DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax: (510) 337-6702 Industry Information: www.fda.gov/oc/industry	04/27/2011-05/06/2011
	FEI NUMBER 3005615655

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: - - -

FIRM NAME	STREET ADDRESS
- - -	- - -
CITY, STATE, ZIP CODE, COUNTRY	**TYPE ESTABLISHMENT INSPECTED**
Palo Alto, CA 94304-1212	Sponsor

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Not all adverse drug experiences that are both serious and unexpected have been reported to FDA within 15 calendar days of initial receipt of the information. Specifically, on 4/21/2001, your firm was made aware of seventy four (74) confirmed death reports for drug product Xyrem retained by your specialty pharmacy during the time period of November 2002-April 2001 that were not expeditiously reported within 15calendar days to the agency. These seventy four (74) confirmed death reports were previously undetected through the monitoring of your specialty pharmacy. A representative sample of these seventy four (74) confirmed death reports exceeding the 15-day reporting time-frame andthat are more than 2000 days late are summarized as follows:

Date Information Received at Specialty Pharmacy	15-Day Report Submission Due Date	15-Day Report Submission Date	Days Late
7/1/2003	7/16/2003	5/6/2011	2851
7/29/2003	8/13/2003	5/6/2011	2823
11/3/2003	11/18/2003	5/6/2011	2726
12/3/2003	12/18/2003	5/6/2011	2696
3/17/2004	4/1/2004	5/6/2011	2591

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Daniel J. Roberts, Investigator	05/06/2011

FORM FDA 483 (09/08) **PREVIOUS EDITION OBSOLETE** **INSPECTIONAL OBSERVATIONS**

FIGURE 32.1 Example of an FDA Form 483, as filled out by an FDA investigator. The issue of this Form 483 was adverse event reporting.

after a delay of many months (19,20). A small number of issued Form 483s are posted on the FDA's website and are available without delay, but the number is too small to provide any real guidance. Fig. 32.1 provides an example of an issued Form 483 (the names of the company and company employees are redacted) (Fig. 32.1).

[19]In this author's own experience, acquired at Cerus Corporation in Concord, CA, it took about 8 months to acquire a document from the Freedom of Information Act Office. The document was a grant application that had been submitted to National Institutes of Health (NIH).

[20]Chen T. Who can see Form FDA 483s, and where do I get them? FDAzilla.com. Yorkville, IL; 2011 (accessed from internet on July 10, 2015).