DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue, 4th Floor Stoneham, MA 02180 (781) 596-7700	10/24, 12/12&18/02, 1/14-15/03, 2/10/03
	FEI NUMBER 3003623877

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Barry J. Cadden, Director of Pharmacy

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

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

The below observations pertain to drug products that personnel prepare at your firm for which you claim are sterile (for example, injections) and are prepared in anticipation of a prescription.

1. For the preparation of sterile drug products distributed by your firm (such as those intended for injection), there is no adequate documentation available to verify that they meet set standards (such as specifications and/or USP limits if applicable) at the time they are distributed or for the shelf life (expiration dating period) of these products. This includes the absence of documentation to verify the following:

A. Personnel performing preparation steps are not contaminating the finished products.

B. Workspaces are cleaned and sanitized to prevent product contamination.

C. Equipment and supplies entering the product preparation area are decontaminated/cleaned to prevent product contamination.

D. The environment in the area where the filling and closing operations are performed is adequate to prevent product contamination (this includes the lack of documentation pertaining to environmental monitoring in the immediate area while product is exposed to the environment, such as during filling and prior to container closure).

E. All autoclave sterilization processes are suitable for the sterilization of drug product preparation equipment and components (which includes vial stoppers and bulk product). Some examples are:

a. Lack of documentation to verify that all critical processing parameters and procedures being used are appropriate in ensuring that final products meet all standards (such as sterility); this includes, sterilization time, temperature, size and nature of load, and chamber loading configuration.

b. Records do not state the actual critical parameters used during processing.

c. Lack of documentation to verify that the autoclave itself is maintained and calibrated to perform its intended function.

d. The autoclave process used on bulk drug products does not have an effect on stability or product specifications.

F. The transfer of bulk drug product and equipment from the autoclave (after it went through an autoclave process) from one room to another room in which further preparation steps are performed in a laminar air flow workbench, is not introducing contamination into the finished product.

G. All components, including drug substances, vials, and rubber stoppers, meet set standards making them suitable for their intended use. This includes that components and process water are not contaminating finished products.

H. Equipment used to measure the amount of ingredients/components are calibrated and maintained to perform their intended function.

I. Testing procedures and sampling procedures being performed for all drug products are representative of the lots/batches being tested.

J. That for each preparation of a sterile product or batch of sterile products there has been appropriate laboratory determination of conformity with purity, ~~strength~~, sterility, and non-pyrogenicity, in accordance with established written specifications and policies.

K. Preparation steps are being performed in a correct manner since batch record preparation instructions are lacking significant preparation steps, which includes mixing procedures.

L. Final containers are capable of maintaining product integrity (i.e. identity, strength, quality, and purity) throughout

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Daryl A. Dewoskin Kristina M Joyce	Daryl A. DeWoskin, CSO Kristina M. Joyce, CSO	2/10/03 2/10/03

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the shelf life of the product.

M All drug products prepared and packaged at your site meet specifications and USP limits (if applicable) for the expiration dating period assigned. According to documentation and your statements, all drug products are assigned an expiration date of 60 days if they do not contain a preservative, three months if they are not filtered, and 6 months if they are filtered. No data was available for any of your products prepared at your firm to support these expiration date periods.

In addition, for all of the items above there were no written procedures available pertaining to the performance of these duties and processes.

2. There are no written procedures pertaining to the handling of complaints, nor does your firm maintain a complaint file.

3. There was no documentation available for the handling and disposition of reports of patient problems, complaints, adverse drug reactions, drug product or device defects, and other adverse events reported. For example, after a medical facility reported adverse events associated with lot 05312002@16, your firm conducted a recall of injectable steroid products and implemented shorter expiration dates and use of pre-sterilized vials. You stated you have no documentation available pertaining to an investigation being performed for this and other related lots which shows that adequate follow-up action was taken.

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