Deaths in Dexmedetomidine Clinical Studies
As Reported by: October 5, 1999

	Number of Deaths				
	By Treatment				Total
	Dex	Placebo	Active Control	None*	
Phase I					
Abbott	0	0	0	0	0
Orion	0	0	0	0	0
Total	0	0	0	0	0
Phase II - Abbott					
W97-249	1	0	0	0	1
W98-263	4	0	0	0	4
W98-264	2	0	0	0	2
W98-274	0	1	0	0	1
Total	7	1	0	0	8
Phase II - Orion					
F-DEX-CL-0192-USA	0	1	0	0	1
3005006	1	1	0	0	2
Total	1	2	0	0	3
Phase II - Abbott + Orion	8	3	0	0	11
Phase III - Abbott					
DEX95-002	2	1	0	0	3
DEX95-004	2	1	0	0	3
DEX96-014	0	1	0	0	1
DEX96-015	3	2	0	0	5
DEX96-021	1	0	0	0	1
W97-245	0	8	0	3	11
W97-246	7	3	0	1	11
Total	15	16	0	4	35
Phase III - Orion					
3005003	0	1	0	0	1
Phase III - Abbott + Orion	15	17	0	4	36
Phases I, II, III					
Abbott	22	17	0	4	43
Orion	1	3	0	0	4
Total	23	20	0	4	47
Academic -GBNI99-102	2	0	0	0	2

* Treatment is 'None' if death occurred prior to treatment

SOURCES:
Abbott Studies - SAGE Report 05Oct99
Orion Studies - Synopses
GBNI99-102 - SAGE Report 05Oct99

ABBOTT
Hospital Products Division
200 Abbott Park Rd.
Abbott Park, IL 60064-3537

To: Dr Susmita Samanta

Company:

FAX #: 301-480-8682

Date: 10/5/99

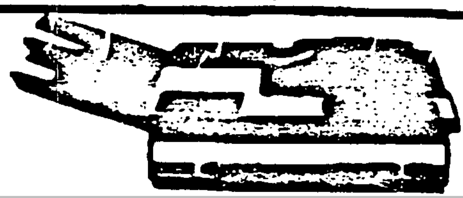
No. of Pages: 4 (including cover page)

From: Jean Conaway
Regulatory Affairs D389/AP30

(847) 937-3413 (telephone)
(847) 938-7867 (fax)

Here is a working draft copy of the cover letter only.
The original will be dated and processed 10/6/99 to the
address on the letter.

Jean Conaway



ABBOTT

Hospital Products Division
Abbott Laboratories
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-3537

October 5, 1999

CENTER FOR DRUG EVALUATION AND RESEARCH
ANESTHETIC, CRITICAL CARE & ADDICTION DRUG PRODUCTS, HFD #170
Attn: DOCUMENT CONTROL ROOM #9B-23
5600 Fishers Lane
Rockville, Maryland 20857-1706

ATTENTION: Cynthia McCormick, M.D.
Director

Fax: Dr. Susmita Samanta
301-480-8682

Re: NDA 21-038 Dexmedetomidine Hydrochloride Injection

Abbott Laboratories hereby amends the above-referenced new drug application for the subject drug product to provide for Case Report Forms (CRFs) and a table for the nine specified patients. We are responding to the teleconference on October 4, 1999 between Dr. Patricia Hartwell and Dr. Susmita Samanta, FDA and Dr. Thomas Willer, Abbott Laboratories.

The Agency requested the following:

REQUEST: **Please provide CRFs for all nine deaths specified in the teleconference between the Agency and Abbott Laboratories on September 28, 1999 and reported in the amendment dated October 1, 1999.**

RESPONSE: The nine patients reported in the amendment dated October 1, 1999 are as follows:

Study No.	Patient Number	CRF Available	PCA No./ Related or Unrelated	Study Drug
W97-245	#01001*	Yes	9906355- Unrelated	Placebo-died 5 days post-study
W97-245	#10401*	Yes	9907455- Unrelated	Placebo-died 12 days post-study
W97-245	#105	No	9905913- Unrelated	None received
W97-245	#6301	No	9906686- Unrelated	None received
W97-245	No # assigned**	No	9906525- Unrelated	None received
W97-246	#704	No	9907483- Unrelated	None received
W97-246	#12406*	Yes	9907027- Unrelated	Placebo- died 35 days post-study
W97-246	#11601	Yes	9906654- Unrelated	Dexmedetomidine- died 5 days post-study
3005003 (Orion)	#0901	Yes	9904548-Probably not related	Placebo- died 1 month post-study

*Included in the Integrated Summary of Safety, Appendix B, submitted as part of NDA-21-038, Volume 301 of 726, page 8/10-238-162. Not included in the clinical safety database.

**Consent form signed, but patient was not randomized prior to the start of surgery. Patient died intraoperatively.

Provided in EXHIBIT I are Case Report Forms for the following five patients:

01001, 010401, 012406, 011601, 0901.

The Case Report Forms for the remaining four patients will be sent to the Agency as soon as available.

REQUEST: **Please provide a table which includes the number of deaths according to the following:**

1. **Groups: dexmedetomidine, placebo and active control groups,**
2. **Sponsor: Abbott , Orion and total,**
3. **Clinical Study Phase: Phase I, II and III.**

RESPONSE: The above request is acknowledged and will be provided as soon as available.

Cynthia McCormick, M.D.
Page Three
October 5, 1999

If you have any additional questions, please do not hesitate to contact me at (847) 937-3413 or after October 7, 1999, Dr. Thomas Willer at (847) 937-6845.

Sincerely,

ABBOTT LABORATORIES

Jean M. Conaway

Jean M. Conaway, R.Ph.
Manager, Regulatory Affairs
Hospital Products Division
Phone: (847) 937-3413
Fax: (847) 938-7867

JMC:jmc

G:\10-99\da.jmc.doc1

APPEARS THIS WAY
ON ORIGINAL

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.