   - The firm only placed the first lot of each API received on stability.
   - The firm has not placed one lot of each API on stability for each calendar year that the API's were repackaged into (b) (4) containers.
   - For Bupivicaine API lot 10-AA-001, the (b) (4) month time point pull was due in May 2012. The (b) (4) month test point was not pulled and tested. In October 2012 the contract test laboratory opened a deviation as the stability pull was missed. To date, the firm does not have data to support the (b) (4) month time point.

3. The master production records are deficient in that not all critical steps are defined in the master record. For example, after the API is filled into the (b) (4) container, the containers are labeled, and placed into a (b) (4) r (b) (4) bag and sealed. After the bag is sealed, another label is placed on the outside of this (b) (4) bag. The operation to label this outer bag is not a documented step in the master batch record.

4. The batch production records are deficient in that:

   - There is no documentation to indicate which operator added the outer label to the (b) (4) bag and there is no documentation that this step was verified.
   - The verification step/witness step of critical operations occurred approximately 2 weeks after lot 12-AC-001 for Hydromorphone HCL was repackaged.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Debra M. Emerson	Debra M. Emerson, Investigator	11/16/12

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."