CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-555

Chemistry Review(s)

CHEMISTRY REVIEW

NDA 21-555

ChloraPrep®

Medi-Flex Hospital Products, Inc.

Rao Puttagunta, Ph.D.
Division of Anti-inflammatory, Analgesic and Ophthalmic
Drug Products (HFD-550)

Table of Contents

Chemistry Review Data Sheet

1. NDA # 21-555

2. REVIEW #: 1

3. REVIEW DATE: 03-OCT-2002

4. REVIEWER: Rao Puttagunta, Ph.D.

5. PREVIOUS DOCUMENTS: N/A

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Original	10-DEC-2001
Amendment (BC)	30-SEP-2002
Amendment (BC)	02-OCT-2002
Amendment (BC)	03-OCT-2002

7. NAME & ADDRESS OF APPLICANT:

Name:	Medi-Flex Hospital products, Inc.
Address:	8717 West 110th Street, Suite 750 Overland Park, KS 66210
Representative:	Michael C. Beckloff, President & C.E.O. Beckloff Associates, Inc. 400 West 110th Street, Suite 720 Overland Park, KS 66210
Telephone:	913-451-3955

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: ChloraPrep®
b) Non-Proprietary Name (USAN): Chlorhexidine Gluconate

c) Code Name/# (ONDC only): N/A
d) Chem. Type/Submission Priority (ONDC only):

- Chem. Type: 6
- Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: 505 (b)(1)

10. PHARMACOL. CATEGORY: Antiseptic

11. DOSAGE FORM: Solution

12. STRENGTH/POTENCY: 2% w/v

13. ROUTE OF ADMINISTRATION: Topical

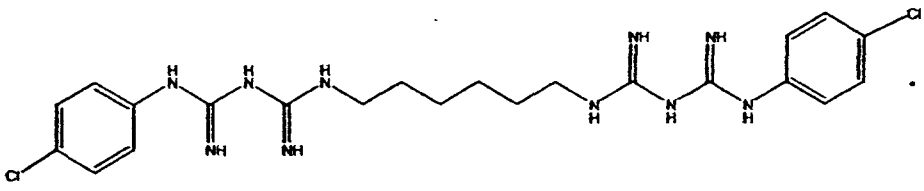
14. Rx/OTC DISPENSED: ___Rx __X_OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

_____SPOTS product – Form Completed

___X___Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:



$\cdot 2C_6H_{12}O_7$

1,1′-hexamethylenebis[5-(p-chlorophenyl)biguanide] di-D-gluconate, $C_{22}H_{30}Cl_2N_{10} \cdot 2C_6H_{12}O_7$, Mol. Wt. 897.77

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
[redacted]	II	[redacted]	Chlorhexidine gluconate.)	3	Adequate	5/04/99	---

[1] Action codes for DMF Table:
1 – DMF Reviewed.
Other codes indicate why the DMF was not reviewed, as follows:
2 –Type 1 DMF
3 – Reviewed previously and no revision since last review
4 – Sufficient information in application
5 – Authority to reference not granted
6 – DMF not available
7 – Other (explain under "Comments")

[2] Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
NDA	20-832	ChloraPrep

18. STATUS:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	N/A		
EES	Acceptable	9/17/02	J. D Ambrogio
Pharm/Tox	N/A		
Biopharm	N/A		
LNC	N/A		
Methods Validation	N/A		
OPDRA	N/A		
EA	Categorical Exclusion		
Microbiology	Approval	10/03/02	Bryan Riley

The Chemistry Review for NDA 21-555

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

From the CMC standpoint this NDA is recommended for approval.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

N/A

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

Drug substance:

Chlorhexidine gluconate, is manufactured by
The CMC information for the drug substance is referenced to DMF

Drug Product:

The Sepp® applicator consists of a glass ampoule containing 0.67 mL of solution enclosed in a plastic tube made of triple wall with a tip of foam bonded to the plastic tube. The applicator is packaged in a blister pack.

The ampoule sizes 3.00 mL, 1.1 mL and 1.5 mL were previously approved under NDA 20-832 for the drug product.

The materials used in the Sepp® applicator and in the packaging are the same as in NDA 20-832. The formulation remains in contact with glass only. The current submission retains the same formulation and specification as in NDA 20-832. The submitted drug product stability data include duration of at 25°C and 6 months at 40°C for the 3.0 mL applicator containing chlorhexidine from the previous supplier An amendment dated 10/03/02 contains the stability data at 25°C for using the chlorhexidine from the current supplier The applicant proposed an expiration dating period of 24 months.

B. Description of How the Drug Product is Intended to be Used

The Sepp® applicator for chlorhexidine 2% (w/v) is used topically as an antiseptic for patient preoperative and preinjection skin preparation. This product is a single use, unit dose applicator with a volume per applicator of 0.67 mL of chlorhexine gluconate 2% (w/v).

At the time of use, the glass ampoule is crushed by finger-tip compression of the molded plastic tube. Broken glass pieces are retained by the applicator tip. Holding the applicator tip down and with a small degree of pressure, the tip is saturated with solution allowing transfer of solution to the skin. The Sepp® applicator is supplied in a blister package.

Recommended storage conditions: 20-25°C (68-77°F).

C. Basis for Approvability or Not-Approval Recommendation

The CMC information of the drug substances chlorhexidine gluconate, was referenced to DMF( )This DMF has been reviewed and found adequate. The test methods for the drug substance were referenced to NDA 20-832 (approved 7/14/00).

In-process, release and stability acceptance criteria for the drug product were referenced to NDA 20-832. The packaging materials were also referenced to NDA 20-832.

The submitted drug product stability data on 3.0 mL applicator for — using chlorhexidine from( )and — with chlorhexidine from( ) (amendment dated 10/03/02) conform to the established acceptance criteria. The applicant also provided stability data on the reserve samples from seven batches of the proposed 0.67 mL applicator for up to — showing conformance with the acceptance criteria. The contact surface remains the Type I [ ] USP in both applicators, the only difference being the ampoule size. The submitted stability data were considered adequate to support the proposed expiration dating period of 24 months.

The information on the [ ] validation for the Sepp® applicators was found adequate by the microbiology reviewer Dr. Bryan Riley, after the applicant provided the results of the process validation (amendment dated 10/02/02).

The NDA 21-555 is recommended for approval based on the submitted CMC information.

III. Administrative

A. Reviewer's Signature N/A

B. Endorsement Block N/A

C. CC Block N/A

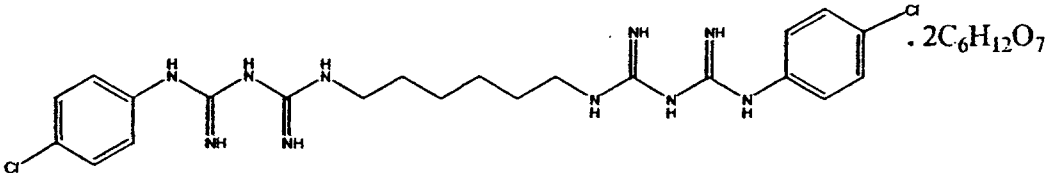
Chemistry Assessment

I. DRUG SUBSTANCE

1. Description & Characterization *Adequate*

a. Description

DMF



b. Characterization / Proof Of Structure

DMF

2. Manufacturer *Adequate*

Establishment	Function
	Manufacturer of chlorhexidine gluconate, BP
	Distributor of chlorhexidine gluconate, manufactured by
	Manufacturer of isopropyl alcohol. USP
	Manufacturer of isopropyl alcohol. USP
	Distributor of isopropyl alcohol, USP manufactured by and

Evaluation: *The original submission included the address of but the EES has shown the location in . The applicant (represented by Ms. Brenda Schlenk of Beckloff Associates) was asked to clarify the discrepancy in a teleconference on 9/25/02. It was clarified that the address in is that of the corporate headquarters and the manufacturing facility is located in*

*The address of the manufacturing facility was provided (amendment dated 9/30/02). **Adequate**.*

3. Synthesis / Method of Manufacture ***Adequate***

DMF

4. Process Controls ***Adequate***

DMF

5. Reference Standard ***Adequate***

NDA 20-832

6. Regulatory Specifications / Analytical Methods ***Adequate***

NDA 20-832

7. Container/Closure System for Drug Substance Storage ***Adequate***

DMF

8. Drug Substance Stability ***Adequate***

DMF

II. DRUG PRODUCT

1. Components/Composition ***Adequate***

Component	Amount/ Ampoule	Batch Formula (ampoules)	Concentration
Chlorhexidine Gluconate,	0.0134 g	kg	2% w/v
Isopropyl Alcohol, USP	0.4690 g	kg	70% w/v
Purified water, USP	0.6700 mL	kg)	q.s.

It was indicated that the Components/composition and batch formula have remained the same as in NDA 20-832 (approved 7/14/00). The only change reported is the theoretical number of 0.67-mL ampoules that can be filled.

2. Specifications & Methods for Drug Product Ingredients *Adequate*

It was stated that all raw materials, containers, closures, applicators, and labeling materials to be used in the manufacture of the product are tested per approved test methods and specifications and released by Medi-Flex Hospital Products, Inc., as referenced in NDA 20-832.

3. Manufacturer *Adequate*

Establishment	Function
Medi-Flex Hospital Products, Inc. 19 Butterfield Trail El Paso, TX 79906	• Manufacturing, packaging, and labeling • In-process testing, release testing and stability testing • Testing and releasing of raw materials including container/closure components
	•

Evaluation: Medi-Flex is a currently approved manufacturing facility listed in NDA 20-832. was listed as the sterilization and sterility testing site in the original submission. EES has shown with the same CFN and address. The applicant (represented by Ms. Brenda Schlenk of Beckloff Associates) was asked to clarify the discrepancy in a teleconference on 9/25/02. It was clarified that there was a change of name for this establishment, but the same establishment is being used by the applicant (amendment dated 9/30/02)

4. Methods of Manufacturing and Packaging *Adequate*

a. Production Operations

The manufacturing process for ChloraPrep® solution was stated to have not changed from that submitted in NDA 20-832.

Filling of Ampoules: The finished bulk solution is filled into a crushable glass ampoule made of USP to a target volume of 0.67 mL ± 10% according to the procedure submitted in NDA 20-832. The filled ampoules are sealed.

Applicator: After filling and sealing, the ampoule is placed in plastic tube made of triple-wall, The tube is sealed at one end by to form a leak-proof bottom prior to insertion of the filled ampoules. At the other end, an applicator tip of foam is bonded to the plastic tube.

Packaging and Labeling: The applicator is packaged in a blister pack. One hundred (100) Sepp applicators are packed into each intermediate carton, 10 cartons are packed into a shipper, and labeled with the Master Shipper Label.

Sterilization: The packaged cartons are
sterilization in the same manner as that used for the 3.0-mL swab-stick applicator submitted in NDA 20-832. The product is tested for chemical analysis and sterility before it is released for distribution.

b. In-Process Controls & Tests

In-process controls and tests were referenced to NDA 20-832.
Fill variability: 0.67 mL ± 10%

c. Reprocessing Operations

N/A

5. Regulatory Specifications and Methods for Drug Product *Adequate*

a. Sampling Procedures

N/A

b. Regulatory Specifications And Methods

Test	Acceptance Criteria
Appearance	Clear and colorless solution
Odor	Strong odor of alcohol
CHG	
PCA	NMT
IPA	

Analytical procedures used for the tests were referenced to NDA 20-832.

6. Container/Closure System *Adequate*

The applicator consists of glass ampoule containing 0.67 mL of solution enclosed in plastic tube made of triple wall with a tip of foam bonded to the plastic tube.
The applicator is packaged in a blister pack.

Evaluation:

The ampoule consists of the same Type I — USP, and the same configuration as that used in the 3.0-mL swab-stick applicator submitted in NDA 20-832.

The materials used in the plastic tube of the applicator, — — were stated to conform to the relevant CFR sections (21 CFR §175.105, 175.230, 175.300 and 177.1200, and §175.105, 177.1680 and 177.2600 respectively) for safety. These compounds are stated to have been used in the 3.0 mL applicator (NDA 20-832) by Mr. Charles Warner of Beckloff Associates in teleconference with the reviewer on 10/01/02.

The — used in the applicator tip were stated to be the same as that submitted in NDA 20-832.

The materials used in the applicator and the blister package were stated to be the same as in NDA 20-832. ***Adequate.***

7. Microbiology ***Adequate***

The — process validation was reviewed by Dr. Bryan Riley of the OPS Microbiology Team. He found the information adequate after the applicant submitted the results of the validation process in an amendment dated 10/02/02. For details see his reviews dated 10/02/02 and 10/03/03 in DFS.

8. Drug Product Stability ***Adequate***

It was stated that the applicant has not manufactured the Sepps® containing the solution made from chlorhexidine supplied by — However, the submission includes the stability data on batches (— at 25°C and 6 months at 40°C) from an ongoing stability study for the ChloraPrep One-Step 3-mL applicator, from the previous supplier, — in support of the proposed 0.67 mL Sepp® applicator. The annual report dated 8/15/02 to NDA 20-832 contains the long-term stability data for — ; for the 3.0 mL applicator with chlorhexidine from the current supplier, —

In an amendment dated 10/03/02 the applicant submitted the stability data at ambient temperature for up to — , on reserve samples from — batches of the 0.67 mL Sepp® applicators containing chlorhexidine supplied by — The applicant (represented by Mr. Charles Warner of Beckloff Associates) was asked to clarify the size of these batches (teleconference on 10/03/02). The applicant's response was not received at the time of this review. The submitted data conform to the established acceptance criteria.

Evaluation: All the submitted stability data for both the applicators conform to the established acceptance criteria. The only difference between the primary containers (glass ampoules) for these two applicators is the size of the glass ampoule. Therefore the stability data on the 3.0 mL applicator were also considered adequate to support the stability of the proposed applicator. ***Adequate.***

Stability Commitment:

The applicant commits to test the first three commercial batches of Sepp® ampoules containing chlorhexidine gluconate supplied by —, at least one additional batch on annual basis thereafter according to the approved stability protocol through the expiration dating period. The results of the stability studies will be submitted in the Annual Reports.

The applicant committed to withdraw from the market any batches of the drug product found to fall outside the approved specifications. It was also stated that any change or deterioration in the distributed drug product would be reported in compliance with 21 CFR 314.81(b)(1)(ii).

Evaluation: Adequate

Expiration Period:

The applicant proposed a 24-month expiration dating period (amendment dated 10/02/02).

Evaluation: *The submitted stability data on the 3.0 mL applicator(NDA 20-832) using chlorhexidine from the — suppliers (— — and the stability data on the proposed 0.67 mL applicator (— conform to the acceptance criteria. The formulation is in the ampoule and is in contact only with the glass surface in both the applicators, the only difference being the size of the ampoule. The submitted stability data were considered adequate to support the proposed expiration dating period.* ***Adequate.***

III. INVESTIGATIONAL FORMULATIONS

N/A

IV. ENVIRONMENTAL ASSESSMENT *Adequate*

The applicant claimed a categorical exclusion from preparing an environmental impact statement under 21 CFR§25.31(b), stating that the Expected Introduction Concentration into the aquatic resources is <1ppb based on the fifth-year marketing projections.

This information was submitted in an amendment dated 9/30/02 in response to a teleconference with the sponsor (represented by Mr. Charles Warner of Beckloff Associates) on 9/26/02. ***Adequate.***

V. METHODS VALIDATION

The analytical procedures were referenced to NDA 20-832, and no new regulatory analytical procedures were proposed.

VI. LABELING

The printed labeling is provided for the 0.67 mL Sepp® Applicator and carton:

The carton label contains Active Ingredients, Use, Warnings, Directions, Storage conditions, and Inactive Ingredients.

Active Ingredients	**Purpose**
Chlorhexidine gluconate 2% w/v	Antiseptic
Isopropyl alcohol 70% v/v	Antiseptic

Inactive ingredients
USP purified water

Storage: 20 - 25°C (68 - 77°F)

Evaluation: *The labeling is reviewed by the Division of Over the Counter Drug Products (HFD-560).*

VII. ESTABLISHMENT INSPECTION

Overall recommendation from the Office of Compliance has been received on 9/17/02 for all the establishments listed in the submission, as acceptable. EER summary report is attached with this review.

VIII. DRAFT DEFICIENCY LETTER

CHEMISTRY REVIEW

Chemistry Assessment Section

02-OCT-2002

FDA CDER EES

ESTABLISHMENT EVALUATION REQUEST SUMMARY REPORT

Application: **NDA 21555/000**
Stamp: **12-DEC-2001** Regulatory Due: **12-OCT-2002**
Applicant: **MEDI FLEX HOSP**
19 BUTTERFIELD TRAIL
EL PASO, TX 79906

Priority: Org Code: **520**
Action Goal: District Goal: **13-AUG-2002**
Brand Name: **CHLORAPREP**
Established Name:
Generic Name: **CHLORHEXIDINE GLUCONATE**
Dosage Form: **SOL (SOLUTION)**
Strength: **2% & 4%**

FDA Contacts:

T. FRAZIER	**(HFD-560)**	**301-827-2222**	**, Project Manager**
R. PUTTAGUNTA	**(HFD-550)**	**301-827-2296**	**, Review Chemist**
J. SMITH	**(HFD-550)**	**301-827-2529**	**, Team Leader**

Overall Recommendation:

ACCEPTABLEon 17-SEP-2002by J. D AMBROGIO (HFD-324)301-827-0062

Establishment:

DMF No:
AADA No:

Profile: **GSP** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **17-SEP-2002**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Responsibilities:

Establishment: **1641653**
MEDI FLEX HOSP PRODUCTS INC
19 BUTTERFIELD TRAIL BLVD
EL PASO, TX 79906

DMF No:
AADA No:

Profile: **LIQ** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **17-SEP-2002**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Responsibilities: **FINISHED DOSAGE LABELER**
FINISHED DOSAGE MANUFACTURER
FINISHED DOSAGE PACKAGER
FINISHED DOSAGE RELEASE TESTER
FINISHED DOSAGE STABILITY TESTER

Establishment:

DMF No:
AADA No:

Profile: **CSN** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **17-SEP-2002**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Responsibilities:

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

/s/

Rao Puttagunta
10/4/02 10:10:29 AM
CHEMIST

John Smith
10/4/02 10:23:01 AM
CHEMIST

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

REQUEST FOR CONSULTATION

(Division/Office): Peter Cooney, HFD-805 (PKLN)			FROM: Rao Puttagunta, Review Chemist, HFD-830/550	
DATE: August 21, 2002	IND NO.	NDA NO.: 21-555	TYPE OF DOCUMENT: Microbiology consult	DATE OF DOCUMENT: 12/10/01
NAME OF DRUG: Chloraprep (chlorhexidine gluconate, 2%)		PRIORITY CONSIDERATION	CLASSIFICATION OF DRUG: Topical Solution	DESIRED COMPLETION DATE: 9/21/02

NAME OF FIRM: Medi-Flex Hospital Products, Inc.

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ MANUFACTURING CHANGE/ADDITION
- ☐ MEETING PLANNED BY
- ☐ PRE-NDA MEETING
- ☐ END OF PHASE II MEETING
- ☐ RESUBMISSION
- ☐ SAFETY/EFFICACY
- ☐ PAPER NDA
- ☐ CONTROL SUPPLEMENT
- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- ■ OTHER *(SPECIFY BELOW)*:

configuration for the current sterilization process.

II. BIOMETRICS

STATISTICAL EVALUATION BRANCH	STATISTICAL APPLICATION BRANCH
☐ TYPE A OR B NDA REVIEW ☐ END OF PHASE II MEETING ☐ CONTROLLED STUDIES ☐ PROTOCOL REVIEW ☐ OTHER (SPECIFY BELOW):	☐ CHEMISTRY REVIEW ☐ PHARMACOLOGY ☐ BIOPHARMACEUTICS ☐ OTHER (SPECIFY BELOW):

III. BIOPHARMACEUTICS

- ☐ DISSOLUTION
- ☐ BIOAVAILABILTY STUDIES
- ☐ PHASE IV STUDIES
- ☐ DEFICIENCY LETTER RESPONSE
- ☐ PROTOCOL-BIOPHARMACEUTICS
- ☐ IN-VIVO WAIVER REQUEST

IV. DRUG EXPERIENCE

- ☐ PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
- ☐ DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
- ☐ CASE REPORTS OF SPECIFIC REACTIONS (List below)
- ☐ COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP
- ☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
- ☐ SUMMARY OF ADVERSE EXPERIENCE
- ☐ POISION RICK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

- ☐ CLINICAL
- ☐ PRECLINICAL

COMMENTS/SPECIAL INSTRUCTIONS:

The applicant is proposing a new applicator with a smaller ampoule size (0.67 mL). Approved applicator ampoule sizes: 3.0mL, 1.5 mL, and 1.1 mL. It is stated that the [redacted] process and site remain the same, with a "slightly" different loading configuration.
Please contact me at 7-2296 if you have questions. Thank you.

Rao Puttagunta, Review Chemist

SIGNATURE OF REQUESTER	METHOD OF DELIVERY (Check one) ■ MAIL ☐ HAND
SIGNATURE OF RECEIVER	SIGNATURE OF DELIVERER

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

/s/

Rao Puttagunta
9/12/02 11:23:26 AM
CHEMIST

CHEMISTRY REVIEW

Chemistry Assessment Section

02-OCT-2002

FDA CDER EES

ESTABLISHMENT EVALUATION REQUEST SUMMARY REPORT

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J. SMITH	**(HFD-550)**	**301-827-2529**	**, Team Leader**

Overall Recommendation:

ACCEPTABLEon 17-SEP-2002by J. D AMBROGIO (HFD-324)301-827-0062

Establishment: ✓ DMF No:
AADA No:

Profile: **GSP** OAI Status: **NONE** Responsibilities: ✓
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **17-SEP-2002**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Establishment: **1641653** DMF No:
MEDI FLEX HOSP PRODUCTS INC AADA No:
19 BUTTERFIELD TRAIL BLVD
EL PASO, TX 79906

Profile: **LIQ** OAI Status: **NONE** Responsibilities: **FINISHED DOSAGE LABELER**
Last Milestone: **OC RECOMMENDATION** **FINISHED DOSAGE MANUFACTURER**
Milestone Date: **17-SEP-2002** **FINISHED DOSAGE PACKAGER**
Decision: **ACCEPTABLE** **FINISHED DOSAGE RELEASE TESTER**
Reason: **DISTRICT RECOMMENDATION** **FINISHED DOSAGE STABILITY TESTER**

Establishment: ✓ DMF No: ( )
AADA No:

Profile: **CSN** OAI Status: **NONE** Responsibilities: ✓
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **17-SEP-2002**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Establishment Information
Medi-Flex Hospital Products, Inc.

Corporate Offices:

8717 West 110th Street, Suite 750
Overland Park, Kansas 66210
Telephone: 913-451-0880
WATTS: 800-523-0502
Telefax: 913-451-8509

Site Functions:

Contact:

Beckloff Associates, Inc.
Commerce Plaza II, Suite 720
7400 West 110th Street
Overland Park, Kansas 66210
Telephone: 913-451-3955
Telefax: 913-451-3846

Manufacturing Facilities:

#19 Butterfield Trail
El Paso, Texas 79906
Telephone: 915-778-6421
WATTS: 800-742-0473
Telefax: 915-778-6425

Establishment Registration Number: 1641653

Site Functions:

Contact:

Beckloff Associates, Inc.
Commerce Plaza II, Suite 720
7400 West 110th Street
Overland Park, Kansas 66210
Telephone: 913-451-3955
Telefax: 913-451-3846

Warehouse Facilities:

#24 Concord
El Paso, Texas 79906
Telephone: 915-778-6477
Telefax: 915-778-6495

Site Functions:

Contact:

Beckloff Associates, Inc.
Commerce Plaza II, Suite 720
7400 West 110th Street
Overland Park, Kansas 66210
Telephone: 913-451-3955
Telefax: 913-451-3846

No Review
Required

Review Completed
on Product in
Orig NDA 20-832
approved
July 2000