CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-910

PROPRIETARY NAME REVIEW(S)

CONSULTATION RESPONSE

DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY
(DMETS; HFD-420)

DATE RECEIVED: April 10, 2006 **DATE OF DOCUMENT:** September 23, 2005	**DESIRED COMPLETION DATE:** June 30, 2006 **PDUFA DATE:** July 26, 2006	**OSE REVIEW #:** 05-0257-1

TO: Norman Stockbridge, MD
Director, Division of Cardiovascular and Renal Products
HFD-110

THROUGH: Linda Kim-Jung, Pharm.D., Team Leader
Denise Toyer, Pharm.D., Deputy Director
Carol Holquist, R.Ph., Director
Division of Medication Errors and Technical Support, HFD-420

FROM: Tselaine Jones Smith, Safety Evaluator
Division of Medication Errors and Technical Support, HFD-420

PRODUCT NAME: Normocarb HF **NDA#:** 21-910	**NDA SPONSOR:** Dialysis Solutions, Inc.

RECOMMENDATIONS:

DMETS recommends implementation of the label and labeling revisions outlined in Section II of this review that might lead to safer use of the product. We would be willing to revisit these issues if the Division receives another draft of the labeling from the manufacturer.

DMETS would appreciate feedback of the final outcome of this consult. We would be willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Diane Smith, project manager, at 301-796-0538.

Division of Medication Errors and Technical Support (DMETS)
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

LABEL AND LABELING REVIEW

DATE OF REVIEW: May 4, 2006

NDA#: 21-910

NAME OF DRUG: Normocarb HF

NDA HOLDER: Dialysis Solutions Inc.

I. INTRODUCTION:

This consult was written in response to a request from the Division of Cardiovascular and Renal Products (HFD-110) to review and comment on the revised container labels and insert labeling for Normocarb HF (NDA 21-910). DMETS previously reviewed the proposed tradename "Normocarb HF" and the labels/labeling in OSE Consult number 05-0257, dated January 26, 2006 in which DMETS objected to the proposed proprietary name, Normocarb HF.

According to the review Division and the Center for Devices and Radiological Health (CDRH), Normocarb (CDRH Regulation Number 876.5280), a device product, was approved as a sterile bicarbonate renal dialysis concentrate for use in Continuous Renal Replacement Therapy (CRRT) on June 30, 2000. The sponsor is currently marketing Normocarb in two different formulations, Normocarb 25 and Normocarb 35. The modifiers, 25 and 35, signify the amount of bicarbonate in each formulation. Normocarb 25 contains more chloride (116.5 mMol\L or 116.5 mEq/L vs.106.5 mMol\L or 106.5 mEq/L) and less bicarbonate (25 mMol\L or 25 mEq/L vs. 35 mMol\L or 35 mEq/L) than Normocarb 35.

The sponsor is now proposing to market two new formulations of Normocarb for hemofiltration for adjunct therapy in Continuous Renal Replacement Therapy (CRRT) as a drug product. The sponsor has proposed the names Normocarb HF 25 and Normocarb HF 35. Normocarb HF 25 and Normocarb HF 35 will have identical formulations to Normocarb 25 and Normocarb 35, respectively. Moreover, the sponsor is modifying the package insert labeling and container label for Normocarb HF. However, Normocarb HF and Normocarb will have two separate package inserts.

The sponsor proposes that both formulations of Normocarb (the device) and Normocarb HF (the proposed drug) will be on the market concurrently.

PRODUCT INFORMATION

Normocarb HF is a sterile bicarbonate hemofiltration concentrate indicated for use as an adjunct therapy in Continuous Renal Replacement Therapy (CRRT) using hemofiltration in adult and pediatric populations. Continuous renal replacement therapy is dialysis continued for twenty four hours a day to treat critically ill patients with renal failure. It is usually administered to patients in intensive care who require dialysis and are hemodynamically unstable, or whose liver function is either impaired or at risk of impairment. The aims of continuous renal replacement therapy are control of fluid balance, control of plasma electrolytes, control of acid–base balance and removal of products of metabolism. Normocarb HF must be diluted before use. For dilution, one 240 mL vial of Normocarb HF 25 or Normocarb HF 35 should be added to 3 liters of sterile water to make 3.24 L of infusate solution. Normocarb HF can be administered pre- or post-filter. The volume administered will depend on the fluid balance of the individual patient, the target fluid balance to be achieved, the patient's body weight and the amount of fluid removed from the patient's circulation during the hemofiltration process. When administered post-filter, the replacement rate should not be greater than one-third of the blood flow rate, e.g. for blood flow of 100 ml/min, equivalent to 6000 ml/hour, post-filter replacement rate should not exceed 2000 mL/min. The dosage of Normocarb HF is individualized per patient and is dosed at the discretion of the physician.

II. LABELING, PACKAGING, AND SAFETY RELATED ISSUES:

In the review of the container labels and insert labeling of Normocarb HF, DMETS has attempted to focus on safety issues relating to possible medication errors. DMETS has identified the following areas of possible improvement, which might minimize potential user error.

A. GENERAL COMMENTS

3 Page(s) Withheld

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✓ Draft Labeling

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Withheld Track Number: Proprietary Name Review- 1

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/s/

Linda Kim-Jung
7/7/2006 02:12:40 PM
DRUG SAFETY OFFICE REVIEWER
Also signing for Tselanie Jones-Smith on July 7, 2006.

Denise Toyer
7/7/2006 02:55:28 PM
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Carol Holquist
7/7/2006 03:52:55 PM
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CONSULTATION RESPONSE

DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF DRUG SAFETY
(DMETS; HFD-420)

DATE RECEIVED:	**DESIRED COMPLETION DATE:**	**ODS CONSULT #:** 05-0257
November 8, 2005	February 6, 2006	
DATE OF DOCUMENT:		
September 26, 2005	**PDUFA DATE:**	
	July 26, 2006	

TO: Norman Stockbridge, MD
Acting Director, Division of Cardiovascular and Renal Products
HFD-110

THROUGH: Kristina C. Arnwine, Pharm.D., Acting Team Leader
Denise Toyer, Pharm.D., Deputy Director
Carol Holquist, R.Ph., Director
Division of Medication Errors and Technical Support

FROM: Tselaine Jones Smith, Pharm.D., Safety Evaluator
Division of Medication Errors and Technical Support

PRODUCT NAME:
Normocarb HF
NDA #: 21-910

SPONSOR: Dialysis Solutions, Inc.

RECOMMENDATIONS:

1. DMETS does not recommend the use of the proprietary name, "Normocarb HF". However, DMETS believes the safest use of this product may be best managed by using the same proprietary name as the currently marketed product, Normocarb, and indicating that the product can be used as either an infusate or diasylate solution. This is considered a tentative decision and the firm should be notified that this name with its associated labels and labeling must be re-evaluated approximately 90 days prior to the expected approval of the NDA. A re-review of the name prior to NDA approval will rule out any objections based upon approvals of other proprietary or established names from the signature date of this document.

2. DMETS recommends implementation of the label and labeling revisions outlined in Section IV of this review to minimize potential errors with the use of this product. Please forward the container labels and carton labeling for review when they become available.

3. [redacted]

DMETS would appreciate feedback of the final outcome of this consult. We would be willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Diane Smith, project manager, at 301-796-5038.

Division of Medication Errors and Technical Support (DMETS)
Office of Drug Safety
HFD-420; PKLN Rm. 6-34
Center for Drug Evaluation and Research

PROPRIETARY NAME REVIEW

DATE OF REVIEW: November 18, 2005

NDA #: 21-910

NAME OF DRUG: Normocarb HF

NDA HOLDER: Dialysis Solutions Inc.

I. INTRODUCTION:

This consult was written in response to a request from the Division of Cardiovascular and Renal Products (HFD-110), for assessment of the proprietary name, Normocarb HF, regarding potential name confusion with other proprietary or established drug names. Container labels and package insert labeling were provided for review and comment.

According to the review Division and the Center for Devices and Radiological Health (CDRH), Normocarb (CDRH Regulation Number 876.5280) was approved as a sterile bicarbonate renal dialysis concentrate for use in Continuous Renal Replacement Therapy (CRRT) on June 30, 2000. The sponsor is currently marketing Normocarb in two different formulations, Normocarb 25 and Normocarb 35. The modifiers, 25 and 35, signify the amount of bicarbonate in each formulation. Normocarb 25 contains more chloride (116.5 mMol\L or 116.5 mEq/L vs.106.5 mMol\L or 106.5 mEq/L) and less bicarbonate (25 mMol\L or 25 mEq/L vs. 35 mMol\L or 35 mEq/L) than Normocarb 35.

The firm is now proposing to market two new formulations of Normocarb for hemofiltration for adjunct therapy in Continuous Renal Replacement Therapy (CRRT). The sponsor has proposed the names Normocarb HF 25 and Normocarb HF 35. Normocarb HF 25 and Normocarb HF 35 will have identical formulations to Normocarb 25 and Normocarb 35, respectively. Moreover, the sponsor is modifying the package insert labeling and container label for Normocarb HF. However, Normocarb HF and Normocarb will have two separate package inserts.

The sponsor proposes that both formulations of Normocarb (the device) and Normocarb HF (the proposed drug) will be on the market concurrently.

PRODUCT INFORMATION

Normocarb HF is a sterile bicarbonate hemofiltration concentrate indicated for use as an adjunct therapy in Continuous Renal Replacement Therapy (CRRT) using hemofiltration in adult and pediatric populations. Continuous renal replacement therapy is dialysis continued for twenty four hours a day to treat critically ill patients with renal failure. It is usually administered to patients in intensive care who require dialysis and are hemodynamically unstable, or whose liver function is either impaired or at risk of impairment. The aims of continuous renal replacement therapy are control of fluid balance, control of plasma electrolytes, control of acid–base balance and removal of products of metabolism. Normocarb

HF must be diluted before use. For dilution, one 240 mL vial of Normocarb HF 25 or Normocarb HF 35 should be added to 3 liters of sterile water to make 3.24 L of infusate or diasylate solution. Normocarb HF can be administered pre- or post-filter. The volume administered will depend on the fluid balance of the individual patient, the target fluid balance to be achieved, the patient's body weight and the amount of fluid removed from the patient's circulation during the hemofiltration process. When administered post-filter, the replacement rate should not be greater than one-third of the blood flow rate, e.g. for blood flow of 100 ml/min, equivalent to 6000 ml/hour, post-filter replacement rate should not exceed 2000 mL/min. The dosage of Normocarb HF is individualized per patient and is dosed at the discretion of the physician.

II. RISK ASSESSMENT:

The medication error staff of DMETS conducted a search of several standard published drug product reference texts[1,2] as well as several FDA databases[3] for existing drug names which sound-alike or look-alike to Normocarb HF to a degree where potential confusion between drug names could occur under the usual clinical practice settings. A search of the electronic online version of the U.S. Patent and Trademark Office's Text and Image Database was also conducted[4]. An expert panel discussion was conducted to review all findings from the searches. In addition, DMETS conducted three requisition studies consisting of two written requisition studies (inpatient and outpatient) and one verbal requisition study, involving health care practitioners within the FDA. This exercise was conducted to simulate the pharmacy ordering process in order to evaluate potential errors in handwriting and verbal communication of the name.

A. EXPERT PANEL DISCUSSION (EPD)

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary name Normocarb HF. Potential concerns regarding drug marketing and promotion related to the proposed name were also discussed. This group is composed of DMETS Medication Errors Prevention Staff and representation from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The group relies on their clinical and other professional experiences and a number of standard references when making a decision on the acceptability of a proprietary name.

1. DDMAC objects to the proposed trade name Normocarb HF as overstating the efficacy of the product and implying superiority over other continuous renal replacement therapy (CRRT) solutions. Inclusion of "Normo" in the first two syllables of the trade name easily leads to "normal," making a representation about this product's ability to rectify acid/base or glycemic status in those receiving CRRT in all situations for all patients. The name suggests patients using this product will have a normal carbohydrate level or stable glycemic status following use. Furthermore, the nature of the efficacy claim imbedded in the name creates an implied superiority claim, suggesting no other hemodialysis solution could produce a stabilized or normal acid/base or glycemic status.

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[1] MICROMEDEX Integrated Index, 2005, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.
[2] Facts and Comparisons, online version, Facts and Comparisons, St. Louis, MO.
[3] AMF Decision Support System [DSS], the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, New Drug Approvals 98-05, and the electronic online version of the FDA Orange Book.
[4] WWW location http://www.uspto.gov/tmdb/index.html.

Please note that 21 CFR 201.10(c)(3) states that a proprietary name that implies that the drug or ingredient has some unique effectiveness or composition would be misleading, if the drug or ingredient is a common substance, the limitations of which are readily recognized when the drug or ingredient is listed by its established name. In addition, the statute also provides that labeling or advertising can misbrand a product if misleading representations are made, whether through a trade name or otherwise; this includes suggestions that a drug is better, more effective, useful in a broader range of conditions or patients, safer, has fewer, or lower incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence or substantial clinical experience. [21 U.S.C 321(n); see also 21 U.S.C.352(a) & (n); 21 CFR 202.1(e)(5)(i);(e)(6)(i)].

Despite DDMAC's objection to the name, per an email from Diane Paraoan, the Division of Cardiovascular and Renal Products has decided to proceed with the safety review of the name Normocarb HF. Therefore, DMETS will continue with the safety review of the proposed proprietary name, Normocarb HF.

2. The Expert Panel identified two proprietary names that were thought to have the potential for confusion with Normocarb HF. These products are listed in table 1 (see below), along with the dosage forms available and usual dosage.

Table 1: Potential Sound-Alike/Look-Alike Names Identified by DMETS Expert Panel

Product Name	Dosage form(s), Established name	Usual adult dose*	Other**
Normocarb HF	Sterile Bicarbonate Hemofiltration Concentrate ($NaCl$, $MgCl_2$, $NaHCO_3$) Normocarb HF 25=> 25 mEq HCO_3, 116.5 mEq Cl Normocarb HF 35 => 35 mEq HCO_3, 106.5 mEq Cl 240 mL vial	Must be diluted with sterile water only Pre-filter or Post-filter Individualized treatment	NA
Normosol R	Magnesium Chloride (30 mg/100ml), Potassium Chloride, (37 mg/100ml), Sodium Acetate (Anhydrous) (222 mg/100ml), Sodium Chloride (526 mg/100ml), and Sodium Gluconate (502 mg/100ml) Injection 500 mL and 1000 mL	Based on the extracellular fluid loss in the individual patient. Up to 3-times the volume of estimated blood loss during and after surgery can be given to correct circulatory volume when there is only a moderate loss of blood. Average normal adult daily fluid requirements ranges from 2—3 L/day.	LA
Normocarb	Sterile Bicarbonate Renal Dialysis Concentrate ($NaCl$, $MgCl_2$, $NaHCO_3$) Normocarb 25=> 25 mEq HCO_3, 116.5 mEq Cl Normocarb 35 => 35 mEq HCO_3, 106.5 mEq Cl 240 mL vial	Must be diluted with sterile water only. Individualized treatment	LA/SA
*Frequently used, not all-inclusive. **L/A (look-alike), S/A (sound-alike)			

B. PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA)

As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. The phonetic search module returns a numeric score to the search engine based on the phonetic similarity to the input text. Likewise, an orthographic algorithm exists which operates in a similar fashion. All names considered to have significant phonetic or orthographic similarities to Normocarb HF were discussed by the Expert Panel (EPD).

C. CENTER FOR DEVICES AND RADIOLOGICAL HEALTH ADVERSE EVENT REPORTING SYSTEM, MAUDE

Normocarb has been marketed as a device since June 30, 2000. Therefore, DMETS requested that the Center for Devices and Radiological Health conduct a search of their adverse event reporting system, MAUDE, for all post-marketing safety reports of errors associated with Normocarb. Their search efforts did not identify any post-marketing safety reports of errors associated with Normocarb.

D. PRESCRIPTION ANALYSIS STUDIES

1. Methodology:

Three separate requisition studies were conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of Normocarb HF with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten requisition or verbal pronunciation of the drug name. These studies employed a total of 122 health care professionals (pharmacists, physicians, and nurses). This exercise was conducted in an attempt to simulate the pharmacy ordering process. Two requisition orders were written, each consisting of a combination of marketed and unapproved drug products and a requisition for Normocarb HF (see below). These requisitions were optically scanned and one requisition was delivered to a random sample of the participating health professionals via e-mail. In addition, the requisition orders were recorded on voice mail. The voice mail messages were then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal requisition orders, the participants sent their interpretations of the orders via e-mail to the medication error staff.

HANDWRITTEN REQUISITION	VERBAL REQUISITION
Requisition Sample #1: 1 | 1245 | Normocarb HF 240mL vial	Item #1245 Normocarb HF #1 240 mL vial
Requisition Sample #2: | 1245 | Normocarb HF #1 240 ml	

2. Results:

Five respondents in the verbal requisition order study interpreted the name as Normocarb HS. Thus, on an order, this can be misinterpreted as giving Normocarb at bedtime rather than administering the new product, Normocarb HF. See Appendix A for the complete listing of interpretations from the verbal and written studies.

E. SAFETY EVALUATOR RISK ASSESSMENT

In reviewing the proprietary name Normocarb HF, the primary concerns related to look-alike and sound-alike confusion with Normcarb and Normosol R. Additionally, DMETS is concerned with the modifier "HF". DMETS would also like to acknowledge that a search found one look-alike and sound-alike medication, Normocard, that is marketed in Poland. Since the look-alike and sound-alike characteristics are obvious, the sponsor should be made aware of the similar foreign name. However, DMETS believes the actual possibility for confusion with this product name to be minimal due to the areas of marketing and context of use.

DMETS conducted requisition studies to simulate the pharmacy ordering process. In this case, there was no confirmation that the proposed name could be confused with any of the aforementioned names. The majority of the responses were misspelled/phonetic variations of the proposed name, Normocarb HF. However, five participants in the verbal study misinterpreted Normocarb HF as Normocarb HS.

1. Look-alike/Sound-alike concerns with Normocarb HF

Two names were identified as having similarity in appearance and pronunciation, Normocarb and Normosol R.

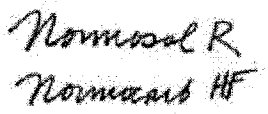
a. Normocarb is identical to Normocarb HF. The sponsor has proposed adding the modifier, "HF" to indicate hemofiltration versus the currently marketed dialysis solution. There is concern that the confusion might occur between the products if the modifier is omitted or misinterpreted as demonstrated in the prescription analysis studies.

Normcarb
Normocarb HF

Normocarb, used in Continuous Renal Replacement Therapy (CRRT), is marketed as a device and is available in two formulations, Normocarb 25 and Normocarb 35. The modifiers, 25 and 35, signify the amount of bicarbonate in each formulation. Normocarb 25 contains more chloride (116.5 mMol\L or 116.5 mEq/L vs.106.5 mMol\L or 106.5 mEq/L) and less bicarbonate (25 mMol\L or 25 mEq/L vs. 35 mMol\L or 35 mEq/L) than Normocarb 35. Normocarb HF and Normocarb share identical product characteristics with regards to active ingredients, dosage form (sterile bicarbonate concentrate), dosage and administration (must be diluted before use) and intended use (continuous renal replacement therapy). The prescriber population and clinical setting is identical between the two drugs as well.

Even when the names are clearly spoken or written, as demonstrated in the verbal order study conducted by DMETS, transcription of the verbal order may result in omission or misinterpretation of the modifier. Thus, the potential for sound-alike and look-alike confusion for Normocarb and Normocarb HF is increased. In the event that the modifier is omitted or misinterpreted and Normocarb is dispensed and administered, there would not be any clinical consequences since Normocarb and Normocarb HF share identical product characteristics. Thus, DMETS questions the rationale for adding a modifier because there are no product differences. Traditionally, modifiers are used to distinguish product differences of a drug with the same root name. Therefore, DMETS does not see the rational for adding the modifier "HF" to the root name, Normocarb because there are not any product differences between Normocarb and Normocarb HF.

b. Normosol R was identified as a name with similar appearance to Normocarb HF. Normosol R is a sterile, nonpyrogenic isotonic solution of balanced electrolytes in water for injection. Both names have identical beginnings with the letters "Normo-". However, the last four letters "-carb" of Normocarb HF and the last three letters "-sol" of Normosol R help to differentiate the two names when written out (see below). Additionally, if the modifier "HF" is not omitted from the order or misinterpreted as "HS", the modifiers "HF" and "R" should also help to differentiate between the two names when scripted.



Normosol R is administered by intravenous infusion. It may also be administered subcutaneously. Normosol R is indicated for parenteral replacement of acute extracellular volume losses in surgery, trauma, burns or shock. Normosol R also can be used as an adjunct to restore a decrease in circulatory volume in patients with moderate blood loss. The amount to be infused is based on replacement losses of extracellular fluid volume in the individual patient. Up to three times the volume of estimated blood loss during and after surgery can be given to correct circulatory volume when there is only a moderate loss of blood.

The products differ with regard to dosage form (sterile bicarbonate hemofiltration concentrate vs. solution) and indication for use (continuous renal replacement therapy vs. replacement of acute losses of extracellular fluid). Additionally, Normosol R is supplied as ready-to-use 500 mL and 1000 mL single-dose flexible plastic containers that do not require further dilution. The prescriber population and clinical setting may differ between the two drugs as well. Normocarb HF is used as adjunct therapy in Continuous Renal Replacement Therapy (CRRT) using hemofiltration in adult and pediatric patients. Normocarb HF will most likely be prescribed by a specialist for use in an intensive care setting where dialysis can be performed. Orders for Normocarb HF will be written per protocol per patient and will indicate that it is to be used for Continuous Renal Replacement Therapy (CRRT). In contrast, Normosol R is indicated for replacement of acute extracellular fluid volume losses in surgery, trauma, burns or shock. Like Normocarb HF, Normosol R can also be administered in an intensive care setting; however, it can also be administered in surgery units, burn units and Shock

Trauma centers. Despite some orthographic similarities between Normocarb HF and Normosol R, product characteristics such as indication and context of use decrease the possibility for confusion.

2. Modifier (HF) Concerns

The sponsor has proposed to associate the modifier "HF" (hemofiltration), to their proprietary name, Normocarb, to differentiate the drug from their currently marketed device, Normocarb. Traditionally, modifiers are used to distinguish product differences between two products with the same root name. For example, the products Detrol and Detrol LA, utilize the modifier "LA" (long acting) to differentiate between the immediate release and extended release formulations, respectively. As Normocarb is currently a marketed device and health care practitioners have already become familiar with the proprietary name Normocarb and its labels and labeling, the addition of a modifier could cause unnecessary confusion in the marketplace. Furthermore, since both Normocarb and Normocarb HF share identical product characteristics with regards to active ingredients, dosage form (sterile bicarbonate concentrate), dosage and administration (must be diluted before use) and intended use (continuous renal replacement therapy), DMETS does not see the rational for adding a modifier because there are not any product differences between the two drugs. Additionally, DMETS is concerned that the two identical products with different proprietary names may be misleading to practitioners, lead to medication errors or lead practitioners to consider Normocarb HF to be the safer product or that it has uniqueness, other than a different indication, that may be beneficial to patients.

Moreover, the letters, "HF", are listed in the 12th edition of *Medical Abbreviations: 26,000 Conveniences at the Expense of Communication and Safety* by Neil M. Davis as an abbreviation for Hageman Factor, hard feces, hay fever, head of fetus, heart failure, high frequency, Hispanic female, hot flashes and house formula. It is unlikely that these interpretations would be associated with a medical order. However, five participants in the verbal study misinterpreted the suffix "HF" as "HS". Thus, on an order, this can be misinterpreted as give Normocarb at bedtime rather than administering the new product.

In summary, DMETS discourages the use of modifiers to differentiate dosage forms that have the same active ingredients, indication of use, dosage and administration. DMETS recommends the use of one proprietary name, Normocarb, for both products. Additionally, in order to minimize confusion between the device and the drug, consider using one package insert labeling for both products with a detailed Dosage and Administration section that distinguishes between the dialysate (Normocarb) and the infusate (Normocarb HF).

IV. LABELING, PACKAGING, AND SAFETY RELATED ISSUES:

In the review of the container labels and package insert labeling of Normocarb HF, DMETS has identified the following areas of possible improvement, which might minimize potential user error. However, draft copies of labels and labeling were provided in black and white, and do not represent the true color of the labels and labeling. Thus, it is not possible to fully assess the safety of the labels and labeling because the information provided does not reflect the presentation that will actually be used in the market place (i.e. color, placement of name, design, etc.). Please forward copies of the revised labels and labeling when available.

2 Page(s) Withheld

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✓ Draft Labeling

____ Deliberative Process

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Appendix A: DMETS Requisition Study Results for Normocarb HF

Requisition Order #1	Requisition Order #2	Voice Requisition Order
Normocarb HF	Norvocarb HF	Normocaul HF
Normscarb ITF	Normocarb HF	Normocarb HF
Normocarb HF	Normocarb HF	Normocarb HS
Normocarb HF	Normocarb HF	Normocail HF
Normocarb HF	Normocarb HF	Normocarb HF
Normocare HF	Normocarb HF	Normocarb ITF
Normacort HF	Nosinocort HF	Normocarb ITF
Normocarb HF	Nounoraub HF	Normscail ITF
Normocarb HF	Normocarb HF	Normocarb ITF
Normocarb HF	Normocort HF	Normocarb HS
Normorcarb HF	Normocarb HF	Normocarb HS
Normocail HF	Normozarb	Normocarb HF
Normocael HF	Nounrarb HF	??? HS
Normocael HF	Normocarb HF	Normocarb HS
Normacarb-HF	Normocarb HF	Normocall HF
Normocarb HF	Nounocarb HF	Normacarb tf
Normocal HF	Nonnocarb HF	Nounoraub HF
Normocarb ITF	Normocarb HF	Normocarb HF
Normocarb HF	Normocarb HF	Normocarb ITF
Normocarb HF	Normocarb HF	Normocaul HF
Normocarb 1 TF		
Normocort HF		
Normocarb HF		

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/s/

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1/25/2006 05:37:12 PM
DRUG SAFETY OFFICE REVIEWER

Denise Toyer
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DRUG SAFETY OFFICE REVIEWER

Carol Holquist
1/26/2006 02:09:56 PM
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