DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781) 596-7700 Facsimile (781) 596-7896	04 / 9, 10, and 16 / 2002
	FEI NUMBER 3003623877

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Barry Cadden, R. Ph, Owner and Director of Pharmacy

FIRM NAME	STREET ADDRESS
New England Compounding Pharmacy, Inc.	697 Waverly Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Framingham, MA 01702	Compounding Pharmacy

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. Betamethasone Repository Injection (Betamethasone Acetate and Betamethasone Sodium Phosphate Suspension 6 mg/ml), a product which is intended to be sterile, is sampled for sterility and endotoxin testing immediately after sterilization of the bulk compounded product in a (b) (4) beaker. Individual vials of Betamethasone Repository are not filled until the test results for sterility and endotoxin (pyrogen) are received from the contract testing laboratory, a process which can take up to one week after the sterilization and sampling of the bulk product have occurred. While laboratory test results are pending, the (b) (4) beaker and its contents are stored in the firm's laminar flow hood. The only other measure taken during this period to prevent recontamination of the bulk suspension is the use of a covering of multiple layers of aluminum foil over the mouth of the beaker.

2. The samples taken immediately after completion of the autoclave sterilization cycle (b) (4) are not representative of product that remains in the original (b) (4) beaker for up to one week past the time of sampling.

3. The firm's validation of the autoclave cycle does not take into account the fact that the autoclaved bulk product is not transfilled into a final container/closure system (vials) for a period of up to one week.

4. On at least one occasion, a lot number (Lot 02 01 2002@027) was generated in the firm's computerized record keeping system, for which no associated records could be retrieved. It cannot be determined whether:

· this lot was distributed and records covering its preparation were never created or are no longer in existence, or
· the preparation of this lot never proceeded, but no record of its cancellation was entered in the record keeping system

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Constance DeSimone, Investigator Kristina M. Joyce, Investigator Mark Lookabaugh, Compliance Officer	04 / 16 / 2002