

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Special Nutritionals

ARMS#

12871



8 - OTHER

**000001**

February 23, 1998

Lori A. Love, M.D., Ph.D.  
Director of Clinical Research and Review Staff  
Office of Special Nutrition  
CFSAN/FDA  
Room 2025  
200 C Street, SW  
HFS 452  
Washington, DC 20204

Dear Dr. Love:

Per our conversation, enclosed you will find the Standard Operating Procedures (SOPs) for the handling of chain of custody cases at [redacted] the quantitation and differentiation of ephedrine and pseudoephedrine and the gas chromatographic/ion trap detection (GC/ITD) confirmation technique. Please note, the SOP for the GC/ITD is general and does not, within its body, contain reference to ephedrine and pseudoephedrine, since this method of detection is used for many compounds. In reference to ephedrine and pseudoephedrine, the GC/ITD analysis would be performed on a specimen aliquot separate from that used for the quantitation. In addition, the second aliquot would be subjected to the same extraction and derivitization processes.

The per-specimen cost for the analyses is \$ 176.60. It is test code [redacted]

Also enclosed is the information regarding the amounts of specimen we have left on the three cases we have in-house.

If you have any additional questions or concerns, please do not hesitate to call me.

Sincerely,

[redacted signature]

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CLINICAL RESEARCH & REVIEW/SN/HFS/452

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5-Jun-98

POSTMORTEM FORENSIC TOXICOLOGICAL ANALYSES FOR EPHEDRINE,  
PSEUDOEPHEDRINE, METHYLEPHEDRINE AND PHENYLPROPANOLAMINE

Control No. [REDACTED]

	EPHEDRINE	PSEUDO-EPHEDRINE	METHYL-EPHEDRINE	PHENYL-PROPANOLAMINE	GC/MS REPORTING LIMIT (nanog/mL)*	LC/MS REPORTING LIMIT (nanog/mL)
SPECIMEN	none detected	none detected	none detected	none detected	4	10
PLASMA						

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[REDACTED]

**Memorandum to ARMS # 12871**

Date: 7/29/99

From: Medical Officer, Clinical Research and Review Staff, Office of Special Nutritionals, HFS-452

Subject: Medical Records Placed in Permanent Storage.

The following types and amounts of records (more than 20 pages total) were placed in permanent storage on this date because they were not considered essential for interpretation of this adverse event.

Approx Pages	Type of Records
	Nursing notes
	Dietitian notes
	Respiratory therapy/occupational therapy/physical therapy notes
	Clergy notes
	Medication records
	Physician's orders
	Vital signs, fluids, input/output records
	Ventilator records
13	Hospital administrative records (e.g., insurance information, living will, etc)
16	Organ Donation

V. Cheesema  
for H. Slifman