[redacted]

From: [redacted]
Sent: Wednesday, December 12, 2007 9:50 AM
To: [redacted]
Cc: Nasr, Samia; [redacted] Anderson, Kathleen R; Levy, Michael
Subject: FW: Complaint received about celestone(betamethasone)

Importance: High

Additional email.

-----Original Message-----
From: [redacted]
Sent: Monday, December 10, 2007 8:26 PM
To: [redacted]
Cc: [redacted], Jeffrey; Nasr, Samia; [redacted]
Subject: RE: Complaint received about celestone(betamethasone)
Importance: High

Compounding issues/concerns are not covered for follow-up by the Drug Quality Reporting Program. Division of New Drugs & Labeling Compliance (DNDLC HFD-310) Pharmacy Compounding Team should receive the e-mail attached below.

[redacted] DQRS/FARS Program Manager Division of Compliance Risk Management & Surveillance Center for Drug Evaluation & Research HFD 330
11919 Rockville Pike
Room 316 (Montrose Metro 2)
Rockville, MD 20852
[redacted]

-----Original Message-----
From: [redacted]
Sent: Monday, December 10, 2007 4:08 PM
To: [redacted]
Cc: [redacted]
Subject: FW: Complaint received about celestone(betamethasone)

Thanks [redacted] This doesn't look like anything for OCI at this time, but if CDER or a DO looks into this compounding center and finds something criminal in nature, we would gladly take a look at it again.

[redacted]
Special Agent
Senior Operations Manager
FDA Office of Criminal Investigations (OCI) Headquarters Office

Documen [redacted]

-----Original Message-----
From:
Sent: Friday, December 07, 2007 6:55 AM
To:
Cc:
Subject: FW: Complaint received about celestone(betamethasone)

From:
Sent: Thursday, December 06, 2007 7:53 PM
To:
Cc:
Subject: FW: Complaint received about celestone(betamethasone)

Do you know if the information in your 33 page FAX of patient reports has been sent to MedWatch? If not, we should talk with about how to approach this.

Thanks,

Associate Director of Emergency Risk Communication Office of Counterterrorism and Emergency Coordination
CDER/FDA White Oak Complex, 1608
10903 New Hampshire Ave.
Silver Spring, MD 20993

From:
Sent: Thursday, December 06, 2007 1:53 PM
To:
Cc: CDER-ER-OPS; FDA Emergency Operations
Subject: Complaint received about celestone(betamethasone)

After hour call received by OEO:

caller:
caller is a physician pain specialist who treats patients with epidural injections. For a period of time, he was treating fibromyalgia patients with epidural injections of betamethasone manufactured by New England Compounding Center,

Framingham(sp) Mass. Product is called celestone(betamethasone)W and he reported that between August 22 and October 5 he noticed that some vials of product were discolored(which he discarded) but others, which appeared normal, were administered and his patients started having problems. He noted that Shering-Plough manufactured this product for a number of years, and he had great success with the NECC material for some time, but ended up having to switch to triamcinolone and eventually to another compounding pharmacy. Sent 33 page fax of patient reports of flare-ups and wanted FDA to be aware of this problem, which he reports has been damaging to his practice. He stated that he would cooperate if we wished to follow-up.

Please follow up with Dr. [redacted]

Thank you,

[redacted]

[redacted]
Emergency Coordinator
Food and Drug Administration
Office of Crisis Management
Office of Emergency Operations
5600 Fishers Lane
HFA-615 Room 12A-55
Rockville, MD 20857
[redacted]

Documen [redacted]