

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

20-900

CHEMISTRY REVIEW(S)

**DIVISION OF MEDICAL IMAGING AND RADIOPHARMACEUTICAL DRUG
PRODUCTS**

Review of Chemistry, Manufacturing, and Controls

NDA #: 20-900

DATE REVIEWED: January 21, 1999

REVIEW #: 4

REVIEWER: Ravi S. Harapanhalli, Ph.D.

<u>SUBMISSION TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
AMENDMENT (NC)	21-SEP-98	22-SEP-98	26-SEP-98
AMENDMENT (AC)	14-DEC-98	15-DEC-98	17-DEC-98
AMENDMENT (BC)	22-DEC-98	07-JAN-99	09-JAN-99
AMENDMENT (NC)	13-JAN-99	14-JAN-99	14-JAN-99

NAME & ADDRESS OF APPLICANT:

ALIMENTERICS INC.,
301 American Road
Morris Plains, NJ 07950
Contact: C. Lawrence Christman, Ph.D.

(973)-285-3100.

DRUG PRODUCT NAME

Proprietary:
Established:
Code Name/#:
Chem.Type/Ther.Class:

PYLORI-CHEK Breath Test Kit
¹³C-Urea, 99%
None
Diagnostic

PHARMACOL. CATEGORY/INDICATION:

Diagnostic for detecting pyloric
infection in adults.

DOSAGE FORM:

STRENGTHS: 100 mg/50 ml water

ROUTE OF ADMINISTRATION:

Rx/OTC:

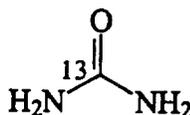
SPECIAL PRODUCTS:

(If yes, fill out the form for special products and
deliver it to TIA through team leader for data entry)

Powder
POTENCY(IES): N/A
Oral
 Rx OTC
 Yes No

**CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA,
MOLECULAR WEIGHT:**

Carbamide, Carbonyldiamine
Molecular Formula: ¹³CH₄N₂O
Molecular Weight: 61.06



SUPPORTING DOCUMENTS:

Type/Number	Subject	Holder	Status	Review Date	Letter Date

RELATED DOCUMENTS (if applicable): None

CONSULTS: None

REMARKS:

[REDACTED]

CONCLUSIONS & RECOMMENDATIONS:

[REDACTED]

From Chemistry, Manufacturing, and Control standpoint, the NDA is recommended for an 'Approval' pending approval from the Office of Compliance on the inspections of Alimentierics [REDACTED]. The sponsor should be reminded of the requirements of submitting [REDACTED] including samples when requested in the future.

Based on cMC all the acceptable inspection status (Jan 25, 1999), it is recommended that NDA 20-900 be approved.

ISI 2/1/99

ISI 01/22/99

Ravi S. Harapanhalli, Ph.D.,
Review Chemist

cc:
Org. NDA 20900
HFD-560/Division File
HFD-160/Harapanhalli/
HFD-560/PM/Anderson
HFD-160/TEAMLEADER/Leutzinger
HFD-820/DIVISION DIRECTOR/Gibbs
R/D Init by: TEAMLEADER/Leutzinger

CHEMIST/SALAKO/NDA 20,900 NC**¹³C-Urea, 2nd Review**

DIVISION OF NEW DRUG CHEMISTRY-II (DMIRDP, HFD-160)

Review of Chemistry, Manufacturing, and Controls

NDA #: 20-900

(Consult to HFD-560)

CHEM.REVIEW #: 3**REVIEW DATE: 02-03-98**

<u>SUBMISSION/TYPE:</u>	<u>DOCUMENT DATE:</u>	<u>CDER DATE:</u>	<u>ASS.DATE:</u>
Original	08-08-97	08-11-97	08-22-97
Amendment (NC)	01-12-98	01-19-98	01-19-98

NAME & ADDRESS OF APPLICANT:

Alimenterics Inc.,
 301 American Road
 Morris Plains, NJ 07950
 Contact Name: Janet G. Murnick, PhD; Phone #: (973) 285 3100

DRUG PRODUCT NAME:

Proprietary:	PYLORI-CHEK Breath Test Kit
Nonproprietary/USAN:	¹³ C-Urea, 99%
Code Names/#'s:	None
Chemical Type/	
Therapeutic Class:	Diagnostic

ANDA SUITABILITY PETITION/DESI/PATENT STATUS: Not Applicable**PHARMACOLOGICAL CATEGORY/INDICATION: Diagnostic, for detecting pyloric infection in adult patients.**

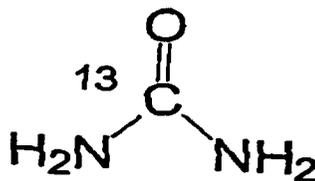
Dosage Form:	Powder
Strengths:	100 mg/50 mL sterile water
Route of Administration:	Oral
Dispensed:	<input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:

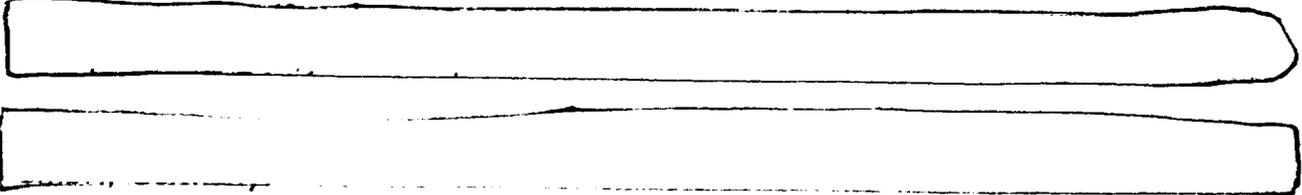
Carbamide, Carbonyldiamine.

Molecular Formula: ¹³CH₄N₂O

Molecular Weight: 61.06



SUPPORTING DOCUMENTS:



RELATED DOCUMENTS: None

CONSULTS: None. Rather, this review was undertaken as a consult for HFD-560.

REMARKS/COMMENTS:

The latest submission (NDA 20,900 NC) contained responses to all chemistry issues from original review of the NDA. The responses were found to be adequate. A few new clarification and commitment issues have been resolved by teleconference with the sponsor (copy attached). Other outstanding non-CMC issues are:

1. Current Good Manufacturing Practice (cGMP) Inspection of Alimenterics and contract labs. Requests for cGMP inspection were filed by EER on 9/11/97. Status as of 01/03/98: cGMP inspection is not yet concluded on the facilities of Alimenterics and [redacted] water supplier).
2. Trademark approval. The request for trademark review was filed on 9/23/97. Status as of 01/03/98: final evaluation on trademark request by the Labeling & Nomenclature committee (chair; Dr. Dan Boring) is not yet known.

CONCLUSION & RECOMMENDATIONS:

From the standpoint of chemistry, NDA 20,900 is recommended for approval subject to satisfactory cGMP inspection and trademark request evaluation by the Agency.

/S/
2/3/98
Gansy Salako, Ph.D.
Review Chemist

CC:Orig. NDA #20,900
HFD-560/CSO/Anderson
HFD-160/Division File
HFD-160/Chemist/Salako
HFD-160/Chemistry Team Leader/Leutzinger
HFD-820/DNDCII/Gibbs

/S/ *2/4/98*

OCT 29 1997

CHEMIST/SALAKO/NDA 20,900

¹³C-Urea, Alimenterics, NJ

DIVISION OF NEW DRUG CHEMISTRY-II (DMIRDP, HFD-160)

Review of Chemistry, Manufacturing, and Controls

NDA #: 20-900
(Consult to HFD-560)

CHEM.REVIEW #: 1

REVIEW DATE: 11-07-97

SUBMISSION/TYPE:
ORIGINAL

DOCUMENT DATE:
08-08-97

CDER DATE:
08-11-97

ASS.DATE:
08-22-97

NAME & ADDRESS OF APPLICANT:

Alimenterics Inc.,
301 American Road
Morris Plains, NJ 07950
Contact Name: Janet G. Murnick, PhD
Phone #: (973) 285 3100

DRUG PRODUCT NAME:

Proprietary:	PYLORI-CHEK Breath Test Kit
Nonproprietary/USAN:	¹³ C-Urea, 99%
Code Names/#'s:	None
Chemical Type/	
Therapeutic Class:	Diagnostic

ANDA SUITABILITY PETITION/DESI/PATENT STATUS: Not Applicable

PHARMACOLOGICAL CATEGORY/INDICATION: Diagnostic, for detecting pyloric infection in adult patients.

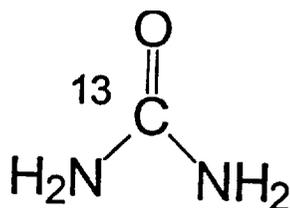
Dosage Form:	Powder
Strengths:	100 mg/50 mL sterile water
Route of Administration:	Oral
Dispensed:	<input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:

Carbamide, Carbonyldiamine.

Molecular Formula: ¹³CH₄N₂O

Molecular Weight: 61.06



SUPPORTING DOCUMENTS:

[Redacted]

[Redacted]

RELATED DOCUMENTS: None

CONSULTS: None. Rather, this review was undertaken as a consult for HFD-560.

REMARKS/COMMENTS:

Application is deficient on several issues from description of BDS molecule to drug product specifications, methods validation, and stability documentation. Though ¹³C-Urea is proposed for oral administration, information on the final dosage form is currently not available. Other deficiencies are on drug product container-closure, labeling and claim categorical exclusion on environmental assessment.

Inspection requests were filed by EER on 9/11/97, results pending.
Request for Trademark review was filed on 9/23/97, results pending.

CONCLUSION & RECOMMENDATIONS:

A list of deficiencies is attached [Redacted] Based on the nature of these CMC deficiencies, NDA 20,900 is considered approvable from the standpoint of chemistry. *pending satisfactory resolution of these deficiencies, and CGMP inspection stated for Alimenterics (Methu Plains, NJ) at*

/S/

11/07/97

[Signature]
Daisy Salako, Ph.D.
Review Chemist

[Redacted]

Also, there are results Pending for the trademark review.

- CC:Orig. NDA #20,900
- HFD-560/CSO/Anderson
- HFD-160/Division File
- HFD-160/Chemist/Salako
- HFD-160/Chemistry Team Leader/Leutzinger
- HFD-820/DNDCII/Gibbs

/S/

11/12/97