CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

73416

CHEMISTRY REVIEW(S)

ANDA APPROVAL SUMMARY

ANDA:	CHEMIST:	DATE:
73-416	Gil Kang	February 23, 2000

DRUG PRODUCT:
Chlorhexidine Gluconate 4% w/v Scrub-Brush/Sponge

FIRM:
Becton Dickinson Division (formerly Becton Dickinson AcuteCare Division, and before that Deseret Medical)

DOSAGE FORM:	STRENGTH:
Sponge/Brush	4%

cGMP:
Acceptable on 23-NOV-1999.

BIO:
The Bio study was found acceptable by H. Nguyen on May 28, 1997.

VALIDATION - *(Description of dosage form same as firm's):*
Method validation by Seattle Laboratory is accptable with firm's response.

STABILITY:
The firm has provided 24 months stability data obtained with Chlorhexidine Gluconate 4% w/v Scrub Brush/Sponge assembly with nail pick. Drug product was stored at room temperature for 24 months (Lot #M7BX021 and Lot #M7BI880) or at ambient temperature with 35% humidity for 24 to 36 months (Batch 02124291A, 2125096D, 960641) in a foil and plastic laminate wrapper. The stability data support Becton's proposed expiration period of 24 months.

LABELING:
Labeling was found satisfactory by L. Golson on February 22, 2000.

STERILIZATION VALIDATION *(If applicable)*:
N/A

SIZE OF BIO BATCH *(Firm's source of NDS ok?)*:
The bulk solution of drug substance (Hibiclens® solution) is manufactured by Zeneca Pharmaceutical inc. (formerly Stuart Pharmaceutical) under NDA 18-423. Becton packages the bulk Hibiclens® solution into Scrub-Brush/Sponge product and controls.
The size of bio Lot #02122234E (foil film) is units packaged in August 1992.

SIZE OF STABILITY BATCHES *(If different from bio batch, were they Manufactured via the same process?):*

Lot #M7BX021: units, experimental lot size packaged February 1987.
Lot #M7BL880: units, packaged February 1987.
Batch 02124291A units, packaged September 1994.
Batch 2125096D: units, packaged April 1995.
Batch 960641: units, packaged June 1996.
All stability batches and bio batch were manufactured via the same process.

PROPOSED PRODUCTION BATCH - MANUFACTURING PROCESS THE SAME?:
Most recent batch size (12-15-98) is sponge/brush units of lot 981204 and no change has been indicated for the manufacturing process.

Signature of chemist:	Signature of supervisor:
Gill Kang /S/ 2-23-00	Paul Schwartz PS 2/23/00

V:\FIRMSAM\BECTON\LTRS&REV\73416NA1.APP

1. CHEMIST'S REVIEW NO.#1

2. ANDA # 73-416

3. NAME AND ADDRESS OF APPLICANT
Deseret Medical, Inc.
9450 South State Street
Sandy, Utah 84070

4. AF NUMBER
N/A

5. SUPPLEMENT(s)
N/A

6. PROPRIETARY NAME
E-Z SCRUB® Scrub Brush/Sponge with HIBICLENS

7. NONPROPRIETARY NAME
Chlorhexidine Gluconate

8. SUPPLEMENT(s) PROVIDE(s) FOR:
N/A

9. AMENDMENTS AND OTHER DATES:

Firm:

-Original submission	8/28/89
-G.C. addressing patent certification issue	9/27/89
-Analytical methodology and methods validation and request for bio waiver.	9/25/89
-G.C. regarding patent issues	11/17/89
-G.C. regarding clarification of reason for filing this application.	1/2/90
-G.C. requesting status of application	3/5/90
-G.C. requesting guidance on filing for site change.	3/6/90
-Letter clarifying relationships of Deseret and Stuart applications for various forms of CHG.	3/21/90
-G.C. regarding requirements to support an additional indication for CHG and CHG sponges.	5/3/90
-Status inquiry	1/14/91
-Status inquiry	1/31/91
-G.C. regarding 3/5/, 3/22, and Clarification of Labeling issues	3/25/91

FDA:

-EER update	9/13/89
-Acknowledgement of receipt	9/18/89
-Microbiology consult-denial of request for bio waiver.	11/1/89
-Reply to status inquiries	2/28/91
-Telecon to clarify relationship among the several ANDA's for this product.	3/12/91
-Telecon re: labeling	3/22/91
-R.C. Adams memo to R. Chastenay re: labeling	4/2/91
-R.C. Adams memo to Dr. R. Jerussi re: this ANDA	5/8/91

10. PHARMACOLOGICAL CATEGORY
Antimicrobial

11. Rx or OTC
OTC

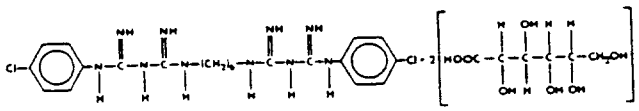
12. RELATED IND/NDA/DMF(s)
ANDA#72-525 - Deseret - 4 % CHG sponge (approved-10/24/89)
#17-768 - Stuart - 4 % CHG solution (approved-
#18-423 - Stuart - 4 % CHG sponge (approved-

DMF

13. DOSAGE FORM
Topical

14. POTENCY
4 %

15. CHEMICAL NAME AND STRUCTURE
2,4,11,13-Tetraazatetradecanediimidamide,N,N''-bis(4-chlorophenyl)-3,12-diimino-,di-D-gluconate.



16. RECORDS AND REPORTS
N/A

17. COMMENTS
This application is but one of five applications either issued or pending to Stuart Pharmaceuticals or Deseret Medical for various forms of Chlorhexidine Gluconate (CHG). Deseret does not manufacture CHG 4% solution - the firm simply buys bulk 4% CHG solution from for bottling and sells it as a topical solution or impregnated in sponges, a 4 % solution in both cases. A summary of these ANDA's follows:

	NDA	SPONSOR	APPROVAL DATE	TYPE	NAME
1.	17-768	Stuart	?	4% sol'n	Hibiclens
2.	18-423	Stuart	?	sponge	Hibiclens
3.					
4.	72-525*	Deseret	10/24/89	sponge	EZ SCRUB®107
5.	73-416*	Deseret	this application	sponge	EZ SCRUB®with Hibiclens

*ANDA

This application was submitted in order to allow Deseret to market a product which is absolutely identical to the product marketed under ANDA#18-423, owned by Stuart. In that application is a contract manufacturer for whereby they impregnate the Scrub-Brush Sponges with 4% CHG Solution supplied by The product prepared and marketed under ANDA#72-525 by Deseret is also identical to this product but does not say "with Hibiclens" on the label. This labeling apparently allows applicant to command a higher price. Applicant's additional reasons for submitting this application are set forth in greater detail in letters of 3/5, 3/22, and 3/25/91.

Following acknowledgement of receipt of this submission on 8/28/89, Mr. A. T. Sheldon performed a microbiological review of the request for waiver of in vivo bioequivalency requirements and he recommended that the request be denied basically because of lack of submitted evidence of equivalence. This review was the basis for an N/A letter sent out on 12/26/89. Applicant responded with an explanatory letter on 3/21/90. After reviewing this letter, Mr. Sheldon concluded that since the subject of this application is in fact identical to a product already on the market made in the same facility,etc. that the recommendation for waiver should be granted and summarized these findings in a 4/26/90 memo.

A review of this ANDA at the Office level resulted in the opinion that since this application is for a product already covered by an approved NDA (18-423), it does not comply with CFR 314.101(e)(1). (See letter).

A labeling review was the subject of a 10/6/89 memo by Y. Mille(copy attached). Several deficiencies were noted and will be communicated to firm at this time.

This application is not approvable due to the fact that it is identical to the product covered by NDA 18-423 [approved] and therefore not in compliance with 21 CFR 314.101(e)(1) which prohibits the filing for a drug product already covered by an approved admission.

18. CONCLUSIONS AND RECOMMENDATIONS
Not approvable.

19. REVIEWER
R.C.Adams

DATE COMPLETED
7/16/91 7/15/91

/S/ 7/16/91

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Chem. Review #1

1. CHEMISTRY REVIEW NO.: #3

2. ANDA # 73-416

3. NAME AND ADDRESS OF APPLICANT

Becton Dickinson AcuteCare
Attention: George Nolan
9450 South State Street
Sandy, Utah 84070-3234

4. BASIS OF SUBMISSION

Original Application

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

E-Z Scrub Brush/Sponge with HIBICLENS

7. NONPROPRIETARY NAME

Chlorhexidine Gluconate

8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A

9. AMENDMENTS AND OTHER DATES:

Original submission: 8-28-89
Label Review: 10-6-89
Letter, specify mfg. site: 6-20-91
Chemistry Review #1: 7-15-91
Deficiency letter #1: 8-2-91
Minor Amendment: 9-10-91
Letter, any questions, call R. Castor: 11-18-91
Deficiency letter #2 (no Review #2): 2-18-92
Phone memo, K. Johnson, ref. of Stuart NDA data: 3-5-92
Letter, can we change the package?: 3-31-92
Phone memo, J. Dawson, request for pkg. stab. data: 4-10-92
Letter, can we start the bio./stab. study?: 5-19-92
Micro-consult report: 7-7-92
Deficiency letter, micro-consult: 8-4-92
Deficiency letter, bio. & stab. must be done: 2-18-93
Deficiency letter, suggest Appl. withdrawl: 3-24-93
Letter, we don't intend to withdraw: 4-13-93
Amendment, bio and stability studies: 5-7-93
Letter, we will clarify any questions: 5-18-93
Phone memo, C. Parise, need a 356h form: 7-27-93

10. PHARMACOLOGICAL CATEGORY

Anti-microbial

11. Rx or OTC

OTC

12. RELATED IND/NDA/DMF(s): **SATISFACTORY per Review #1**

ANDA #72-525: Deseret 4% CHG sponge (Appr. 10-24-89)
NDA #17-768: Stuart 4% CHG solution (Appr.)
NDA #18-423: Stuart 4% CHG sponge (Appr.)
NDA
DMF

13. DOSAGE FORM

Topical

14. POTENCY

4%

15. CHEMICAL NAME AND STRUCTURE: **SATISFACTORY per Review #1**

16. RECORDS AND REPORTS: N/A

17. COMMENTS

18. CONCLUSIONS AND RECOMMENDATIONS: **NOT APPROVABLE, MAJOR**

19. REVIEWER:

Timothy A. Anderson

Endorsed by P.Schwartz, Ph.D

DATE COMPLETED:

August 03, 1993

October 13, 1993

10-21-93

cc: ANDA #73-416
ANDA #73-416/DUP/Division File

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Chem Review #3

OFFICE OF GENERIC DRUGS

Review of Amendment to ABBREVIATED NEW DRUG APPLICATION

ANDA: 73-416

CHEMIST'S REVIEW NO. 4 (four)

NAME AND ADDRESS OF APPLICANT:

Becton Dickinson AcuteCare
Div. Becton Dickinson and Company
Attention: George Nolan
9450 South State Street
Sandy, Utah 84070

Tel: (801) 565-2300
Fax: (801) 565-2740

PURPOSE OF AMENDMENT:

Response to deficiency letter dated 11-2-93.

DATE(S) OF SUBMISSION(S):

8-28-89	Date of ANDA submission
11-2-93	Deficiency letter based on Review # 3 dated 8-3-93
5-30-95	Response to deficiency letter of 11-2-93 (CMC issues)
6-28-95	Response to deficiency letter of 11-2-93 (label issues)
7-14-95	Request letter for additional bioequivalence data

(Note: See Review #3 for an extensive list of previous dates.)

PHARMACOLOGICAL CATEGORY:

Topical antibacterial; disinfectant

TRADE NAME:

E-Z SCRUB 106
Antimicrobial Surgical Scrub Brush/Sponge

NONPROPRIETARY NAME:

Chlorhexidine Gluconate 4% w/v

DOSAGE FORM:	POTENCY:	RX OR OTC:
Topical	4%	OTC

SAMPLES:

Applicant has acknowledged that samples will be requested for the purposes of methods validation.

RELATED IND/NDA/DMF:

DMF

STERILIZATION:

Not applicable.

LABELING:

Comments to be reviewed and any comments to communicated to applicant.

BIOEQUIVALENCY STATUS:

Bioequivalence evaluation is still under evaluation. A letter has been sent to the applicant requesting additional information (7-14-95).

ESTABLISHMENT INSPECTION:

To be issued at the appropriate time.

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS:

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REMARKS AND CONCLUSION:

Minor amendment pending bioequivalence review.

ORDER OF REVIEW:

The application submission(s) covered by this review was taken in the order of receipt:

Yes___XXX____ No_____

If no, explain reason(s) below:

RECALLS:
None

Reviewer:
A.J. Mueller

Date Completed:
August 31, 1995

cc: ANDA #73-416
ANDA #73-416/Division File
Field Copy

/S/

Not Approvable - ~~Major~~
Minor

Review of Amendment to ABBREVIATED NEW DRUG APPLICATION

1. CHEMISTRY REVIEW NO.: 5

2. ANDA #: 73-416

3. NAME AND ADDRESS OF APPLICANT:

Becton Dickinson AcuteCare
Div. Becton Dickinson and Company
Attention: George Nolan
9450 South State Street
Sandy, Utah 84070

Tel: (801) 565-2659
Fax: (801) 565-2430

4. LEGAL BASIS FOR SUBMISSION: See review No.1

5. SUPPLEMENT(s): N/A

6. PROPRIETARY NAME:

E-Z SCRUB® 106

7. NONPROPRIETARY NAME:

Chlorhexidine Gluconate 4% w/v

8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A

9. AMENDMENTS AND OTHER DATES:

8-28-89	Date of ANDA submission.
(See Review #3 for an list of previous dates)	
11-2-93	Deficiency letter based on Review #3 dated 8-3-93.
5-30-95	Response to deficiency letter of 11-2-93 (CMC issues).
6-28-95	Response to deficiency letter of 11-2-93 (label issues).
7-14-95	Request letter for additional bioequivalence data.
8-28-95	Response to request letter of 7-14-95.
2-13-96	NA letter based on Review # 4.
2-22-96	Request of method validation.
3-5-96	Request of inspection.
3-27-96	Response to letter of 2-13-96.
3-12-97	The result of method validation.

3-26-97 Consult result from the Division of Anti-infective Drug Products appended with Statistical review suggested reservations on accepting the bioequivalence study dated 10-24-95.
5-28-97 Bioequivalence review on amendment dated 7-14-95.
1-15-98 Minor amendment

10. PHARMACOLOGICAL CATEGORY:
Topical antibacterial; disinfectant

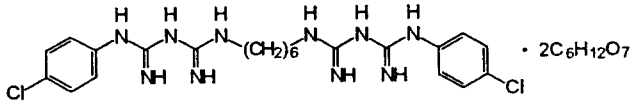
11. Rx or OTC: OTC

12. RELATED IND/NDA/DMF(s):
DMF

13. DOSAGE FORM: Topical

14. POTENCY: 4%

15. CHEMICAL NAME AND STRUCTURE:
2,4,11,13-Teraazateradecanediimidamide, *N,N*"-bis(4-chlorophenyl)-3,12-diimino-, di-D-gluconate.
$C_{22}H_{30}Cl_2N_{10} \cdot 2C_6H_{12}O_7$. Mol. Wt 897.77.



16. RECORDS AND REPORTS:
The result of method validation is described on the review

17. COMMENTS:
Comments are described in the review

18. CONCLUSIONS AND RECOMMENDATIONS:
The amendment is not responded satisfactorily.
The application is not approvable.

19. REVIEWER: Gil Kang DATE COMPLETED: 3-9-98

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Chem Review #5

AADA/ANDA: 73-416 APPLICANT: Becton Dickinson AcuteCare

DRUG PRODUCT: E-Z SCRUB® (Chlorhexidine 4% Gluconate Scrub-Brush/Sponge)

The deficiencies presented below represent MINOR deficiencies.

A. Deficiencies:

Redacted 1

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Specs

Sincerely yours,

/S/ 3/17/98

Rashmikant M. Patel, Ph.D.

Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 73-416
ANDA 73-416/Division File
Field Copy
HFD-600/Reading file
HFD-92

NOT APPROVABLE - Minor

Review of Amendment to ABBREVIATED NEW DRUG APPLICATION

1. CHEMISTRY REVIEW NO.: 6

2. ANDA #: 73-416

3. NAME AND ADDRESS OF APPLICANT:
Becton Dickinson Division
Attention: George Nolan
9450 South State Street
Sandy, Utah 84070

Tel: (801) 565-2659
Fax: (801) 565-2430

4. LEGAL BASIS FOR SUBMISSION:

This ANDA was submitted as a hand scrub. This is for a product (antimicrobial surgical scrub brush/sponge) packaged and controlled by Becton Dickinson Division (formerly Becton Dickinson AcuteCare Division, and before that Deseret Medical) using the bulk Hibiclens solution obtained from

This product is identical to the product marketed over ten years under Zeneca NDA 18-423. With approval of this application, Becton can operate its packaging and testing without Zeneca's oversight.

The authorization letter from to refer to this NDA 18-423 for Hibiclens® (Chlorhexidine Gluconate) Sponge Brush has been provided (page 15, vol. No.1).

5. SUPPLEMENT(s): N/A

6. PROPRIETARY NAME:
E-Z SCRUB® 106

7. NONPROPRIETARY NAME:
Chlorhexidine Gluconate 4% w/v Scrub-Brush/Sponge

8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A

9. AMENDMENTS AND OTHER DATES:

8-28-89 Date of ANDA submission.
(See Review #3 for an list of previous dates)

11-2-93	Deficiency letter based on Review #3 dated 8-3-93.
5-30-95	Response to deficiency letter of 11-2-93 (CMC issues).
6-28-95	Response to deficiency letter of 11-2-93 (label issues).
7-14-95	Request letter for additional bioequivalence data.
8-28-95	Response to the letter of 7-14-95.
2-13-96	NA letter based on Review # 4.
2-22-96	Request of method validation.
3-5-96	Request of inspection.
3-27-96	Response to letter of 2-13-96.
3-12-97	The result of method validation.
3-26-97	Consult result from the Division of Anti-infective Drug Products appended with Statistical review suggested reservations on accepting the bioequivalence study dated 10-24-95.
5-28-97	Bioequivalence review on amendment dated 7-14-95 (acceptable).
1-19-98	Response to deficiency letter of 2-13-96.
3-13-98	NA letter based on review # 5.
10-5-98	Response to deficiency letter of 3-13-98 (chemistry).
11-2-98	Response to deficiency letter of 3-13-98 (labeling).
12-5-98	Telephone amendment (regarding the response of 10-5-98).
12-22-98	Telephone amendment by fax.
1-25-99	Response to the request for validation samples.
2-9-99	Phone amendment by fax regarding site withdrawal.
4-19-99	Phone amendment regarding method validation.
6-25-99	Phone amendment regarding method validation.

10. PHARMACOLOGICAL CATEGORY:
Topical antibacterial; disinfectant

11. Rx or OTC: OTC

12. RELATED IND/NDA/DMF(s):
DMF

DMF
DMF

13. DOSAGE FORM: Sponge/Brush

14. POTENCY: 4%

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Chem Review #6

38. Chemistry Comments to be Provided to the Applicant

ANDA: 73-416 APPLICANT: Beckton Dickinson Division

DRUG PRODUCT: Chlorhexidine Gluconate 4% w/v Scrub-Brush/Sponge

The deficiency presented below represent a Minor deficiency.

A. Deficiency:

DMF for Chlorhexidine Gluconate 20% solution, as referenced in NDA 18-423 for Chlorhexidine Gluconate 4% w/v, is inadequate. The DMF holder has been notified of the deficiencies. Please do not respond to this letter until you have obtained a letter from the DMF holder stating that the DMF deficiencies have been satisfactorily resolved.

B. In addition to responding to the deficiency presented above, please note and acknowledge the following comment in your response.

Firms referenced in this ANDA and Zeneca Pharmaceuticals in England, manufacturer of Chlorhexidine Gluconate 20% solution, should be in compliance with current good manufacturing practices at the time of approval.

Sincerely yours,

/S/

Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

MAR 13 1998

AADA/ANDA: 73-416 APPLICANT: Becton Dickinson AcuteCare

DRUG PRODUCT: E-Z SCRUB® (Chlorhexidine 4% Gluconate Scrub-Brush/Sponge)

The deficiencies presented below represent MINOR deficiencies.

A. Deficiencies:

Redacted 1

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Specifications

Sincerely yours,

/S/

Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

Review of Amendment to
ABBREVIATED NEW DRUG APPLICATION

1. CHEMISTRY REVIEW NO.: 7

2. ANDA #: 73-416

3. NAME AND ADDRESS OF APPLICANT:
Becton Dickinson Division
Attention: Jane Stickel
9450 South State Street
Sandy, Utah 84070

Tel: (801) 565-2300
Fax: (801) 565-2740

4. LEGAL BASIS FOR SUBMISSION:

This ANDA was submitted as a hand scrub. This is for a product (antimicrobial surgical scrub brush/sponge) packaged and controlled by Becton Dickinson Division (formerly Becton Dickinson AcuteCare Division, and before that Deseret Medical) using the bulk Hibiclens solution obtained from

This product is identical to the product marketed over ten years under Zeneca NDA 18-423. With approval of this application, Becton can operate its packaging and testing without Zeneca's oversight.

The authorization letter from to refer to this NDA 18-423 for Hibiclens® (Chlorhexidine Gluconate) Sponge Brush has been provided (page 15, vol. No.1).

5. SUPPLEMENT(s): N/A

6. PROPRIETARY NAME:
E-Z SCRUB® 106

7. NONPROPRIETARY NAME:
Chlorhexidine Gluconate 4% w/v Scrub-Brush/Sponge

8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A

9. AMENDMENTS AND OTHER DATES:

8-28-89 Date of ANDA submission.

(See Review #3 for an list of previous dates)

11-2-93	Deficiency letter based on Review #3 dated 8-3-93.
5-30-95	Response to deficiency letter of 11-2-93 (CMC issues).
6-28-95	Response to deficiency letter of 11-2-93 (label issues).
7-14-95	Request letter for additional bioequivalence data.
8-28-95	Response to the letter of 7-14-95.
2-13-96	NA letter based on Review # 4.
2-22-96	Request of method validation.
3-5-96	Request of inspection.
3-27-96	Response to letter of 2-13-96.
3-12-97	The result of method validation.
3-26-97	Consult result from the Division of Anti-infective Drug Products appended with Statistical review suggested reservations on accepting the bioequivalence study dated 10-24-95.
5-28-97	Bioequivalence review on amendment dated 7-14-95 (acceptable).
1-19-98	Response to deficiency letter of 2-13-96.
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10-5-98	Response to deficiency letter of 3-13-98 (chemistry).
11-2-98	Response to deficiency letter of 3-13-98 (labeling).
12-5-98	Telephone amendment (regarding the response of 10-5-98).
12-22-98	Telephone amendment by fax.
1-25-99	Response to the request for validation samples.
2-9-99	Phone amendment by fax regarding site withdrawal.
4-19-99	Phone amendment regarding method validation.
6-25-99	Phone amendment regarding method validation.
10-22-99	NA letter based on review # 6.
1-13-00	Response to deficiency letter of 10-22-99.

10. PHARMACOLOGICAL CATEGORY:
Topical antibacterial; disinfectant

11. Rx or OTC: OTC

12. RELATED IND/NDA/DMF(s):
DMF

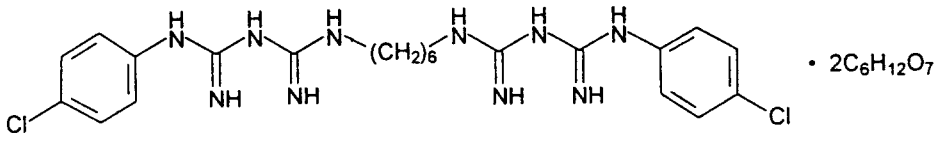
DMF
DMF

NDA 18-423 Hibiclens; Zeneca

13. DOSAGE FORM: Sponge/Brush

14. POTENCY: 4%

15. CHEMICAL NAME AND STRUCTURE:
2,4,11,13-Tetraazatetradecanediimidamide, *N,N"*-bis(4-chlorophenyl)-3,12-diimino-, di-D-gluconate. $C_{22}H_{30}Cl_2N_{10}\bullet 2C_6H_{12}O_7$.
Mol. Wt 897.77.



16. RECORDS AND REPORTS:
The result of method validation from FDA Denver laboratory (3-12-97) is described in the review item #31. After receiving comments from FDA Denver laboratory, firm proposed to change assay method for from In addition, they modified the assay method for chlorhexidine.

The assay for chlorhexidine from bulk solution products and final scrub products (CAP 17) and the assay for from bulk solution products and final scrub products (CAP 66) were sent to FDA Seattle laboratory for method validation. The result of method validation are satisfactory with the responses (4-19-99 and 6-25-99 amendments) to the deficiencies. See review item #31.

17. COMMENTS: None

18. CONCLUSIONS AND RECOMMENDATIONS:

The application is **approvable.**

19. REVIEWER: Gil Kang DATE COMPLETED: 7-FEB-2000
corrected: 29-FEB-2000

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Chem Review #7

OCT 2 2 1999

38. Chemistry Comments to be Provided to the Applicant

ANDA: 73-416 APPLICANT: Beckton Dickinson Division

DRUG PRODUCT: Chlorhexidine Gluconate 4% w/v Scrub-Brush/Sponge

The deficiency presented below represent a Minor deficiency.

A. Deficiency:

DMF for Chlorhexidine Gluconate 20% solution, as referenced in NDA 18-423 for Chlorhexidine Gluconate 4% w/v, is inadequate. The DMF holder has been notified of the deficiencies. Please do not respond to this letter until you have obtained a letter from the DMF holder stating that the DMF deficiencies have been satisfactorily resolved.

B. In addition to responding to the deficiency presented above, please note and acknowledge the following comment in your response.

Firms referenced in this ANDA and Zeneca Pharmaceuticals in England, manufacturer of Chlorhexidine Gluconate 20% solution, should be in compliance with current good manufacturing practices at the time of approval.

Sincerely yours,

/S/

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