CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

18896Orig1s012

Trade Name:	**Potassium Acetate Injection**
Generic or Proper Name:	
Sponsor:	HOSPIRA INC
Approval Date:	December 24, 2004
Indication:	**Potassium Acetate Injection** is indicated as a source of potassium, for the addition to large volume intravenous fluids, to prevent or correct hypokalemia in patients with restricted or no oral intake. It is also useful as an additive for preparing specific intravenous fluid formulas when the needs of the patient cannot be met by standard electrolyte or nutrient solutions.

CENTER FOR DRUG EVALUATION AND RESEARCH

18896Orig1s012

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18896Orig1s012

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-896/S-012

Abbott Laboratories
D-389, Bldg. J45-2N
200 Abbott Park Road
Abbott Park, Illinois 60064-6133

Attention: Nicohl R. Wilding
Regulatory Specialist

Dear Ms. Wilding:

Please refer to your supplemental new drug application dated July 25, 2002, received July 26, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Potassium Acetate Injection, USP, in Plastic Vials.

We acknowledge receipt of your submission dated August 16 and October 31, 2002.

This "Changes Being Effected" supplemental new drug application provides for a revised package insert. The WARNINGS and PRECAUTIONS sections are revised to include the statement regarding the aluminum content per the requirements of 21 CFR 201.323.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted July 25, 2002, immediate container and carton labels submitted August 16, 2002). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Victoria Kao, Regulatory Project Manager, at (301) 827-7416.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Acting Director
Division of Anesthetic, Critical Care,
And Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Bob Rappaport

12/24/02 12:43:17 PM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18896Orig1s012

LABELING

20 mL Single-dose

POTASSIUM ACETATE

Injection, USP

40 mEq (2 mEq/mL)

CAUTION: MUST BE DILUTED.
FOR I.V. USE.

ABBOTT LABS., N. CHICAGO, IL 60064, USA

K+

NDC 0074-8183-01

Each mL contains potassium acetate, anhyd. 196 mg. 4 mOsmol/mL (calc). pH 6.2 (5.5 to 8.0). May contain acetic acid for pH adjustment. Sterile, nonpyrogenic. Usual dose: See insert. Use only if clear and seal is intact and undamaged. Contains no bacteriostat; use promptly, discard unused portion. Contains no more than 200 mcg/L of aluminum.

℞ only

58-3832-3/R12-10/02

USE ASEPTIC TECHNIQUE

Remove cover from Fliptop vial and cleanse stopper with antiseptic.
Add to a suitable solution in an I.V. container.

Store at controlled room temperature 15° to 30°C (59° to 86°F).

257

20 mL Single-dose

POTASSIUM ACETATE Injection, USP
40 mEq (2 mEq/mL)

℞ only

ABBOTT LABORATORIES, N. CHICAGO, IL 60064, USA

CAUTION:
MUST BE DILUTED.
FOR I.V. USE.

25 Units/**NDC 0074-8183-01**

20 mL Single-dose

POTASSIUM ACETATE Injection, USP
40 mEq (2 mEq/mL)

℞ only

ABBOTT LABORATORIES, N. CHICAGO, IL 60064, USA

CAUTION:
MUST BE DILUTED.
FOR I.V. USE.

25 Units/**NDC 0074-8183-01**

(01) 1 030074 818301 8

Each mL contains potassium acetate, 196 mg.
May contain acetic acid for pH adjustment.
4 mOsmol/mL (calc). pH 6.2 (5.5 to 8.0).
Usual dose: See insert.
Sterile, nonpyrogenic.

Aseptically add to a suitable I.V. solution. Contains no bacteriostat; use promptly; discard unused portion. Use only if clear and seal is intact and undamaged.

98-4482.3/R7-10/98

Printed in USA

POTASSIUM ACETATE
Injection, USP
40 mEq in 20 mL
(2 mEq K^+ and 2 mEq CH_3COO^-/mL)
FOR ADDITIVE USE ONLY AFTER DILUTION IN I.V. FLUIDS
Plastic Vial ℞ only

DESCRIPTION
Potassium Acetate Injection, USP, 40 mEq (2 mEq/mL) is a sterile, nonpyrogenic, *concentrated solution* of potassium acetate in water for injection. The solution is administered after dilution by the intravenous route as an electrolyte replenisher. *It must not be administered undiluted.*

58- 6820 -R13-Rev. April, 2002

Each 20 mL vial contains 3.93 g of potassium acetate which provides 40 mEq each of potassium (K^+) and acetate (CH_3COO^-). It contains no bacteriostat, antimicrobial agent or added buffer. May contain acetic acid for pH adjustment. pH 6.2 (5.5 to 8.0). The osmolar concentration is 4 mOsmol/mL (calc.).

The solution is intended as an alternative to potassium chloride to provide potassium ion (K^+) for addition to large volume infusion fluids for intravenous use.

Potassium acetate, USP is chemically designated CH_3COOK, colorless crystals or white crystalline powder very soluble in water.

The semi-rigid vial is fabricated from a specially formulated polyolefin. It is a copolymer of ethylene and propylene. The safety of the plastic has been confirmed by tests in animals according to USP biological standards for plastic containers. The container requires no vapor barrier to maintain the proper drug concentration.

CLINICAL PHARMACOLOGY

As the principal cation of the intracellular fluid, potassium plays an important role in fluid and electrolyte balance. The normal potassium concentration in the intracellular fluid compartment is about 160 mEq/liter. The normal serum potassium range is 3.5 to

5.0 mEq/liter. The kidney normally regulates potassium balance but does not conserve potassium as well or as promptly as it conserves sodium. The daily turnover of potassium in the normal adult averages 50 to 150 mEq (milliequivalents) and represents 1.5 to 5% of the total potassium content of the body.

Acetate (CH_3COO^-), a source of hydrogen ion acceptors, is an alternate source of bicarbonate (HCO_3^-) by metabolic conversion in the liver. This has been shown to proceed readily, even in the presence of severe liver disease.

INDICATIONS AND USAGE

Potassium Acetate Injection, USP, 40 mEq is indicated as a source of potassium, for the addition to large volume intravenous fluids, to prevent or correct hypokalemia in patients with restricted or no oral intake. It is also useful as an additive for preparing specific intravenous fluid formulas when the needs of the patient cannot be met by standard electrolyte or nutrient solutions.

CONTRAINDICATIONS

Potassium administration is contraindicated in patients with severe renal insufficiency or adrenal insufficiency and in diseases where high potassium levels may be encountered.

WARNINGS

Potassium Acetate Injection, USP, 40 mEq must be diluted before use.

To avoid potassium intoxication, infuse potassium-containing solutions slowly. Potassium replacement therapy should be monitored whenever possible by continuous or serial electrocardiography (ECG). Serum potassium levels are not necessarily dependable indicators of tissue potassium levels.

Solutions which contain potassium ions should be used with great care, if at all, in patients with hyperkalemia, severe renal failure and in conditions in which potassium retention is present.

In patients with diminished renal function, administration of solutions containing potassium ions may result in potassium retention.

Solutions containing acetate ions should be used with great care in patients with metabolic or respiratory alkalosis. Acetate should be administered with great care in those conditions in which there is an increased level or an impaired utilization of this ion, such as severe hepatic insufficiency.

WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature

neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

PRECAUTIONS

Do not administer unless solution is clear and seal is intact. Discard unused portion.

Potassium replacement therapy should be guided primarily by ECG monitoring and secondarily by the serum potassium level.

High plasma concentrations of potassium may cause death by cardiac depression, arrhythmias or arrest.

Use with caution in the presence of cardiac disease, particularly in digitalized patients or in the presence of renal disease.

Solutions containing acetate ion should be used with caution as excess administration may result in metabolic alkalosis.

Pregnancy Category C.
Animal reproduction studies have not been conducted with potassium acetate. It is also not known whether potassium acetate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Potassium acetate should be given to a pregnant woman only if clearly needed.

Pediatric Use: The safety and effectiveness of potassium acetate have been established in pediatric patients.

Geriatric Use: An evaluation of current literature revealed no clinical experience identifying differences in response between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Potassium ions are known to be substantially excreted by the kidney, and the risk of toxic reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

ADVERSE REACTIONS

Adverse reactions involve the possibility of potassium intoxication. The signs and symptoms of potassium intoxication include paresthesias of the extremities, flaccid paralysis, listlessness, mental confusion, weakness and heaviness of the legs, hypotension, cardiac arrhythmias, heart block, electrocardiographic abnormalities such as disappearance of P waves, spreading and slurring of the QRS complex with development of a biphasic curve and cardiac arrest. See WARNINGS and PRECAUTIONS.

OVERDOSAGE

In the event of overdosage, discontinue infusion containing potassium acetate immediately and institute corrective therapy as indicated to reduce elevated serum potassium levels and restore acid-base balance if necessary. See WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.

DOSAGE AND ADMINISTRATION

Potassium Acetate Injection, USP, 40 mEq is administered intravenously *only after dilution in a larger volume of fluid.* The dose and rate of administration are dependent upon the individual needs of the patient. ECG and serum potassium should be monitored as a guide to dosage. Using aseptic technique, all or part of the contents of one or more vials may be added to other intravenous fluids to provide any desired number of milliequivalents (mEq) of potassium (K^+) with an equal number of milliequivalents of acetate (CH_3COO^-).

Maximum infusion rate: The infusion rate should not exceed 1 mEq/kg/hr.

Normal daily requirements:

Newborn:	2-6 mEq/kg/24 hr.
Children:	2-3 mEq/kg/24 hr.
Adult:	40-80 mEq/24 hr.

Intraosseous infusion can be an alternate route for drug administration when intravenous access is not readily available.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. See PRECAUTIONS.

HOW SUPPLIED

Potassium Acetate Injection, USP, 40 mEq (2 mEq/mL) of K^+ is supplied in a 20 mL partial-fill single-dose fliptop vial (List 8183).

Each container is partially filled to provide air space for complete vacuum withdrawal of the contents into the I.V. container.

Store at controlled room temperature 15° to 30°C (59° to 86°F) (see USP).

Printed in USA

ABBOTT LABORATORIES, NORTH CHICAGO, IL 60064, USA

POTASSIUM ACETATE
Injection, USP
40 mEq in 20 mL
(2 mEq K^+ and 2 mEq CH_3COO^-/mL)
FOR ADDITIVE USE ONLY AFTER DILUTION IN I.V. FLUIDS
Plastic Vial

℞ only

DESCRIPTION

Potassium Acetate Injection, USP, 40 mEq (2 mEq/mL) is a sterile, nonpyrogenic, *concentrated solution* of potassium acetate in water for injection. The solution is administered after dilution by the intravenous route as an electrolyte replenisher. *It must not be administered undiluted.*

58- 6820 -R13-Rev. April, 2002

APPROVED

DEC 24 2002

20 mL Single-dose

POTASSIUM ACETATE
Injection, USP
40 mEq (2 mEq/mL)

CAUTION: MUST BE DILUTED.
FOR I.V. USE.

ABBOTT LABS., N. CHICAGO, IL 60064, USA

K^+

NDC 0074-8183-01

Each mL contains potassium acetate, anhyd. 196 mg, 4 mOsmol/mL (calc), pH 6.2 (5.5 to 8.0). May contain acetic acid for pH adjustment. Sterile, nonpyrogenic. Usual dose: See insert. Use only if clear and seal is intact and undamaged. Contains no bacteriostat; use promptly, discard unused portion. Contains no more than 200 mcg/L of aluminum.

℞ only

58-3343-3/R11-4/02

Labeling: SCS-012 BL

NDA No 18896 Rec'd 8-16-02

Reviewed by: [signature] 1/28/03

APPROVED

DEC 2 4 2002

20 mL Single-dose

POTASSIUM ACETATE
Injection, USP
40 mEq (2 mEq/mL)

K+

CAUTION: MUST BE DILUTED. FOR I.V. USE.

ABBOTT LABS., N. CHICAGO, IL 60064, USA

NDC 0074-8183-01

Each mL contains potassium acetate, anhyd. 196 mg. 4 mOsmol/mL (calc). pH 6.2 (5.5 to 8.0). May contain acetic acid for pH adjustment. Sterile, nonpyrogenic. Usual dose: See insert. Use only if clear and seal is intact and undamaged. Contains no bacteriostat; use promptly, discard unused portion. Contains no more than 200 mcg/L of aluminum.

℞ only

58-3343-3/R11-4/02

Labeling: SES→12 BL

NDA No 18996 Rec'd 8.16→2

Reviewed by: VDa

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18896Orig1s012

PRODUCT QUALITY REVIEW(S)

	1.ORGANIZATION	2. NDA NUMBER
CHEMIST'S REVIEW	DMEDP, HFD-510	18-896
3. NAME AND ADDRESS OF APPLICANT		4.SUPPLEMENT NUMBER,DATE
Abbott Laboratories, Hospital Products Division D-389, Building J45-2N, 200 Abbott Park Road Abbott Park, Illinois 60064-6133		SCS-012 (CBE-0), dated 7-25-02 User Fee Date: 1-26-02
5. NAME OF THE DRUG	6. NONPROPRIETARY NAME	
Potassium Acetate Injection, USP, in Plastic Vials	Potassium Acetate Injection, USP	
		8.AMENDMENTS/REPORT,DATE
7. SUPPLEMENT PROVIDES FOR:		Amendment dated 10-31-02
Aluminum content labeling per 21 CFR 201.323.		
9. PHARMACOLOGICAL CATEGORY	10. HOW DISPENSED	11.RELATED IND/NDA/DMF
Small volume parenteral (SVP)	Rx only	
12. DOSAGE FORM	13. POTENCY	
Sterile solution for injection	40 mEq/vial (2 mEq/mL in 20 mL vials)	

14. CHEMICAL NAME AND STRUCTURE.

Potassium Acetate, USP ($CH_3COO^- K^+$), 98.14 g/mol

15. COMMENTS

NDA 18-896/SCS-012 is a Changes Being Effected (CBE-0) supplement providing aluminum labeling in accordance with the requirements of 21 CFR 201.323. This review is being done as a consult for the Division of Anesthetic and Critical Care Drug Products (HFD-170). The supplement provides a warning statement about aluminum toxicity (included in the WARNINGS section of the package insert) per 201.323 (d) and a statement of the maximum level of aluminum at expiry (on the immediate container label) per 201.323 (c). In addition, information is provided regarding a validated analytical method for the determination of aluminum per 201.323 (e) and data is provided in support of the aluminum content statement per 201.323 (c) (1), (2), and (3). The labeled aluminum content for potassium acetate injection, USP (List 8183) is "Not more than 200 mcg/mL of aluminum". This sNDA did not involve microbiological or site-specific (inspection) issues. The amendment dated October 31st, 2002 provided an updated stability specification for the drug product.

16. CONCLUSION AND RECOMMENDATION

Adequate information was provided regarding chemistry, manufacturing and controls. The application may be approved from the standpoint of chemistry. Issue and approval letter.

17. NAME	REVIEWER SIGNATURE	DATE COMPLETED
David B. Lewis, Ph.D.		November 15th, 2002

DISTRIBUTION: ORIGINAL JACKET CSO REVIEWER DIVISION FILE

Chemist's Review Notes:

A: Drug Substance: Chemistry, manufacturing and controls information regarding the drug substance, potassium acetate, USP, is unchanged from that, which was previously approved. The supplier of (b) (4) as provided for the original NDA (submitted in November 1982). Potassium acetate is supplied (b) (4) (b) (4) and the (b) (4) (b) (4)

B: Drug Product: The drug product, Potassium Acetate Injection, USP in Plastic Vials (List 81831) is provided as a 2 mEq/mL injection in 20-mL fliptop plastic vials). The total dose is 40 mEq per vial. No changes were provided regarding components & composition, raw material controls, manufacture (processes or manufacturing site), regulatory specifications at release, or container closure. This sNDA provides a revised stability protocol containing a new test for aluminum determination and aluminum content labeling statements, as required by 21 CFR 201.323.

1. Components and Composition: Unchanged (N/A)
2. Raw Material Controls: Unchanged (N/A)
3. Manufacturer: Abbott Laboratories, at the following facilities:

(b) (4)

Comments: These facilities are approved for the drug product. No CMC-related changes were provided in this supplemental application except for the reduction in expiry; thus, no cGMP inspection was required.

4. Manufacturing and Packaging: Unchanged (N/A)
5. Specifications and Analytical Methods: Unchanged. (b) (4) (b) (4) since this drug product is an SVP. There is no regulatory limit for aluminum content. Aluminum testing was added to the stability specification, and is reviewed in Section 7 "Stability of the Drug Product" of this review.
6. Containers: Unchanged (N/A)
7. Stability of the Drug Product: The stability protocol has been revised (b) (4) (b) (4)

Background: (b) (4) (b) (4)

3 Page(s) has been Withheld in Full as b4 (CCI/TS) immediately following this page

(b) (4)

From these results, Abbott has labeled Potassium acetate injection, USP (List 8183) as follows:

"Contains no more than 200 micrograms/Liter of aluminum".

The method by which this level was determined in provided in EXHIBIT IV, p. 27 (INTEROFFICE COMMUNICATION dated August 2nd, 2001). The following criteria apply to the setting of aluminum levels (label claim & stability acceptance criteria) for SVP drug products:

(b) (4)

Comments: According to 21 CFR 201.323(c), the labeled amount of aluminum (maximum potential level) must be stated as the highest of the following determinations:

(1) The highest level for the batches produced during the last 3 years
(2) The highest level for the latest 5 batches
(3) The maximum historical level, but only until completion of production of the 1st 5 batches after January 26th, 2001

Evaluation: *Adequate*. Data was accumulated for 5 batches (b) (4) (b) (4) The data was obtained per 21 CFR 201.323(c)(3). (b) (4) This is acceptable, since the label claim is a more conservative estimate of aluminum content (b) (4)

A revised stability protocol was provided in the amendment dated October 31st, 2002. (b) (4) (b) (4)

Comments: The testing schedule for aluminum (b) (4) was agreed upon in a meeting between the FDA (b) (4) held on June 1st, 2000. (b) (4) (b) (4)

Evaluation: *Adequate*. Since there is no regulatory limit for aluminum content in SVP drug products utilized as total parenteral nutritional additives, the claim (b) (4) is acceptable. In the case of aluminum determination (b) (4) (b) (4)

C: Labeling: Twelve (12) copies of Final printed Labeling (FPL) were provided in EXHIBIT V (package insert). There were no copies of the immediate container label, but a statement was made in the cover letter of the supplement that the statement "Contains no more than 200 mcg/L of aluminum" will be added to the immediate container label.

The package insert includes the aluminum toxicity statement, as required in 21 CFR 201.323(d) under ***WARNINGS***. SVP drug products are not required to provide an aluminum content statement in the package insert; this is only required for LVP drug products, which must comply with a limit of 25 mcg/L of aluminum.

Comments and evaluation: *Adequate*. The labeling complies with the requirements of 201.323 (c) and (d).

D: Environmental Impact Analysis Report: N/A

E: Sample and Results: N/A

F: Establishment Inspection: N/A

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/s/

David Lewis
12/12/02 02:09:08 PM
CHEMIST
The application may be approved from the standpoint of chemistry.

Sheldon Markofsky
12/13/02 08:09:57 AM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18896Orig1s012

OTHER REVIEW(S)

Division of Anesthetic, Critical Care, and Addiction Drug Products

PROJECT MANAGER REVIEW

Application Number: NDA 18-896 SCS-012

Name of Drug: Potassium Acetate Injection, USP, in Plastic Vials

Sponsor: Abbott Laboratories

Project Manager: Victoria Kao

Material Reviewed

Final Printed Labeling, dated July 25 and August 16, 2002, submitted pursuant 21 CFR 201.57(f)(9)(vii), in compliance with 21 CFR §201.323, *Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition.*

Background and Summary Description:

In accordance with 21 CFR 201.57(f) (10)(ii)(A), the sponsor submitted Final Printed Labeling (FPL) that included newly added statements concerning aluminum. The FPL is compared with the labeling approved immediately prior (AP'd February 11, 2000) and the "aluminum" additions, as well as other noted additions and revisions, are isolated below.

Status Report

Reviews Completed: Project Manager Label review – December 12, 2002/December 19, 2002

Project Manager Review

BOX WARNING: N/A

DESCRIPTION: No changes noted.

CLINICAL PHARMACOLOGY: No changes noted.

INDICATIONS AND USAGE: No changes noted.

CONTRAINDICATIONS: No noted changes

WARNING:

Labeling immediately prior to this submission (AP February 11, 2000)	July 25, 2002 draft package insert
No such wording	WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum. Research indicates that patients with impaired kidney function, including premature neonates, who received parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

PRECAUTIONS: No changes noted

ADVERSE REACTIONS: No changes noted.

DRUG ABUSE AND DEPENDENCE: No changes noted.

OVERDOSAGE: No changes noted.

DOSAGE AND ADMINISTRATION: No changes noted.

STORAGE CONDITIONS: No changes noted.

HOW SUPPLIED: No changes noted.

PATIENT INFORMATION: No changes noted.

Project Manager Review of Container Label

Container Label - AP'd August 31, 1999	Currently Proposed Container Label
(b) (4)	No such wording

Container Label - AP'd August 31, 1999	Currently Proposed Container Label
No such wording	"Contains no more than 200 mcg/L of aluminum."

****

N18-896 SLR 012 Chemistry Review (November 15, 2002) recommends approval
Supervisory CSO concurred with PM review (December 20, 2002)
Supplement may be approved.

_____
Project Manager

_____
Supervisory Comment/Concurrence

Archival NDA 18-896/SLR-012
HFD-170/Division files
HFD-170/V.Kao/
HFD-510/D. Lewis/
Initialed by: JaniP/
Final: V.Kao/

File name:N18896 alum rev 8-9-02.doc

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/s/

Victoria Kao
12/20/02 05:43:11 PM
CSO