CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

73416

ADMINISTRATIVE DOCUMENTS

REVIEW OF PROFESSIONAL LABELING

ANDA

DRAFT - Container Labels, Carton Labeling

DATE OF REVIEW: 10-6-89

ANDA #:73-416 NAME OF FIRM: Deseret Medical Inc.

NAME OF DRUG: Trade: E-Z Scrub
Generic: Chlorhexidine Gluconate Scrub-Brush/Sponge, 4%

DATE OF SUBMISSION: 8-28-89

COMMENTS:

CONTAINER: Not Satisfactory

A. Main Panel

1. Revise the lines beneath "E-Z Scrub" to read:

   Antimicrobial Surgical Scrub Brush/Sponge with
   HIBICLENS*
   *Filled with...

2. We note you have included the word "antiseptic" on the main panel. Please explain why you believe the antiseptic claim for Hibiclens Topical Solution is applicable to your Scrub Brush/Sponge.

3. Chlorhexidine gluconate (rather than E-Z Scrub sponge/brush) provides rapid bactericidal action...

4. Add "Discard After Use". It should appear after "For Single Use Only".

5. Add the temperature in degrees Celsius to the storage recommendations. ...40°C (104°F).

6. We encourage you to include the words "FOR SURGICAL HAND SCRUB" on the label.

B. WARNINGS

Revise this statement to read:

WARNINGS: FOR EXTERNAL USE ONLY. KEEP OUT OF EYES, EARS AND MOUTH. CHLORHEXIDINE CONTAINING PRODUCTS SHOULD NOT BE USED AS A PREOPERATIVE SKIN PREPARATION OF THE FACE AND HEAD. MISUSE OF CHLORHEXIDINE CONTAINING PRODUCTS HAS BEEN REPORTED TO CAUSE SERIOUS AND PERMANENT EYE INJURY WHEN PERMITTED TO ENTER AND REMAIN IN THE EYE DURING SURGICAL PROCEDURES. IF HIBICLENS SHOULD CONTACT THESE AREAS, RINSE OUT PROMPTLY AND THOROUGHLY WITH WATER. Avoid contact with

meninges. This product should not be used by persons who have a sensitivity to it or its components. Chlorhexidine gluconate has been reported to cause deafness when instilled in the middle ear through perforated ear drums. Irritation, sensitization and generalized allergic reactions have been reported with chlorhexidine-containing products, especially in the genital areas. If adverse reactions occur, discontinue use immediately and if severe, contact a physician.

Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

C. Directions For Use - Please revise this section so it is in accord with the directions for use which appear on your other chlorhexidine gluconate scrub-brush/sponge [ANDA 72-525].

CARTON: Not Satisfactory

A. See comments A and B under Container.

B. Be sure the words "FOR SURGICAL HAND SCRUB" remain on the carton labeling.

C. Directions For Use
Item 4, sentence 2 - The word "Repeat" should appear in bold print.

Additional Comment

We are considering the proper statement of manufacturer for this product. We would like you to make comment as to why you are the sole manufacturer. [Please refer to 21 CFR 201.1 for additional information.]

Chemist has determined this statement is not appropriate [illegible] 12/6/91

RECOMMENDATIONS:

1. Inform the firm of the above comments.

2. Request the firm revise their labels and labeling, then prepare and submit draft copy for our review and comment.

3. Chemist

   a. Has the firm provided data to support the storage recommendations? In other words, have studies been done at 40°C (104°F).

   b. Please confirm the inactive ingredients as they appear on the label.

4. FOR THE RECORD

A. I am concerned about the statement of manufacturer. Should this be a "jointly manufactured by" statement? Could it be covered by 21 CFR 201.1(c)(2) since BD "fills" this sponge with solution.

B. See comment A.2. under Container. Should the word "antiseptic" be a carryover claim since Hibiclens has this claim? or does the packaging of this product influence the claim?

/S/
/Yana Mille

10/12/89 10/12/89

cc: YMille/TPoux/sb/10/11/89
8391A pg: 2-4 /REV. OF PROF. LBL.

May 8, 1991

TO: Dr. R. A. Jerussi

FROM: R.C. Adams

SUBJECT: ANDA 73-416

Since much confusion reigns in nearly everyone's mind concerning this and related applications I thought that it would be helpful to take a stab at clarifying some of the issues.

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 Chlorhexidine base. The firm either buys bulk Chlorhexidine Digluconate already prepared by and sells it as a topical solution or impregnated in sponges (a 4 % solution in both cases) or buys the Chlorhexidine base from one of three suppliers and then prepares the digluconate by Thus when Deseret prepares its own CHG from purchased base, the firm cannot include "with Hibiclens" in the labeling (since Hibiclens is the registered trademark of CHG) which means that the product commands a lower price, hence the reason for Deseret's desire to market the product which is the subject of this application. A summary of these ANDA's follows:

	ANDA	SPONSOR	CHG SOURCE	TYPE	NAME
1.	17-768	Stuart	Stuart	4% sol'n	Hibiclens
2.	18-423	Stuart	Stuart	sponge	Hibiclens
3.					
4.	72-525	Deseret	Deseret	sponge	EZ SCRUB®107
5.	73-416	Deseret	Stuart	sponge	EZ SCRUB®with Hibiclens

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. The product marketed under ANDA#72-525 by Deseret is also the same as this product but the CHG is prepared by Deseret from purchased base and thus does not say "with Hibiclens" on the label. This labeling apparently allows applicant to command a higher price.

As regards the stability questions raised by you, applicant states "...the applicator (brush/sponge), the packaging material, the packaging process, the drug component, the fill volume, and in process controls are unchanged from those approved via NDA 18-423. That is, the stability of the product has already been established for the product.....Also, although E-Z SCRUB® 106 was technically a Stuart Pharmaceuticals product covered by their NDA 18-423, we did run routine checks. Data demonstrating stability in excess of 24 months is included." (see pp.311-359 for actual stability data). In addition, the firm includes a stability commitment on page 310.

I hope the foregoing clarifies this confusing situation. Perhaps after you have had time to look at this memo it would be useful for us (RAJ, JDH, KRJ, RCA) to have one more meeting so that we can finally reach a conclusion on the appropriate course of action for this application.

/S/
R. C. Adams

cc:
JHarrison
KJohnson
YMille

RECORD OF TELEPHONE CONVERSATION/MEETING

DATE: April 25, 1991

NDA NUMBER:

IND NUMBER:

TELECON/MEETING

INITIATED BY: ☐ APPLICANT/SPONSOR ☐ FDA

MADE: ☐ BY TELEPHONE ☐ IN PERSON

PRODUCT NAME: Chlorhexidine gluconate sponge

FIRM NAME: Desert

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD: Dick Christovey, Chief, DDL C

TELEPHONE NO.:

Dick Christovey returned a tele call to me on the subject of the Desert Sponge - Hibiclens - single mfgr issue, in response to our consult on this topic of several weeks ago. ← Div of Drug Labeling Compl

their discussions concluded that:

1) if Hibiclens/Stuart were not noted, then there is no problem with single mfgr.

2) because Desert chose to prominently cite Hibiclens, they have introduced a new issue into the problem, and there is some objection to noting only one mfgr.

MY OWN NOTES —

1) I did not feel this recommendations were especially strong, as were given with much conviction.

2) I do not believe the variable cited has any relevance to one vs two mfgrs.

3) I do not believe we should feel obligated to follow the comments, if we have a supportable reason to vary.

SIGNATURE: /S/

DIVISION:

FORM FD 2587 (11/77)

ORIGINAL IND/NDA

(117)

April 2, 1991

TO: Mr. R. Chastenay

FROM: R.C. Adams

SUBJECT: ANDA 73-416 Proposed Labeling

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 - the firm simply buys bulk CHG from Stuart and sells it as a topical solution or impregnated in sponges, a 4 % solution in both cases. A summary of these ANDA's follows:

	ANDA	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

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. The product 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.

Attached is a 3/22/91 letter from applicant with copies of existing labeling under the approved NDA 18-423 (Stuart) facing the proposed labeling under the pending ANDA 73-416. Also attached is a 3/25/91 letter from applicant elaborating upon the rationale for the proposed labeling under ANDA 73-416.

Do you think applicant's proposal for labeling is satisfactory or is a statement regarding "jointly manufactured" on the label preferable?

My telephone number is 295-8370 should you require additional information. I am trying to take action on this application before I leave for a trip/vacation this Saturday.

Thank you for your time.

Sincerely yours,

Richard C. Adams

cc:
JHarrison
KJohnson

M E M O R A N D U M

Department of Health & Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research

DATE: February 22, 1991

TO: Robert Pollock

FROM: Roger L. Williams

SUBJECT: Deseret Medical

Would you please review attached letter and give me an update so that I can respond to the firm in writing? Thank you.

It is in your in Box
Bob

RECORD OF TELEPHONE CONVERSATION/MEETING

DATE
March 12, 1991

NDA NUMBER
73-416

IND NUMBER

TELECON/MEETING

INITIATED BY
☐ APPLICANT/SPONSOR
☒ FDA

MADE
☒ BY TELEPHONE
☐ IN PERSON

PRODUCT NAME
CHLORHEXIDINE GLUCONATE (CHG)

FIRM NAME
DESERET MEDICAL

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD
Charles Welle
Director, Regulatory affairs

TELEPHONE NO.
801-565-2300

I called this firm to attempt to clarify, in my mind, the relationship that Deseret has with Stuart (their supplier of bulk CHG) and the relationship among the five ANDA's either resined or pending to/for Deseret/Stuart/CHG topical solution and impregnated sponges. Mr. Welle's explanation was lengthy, confused, etc. but the essence of my understanding can be found in the Comments section of the review for ANDA-73-416, to be issued shortly ~~for at least forwarded to labels~~ (will be an N/A letter due to labeling deficiencies).

SIGNATURE
/S/

DIVISION
OGD, Div II.

FORM FD 2587 (11/77)

DIVISION FILE

U. S. GOVERNMENT PRINTING OFFICE-1984-421-976/7126

RECORD OF TELEPHONE CONVERSATION/MEETING

DATE
Mar. 22, 1991

NDA NUMBER
ANDA - 73-416

IND NUMBER

TELECON/MEETING

INITIATED BY
☐ APPLICANT/SPONSOR
☒ FDA

MADE
☒ BY TELEPHONE
☐ IN PERSON

PRODUCT NAME
Chlorhexidine Gluconate

FIRM NAME
Deseret Medical

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD
Charles Welle
Mgr. Regulatory Affairs

TELEPHONE NO.
801-565-2300

Background:

The Welby Labeling Review Branch (Yona Wille) expressed concern that the proposed labeling should attribute manufacture of Hibiclens to Stuart Pharmaceutical since Deseret does no further processing of the solution but merely impregnate the sponges and wrappers. We (DOH/RCA) discussed this subject at length with Tom Temple/Yona Wille/K. Johnson. Mr. Johnson then discussed the topic with Mr. Tripp and Mr. Chesney who suggested that we solicit further justification from the firm for the proposed labeling.

Before:

I called Mr. Welle and suggested that he do one of two things:

1) revise the labeling to attribute manufacture of Hibiclens to Stuart
2) send a letter to us articulating Deseret's rationale for ~~eg~~ excluding Stuart.

He indicated he would talk to marketing, Stuart, and get back to me.

NATURE
|S|

DIVISION
CGD

JM FD 2587 (11/77)

DIVISION FILE

U. S. GOVERNMENT PRINTING OFFICE-1984-421-576/7126

RECORD OF TELEPHONE CONVERSATION/MEETING

DATE: 3-5-92 3:00 — 3:30pm

NDA NUMBER: 73-416

IND NUMBER:

TELECON/MEETING

INITIATED BY: ☒ APPLICANT/SPONSOR ☐ FDA

MADE: ☐ BY TELEPHONE ☐ IN PERSON

PRODUCT NAME: CHG Scrub Brush

FIRM NAME: Deseret (Becton-Dickinson

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD: Wells C, Noland G, Lamm, Kahn Mohammed, Johnson K, Pollock R, Hare D

TELEPHONE NO.:

Tele conf call between Deseret & FDA to discuss the FDA letters of Aug 2, 91 and Feb 18, 92 and the BD letter of Sept 10, 91.

At issue is the rationale and need to provide data from a special batch under the proposed ANDA, when it is made in the same manner as the Stuart NDA.

The FDA reps made it clear that such info was necessary to support an ANDA. Also, if right of reference was granted from the Stuart Hibiclens appl., then it must be clearly noted date and page of reference; and supplements must be filed in the ANDA as approp, whenever the Hibiclens changes.

Johnson asked BD to submit a letter of their intent and we could answer promptly.

SIGNATURE: /S/

DIVISION:

FORM FD 2587 (11/77) ORIGINATOR

REVIEW OF PROFESSIONAL LABELING - #2

Orig. Amendment

DRAFT - Container and Carton Labeling

DATE OF REVIEW: 8-24-93

ANDA #: 73-416

NAME OF FIRM: Becton Dickinson AcuteCare

NAME OF DRUG: Trade: E-Z Scrub 106
Generic: Chlorhexidine Gluconate Scrub Brush Sponge, 4%

DATE OF SUBMISSION: 9-10-91

COMMENTS:

General Comment:

Please revise your labels and labeling to include the established name with your tradename, as follows:

E-Z Scrub® 106 Antimicrobial Surgical Scrub Brush/Sponge with Hibiclens® (Chlorhexidine Gluconate 4% w/v)

Container:

1. Warnings Statement

   a. Line 4 - Revise to read:

      ... **WHEN PERMITTED** ... (Delete)

   b. Delete the storage recommendations from this section.

   c. Line 10 -

      ... and, if severe, contact ... (add comma)

2. Directions for use - Revise as follows:

   DIRECTIONS FOR USE - 6 MINUTE SCRUB.

   1. Wet hands and forearms with warm water.
   2. Use nail cleaner and then apply chlorhexidine gluconate from sponge side. Work up lather.
   3. Scrub difficult areas thoroughly for 3 minutes with brush side and the hands and forearms with the sponge side.
   4. Rinse with warm water.

5. **REPEAT** scrub for 3 more minutes, use sponge side only.
6. Rinse hands and arms thoroughly.
7. Dry thoroughly.

Carton: 30's

1. Warnings statement

   a. Line 6 - Revise to read:

      ... WHEN PERMITTED ... (Delete

   b. Delete the storage recommendations from this section.

   c. Line 14 -

      ... and, if severe, contact ... (add comma)

2. Directions for Use - Revise to read:

   DIRECTIONS FOR USE:
   Six Minute Scrub Procedure

   1. Wet hands and forearms to the elbows with warm water. Avoid using very cold or very hot water.
   2. Open the package. Use nail cleaner to clean under fingernails. Apply scrub solution from the sponge side and work up an adequate lather on the skin.
   3. Scrub for 3 minutes as follows: With the brush side of the product scrub nails, cuticles and interdigital spaces. With sponge side, scrub the hands and forearms.
   4. Rinse thoroughly with warm water. **Repeat** the scrub using the sponge side only, for an additional 3 minutes. Add water as necessary to product eh desired level of suds.
   5. Discard the used product and rinse hands and arms thoroughly.
   6. Dry thoroughly.

3. See comment (3) under Container.

RECOMMENDATIONS:

1. Inform the firm of the above comments.

2. Request the firm revise their labels and labeling, then prepare and submit twelve final printed container labels and carton labeling. Should further information become available relating to the safety and efficacy of this product, you may be asked to further revise your labeling prior to approval.

3. FOR THE RECORD

a. This review is based on the labeling for ANDA 72-525, approved 10-24-89.

b. Storage/dispensing recommendations:

ANDA: avoid heat above 40°C

NDA: avoid heat above 40°C

/S/ 8-26-93

Khyati Roberts

cc: HFD-638/KRoberts/JPhillips (no cc)
mpd/8/26/93/73416sep.91
REVIEW
Final

/S/ 7/26/93

Record of Telephone Conversation

ANDA #73-416
Product: Chlorhexidine gluconate
FDA participants: Gil Kang (reviewer), Paul Schwartz (team leader)
Becton Dickinson: George Nolan (QA/RA manager)
Date: February 9, 1999

Becton was called to clarify the release criteria of pH for EZ® scrub 106-5 acceptance form in attachment #3 of the amendment submitted January 25, 1999. Becton responded it is a typographical error and corrected it as In addition, Becton explained that the "specifications for Hibiclens sponge brush drug product" in attachment #3 is Zeneca's release specification.

RECORD OF TELEPHONE CONVERSATION

At Dr. Kang's request, I called the firm for clarification of two issues.

1. Please clarify if lots TSCT 23 and 31 are the same. Also, clarify if lots TSMT 3 and 35 are the same.

2. Provide the lot size for lots:

02122234E
M7BX021
M7BI880

Mr. Nolan will submit a t-amendment by fax.

Cc:
T-con Binder
ANDA

DATE
12/22/98

APPLICATION NUMBER
73-416

IND NUMBER

TELECON

INITIATED BY FDA

PRODUCT NAME
Chlorhexidine Gluconate

FIRM NAME
Becton Dickinson

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD
George Nolan

TELEPHONE NUMBER

SIGNATURE
Joe Buccine

/S/

Record of Telephone Conversation

ANDA #73-416
Product: Chlorhexidine gluconate
FDA participants: Gil Kang (reviewer), Paul Schwartz (team leader)
Becton Dickinson: George Nolan (QA/RA manager)
Date: December 3, 1998

Becton was called to discuss following issues regarding amendment (responses) submitted October 5, 1998, to the deficiency letter of March 13, 1998.

1. Becton was asked to send three copies of updated methods, for method validations to the agency Assay for chlorhexidine from bulk solution products and final scrub products, Assay for from bulk solution products and final scrub products).

2. Beckton committed to add ID test with its method and specification in section 2.2

3. Becton has not observed any other related impurities by the new method for Therefore, they agreed to provide the limit for total impurities as same as that for

FILE

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: July 13, 1995

TO: The File
ANDA 73-416
Chlorhexadine

FROM: J. Gross
Chief, CSO
Division of Bioequivalence

7/12/95

SUBJECT: Disposition of documents from firm, letter dated 4/13/93, and 05/07/93.

These documents and application are being jointly reviewed by HFD-650 and HFD-520. It is customary HFD-520 to complete their review before HFD-650 proceeds with their portion.

HFD-520 has identified some potential problems with the application (see E-mail A. Sheldon, dated 6/22/95), which need to be resolved before HFD-520 will be able to complete the review. HFD-650 will issue a letter to the firm citing the concerns outlined in the afore mentioned E-mail.

Actions:

1. The E-mail from A. Sheldon (HFD-520), dated 6/22/95, will serve to close all outstanding bio-reviews.

2. A letter will issue from HFD-650, to the firm requesting the firm to submit the data requested in the afore mentioned E-mail.

3. When the response is received it will be reviewed per review policy, and the reviews will commence

cc: ANDA 73-416
DIV, Orig

Memorandum of Telephone Conversation

Between: John H. Dawson, Consumer Safety Officer, Chemistry Branch IV, Office of Generic Drugs, (HFD-633)

And: George E. Nolan; Becton Dickinson Acute Care 801-565-2300

Date: 4/10/92

Subject: 73-416 Chlorhexidine Gluconate Scrub-Brush/Sponge (E-Z Scrub)

Summary: I spoke with Mr. Nolan regarding his question regarding a possible packaging change and how this request for change might affect the timing of the application approval. I told him that either an amendment to the original application or a supplement could be submitted in support of the requested change in packaging. I indicated that in support of the change, the firm would need to provide stability data using the same proposed packaging material and that the finished dosage form test material must be from the same lot as the bio batch was made from (or be able to relate it to the bio batch). Also they would need to perform either accelerated stability or actual room temperature stability data to support the new package material. I recommended that all of the data be submitted at one time, but that in either case, the submitted material would be placed in a queue for review processing. He said that the information would be helpful in making their decision.

/S/

John Dawson

CONTROLLED DOCUMENT
CENTER FOR DRUG EVALUATION & RESEARCH
OFFICE OF DRUG EVALUATION II
CONTROL FORM

FROM: Division of Generic Drugs, HFD-630

TO: HFD-520, thru HFD-500

SUBJECT: **Request for Consultation - NDA #73-416 - Chlorhexidine Gluconate - Scrub Brush Sponge**

DATE OF DOCUMENT: May 19, 1992

DATE REFERRED: June 12, 1992

DUE DATE: July 12, 1992

CONTROL NUMBER: 500-0078

ROUTING SECTION

OFFICE	**DATE REFERRED**
HFD-500	June 12, 1992
HFD-520/MML	June 12, 1992 - 6/15/92 6/15/92 @
LG	6/17/92
BOSTWICK D. (for SA)	500-7/14/92
ATS-6/19/92	

INSTRUCTIONS: Please review and comment on clinical protocol for a glove juice evaluation. The firm intends to initiate a bioequivalence study for the chlorhexidine gluconate surgical brush/sponge.

REMARKS: Response thru HFD-500/Lee Ripper/Zulema Collins/ 443-2544/HFD-500/Rm. 13B-28.

COMMENTS:

Dmid 6/19/92 JA

MEMORANDUM

DEPARTMENT OF HUMAN AND HEALTH SERVICES
PUBLIC HEALTH SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: July 7, 1992

FROM: Supervisory Microbiologist 7/8/92
Division of Anti-Infective Drug Products
(HFD-520)

Through: Director, mml 7/13/92
Division of Anti-Infective Drug Products
(HFD-520)

TO: Division of Generic Drugs
(HFD-630)

SUBJECT: NDA# 73-416; Chlorhexidine gluconate-Scrub Sponge Brush Protocol.

The May 21, 1992 submission contains a protocol that is designed to "simulate" a surgical handscrub as performed by a surgeon prior to surgery. The protocol is numbered 920402 and titled Single Blind Surgical Handscrub Evaluation (Glove Juice) of Two Test Products and One Standard Control Product. The study is to be performed by

It should be noted that this is a new test facility that was established by , after he left also located in Since is no longer performing these studies at the we would recommend that an on site inspection be performed of the new facility to assure compliance with good laboratory practices (GLPs).

The protocol was reviewed and found to be satisfactory. The study is designed to obtain 18 evaluable patients per product/control being tested, baseline values will be obtained over a one week period to assure microbial populations of $1x10^5$ cfu/hand and enumerations will be performed using the standard glove occlusion method. However, we have the following recommendations which should allow us to obtain more meaningful results.

1). The positive control, Hibiclens, must be used according to the directions approved for surgical handscrub use. This includes

volume of product, duration of scrub and frequency of scrub.

2). The number of subjects to be enumerated as presented in Table II (Exhibit B) for each time point could be improved to maximize the statistical significance of the results. Instead of performing "Test Week" enumerations on 18 hands at time zero, 9 hands at time 3 hours and 9 hands at time 6 hours (for a total of 36 hands), we would recommend enumerating 12 hands at time zero, 12 hands at time 3 hours and 12 hands at time 6 hours. The equal distribution of subjects should result in better confidence intervals for the 3 and 6 hour time points.

3). The "Study Description and Informed Consent Form" (Addendum I) states in the fourth paragraph of page 1 that enumerations will be performed by This statement should be corrected to reflect the fact that

will be used.

4). The "Study Description and Informed Consent Form" (Addendum I) states in the second paragraph of page 2 that persons having sensitivity or allergy to thetest materials will not participate in the study. How will this be determined? Also, the investigator needs to determine whether the panelist have participated in previous studies of this type. If they have, we would recommend that at least a two week washout period be used before panelist are used again.

5). It is stated in section 7.7, Statistical Analysis, that two final reports will be issued. It should be noted that although a % CHG product is also being tested, our concern is only with the subject of this NDA which is the 4.0% CHG product. If the applicant is considering submission of an NDA for the % CHG product, then they must assure that a concomitant control is run with each test product. For example, 3 groups of two panelist could be run on day one, with each group of two assigned to one of the three products to be tested. In this manner, test and control product products are run concomitantly.

6). Finally, no information has been submitted regarding the demonstration of the neutralization potential of the neutralizers incorporated with the dilution blanks for this particular formulation. Therefore, the sponsor should submit a protocol designed to demonstrate that the neutralization system will function as suggested. The concentrations of CHG used to validate the neutralization system should mimic expected CHG carry over in the fluid used to obtain the primary sample for enumeration.

RECORD OF TELEPHONE CONVERSATION/MEETING

DATE: 10 Mar 93

NDA NUMBER: 73-416

IND NUMBER:

TELECON/MEETING

INITIATED BY
- ☐ APPLICANT/SPONSOR
- ☒ FDA

MADE
- ☐ BY TELEPHONE
- ☐ IN PERSON

PRODUCT NAME: Chlorhexidine Rinse/Swab

FIRM NAME: Becton Dickinson

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD: secretary

TELEPHONE NO.: 1-800-453-4538

Called firm to confirm point of contact and mailing address. The name of the Division is now Becton Dickinson Vascular Access, with the rest of the information remaining the same as our FDA letter dated Aug 4, 1992.

SIGNATURE: /S/

DIVISION: OGD

FORM FD 2587 (11/77)

ORIGINAL IND/NDA

U. S. GOVERNMENT PRINTING OFFICE-1984-432-976/7126

RECORD OF TELEPHONE CONVERSATION/MEETING

DATE: 1-3-94 9:10A

ANDA NUMBER: 73-416

TELECON/MEETING

INITIATED BY: [X] APPLICANT/SPONSOR [X] FDA

MADE: [X] BY TELEPHONE [ ] IN PERSON

PRODUCT NAME: E-Z Scrub Chlorhexidine Gluconate Scrub/Brush 4%

FIRM NAME: Becton Dickinson

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD: George Nolan

TELEPHONE NO.: 801-565-2300

Called and spoke to George Nolan concerning his question in his letter dated December 27, 1993 (FAXed) regarding Comment 3 under CARTON of our letter of November 2, 1993 which states "See comment 3 under Container.". This referenced comment does'nt appear in our letter.

I informed Mr. Nolan to disregard Comment 3 under CARTON - that it is a typo. (I explained to him, as an aside, that Comment 3 under CONTAINER became the GENERAL COMMENT when letter went to final).

Mr. Nolan indicated he would disregard Comment 3 under CARTON.

SIGNATURE: /S/

DIVISION: Labeling Branch

ORIGINATOR

FORM FD 356 (4/91)

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: April 19, 1995

FROM: Bill Russell, CSO

SUBJ: Pending Applications

TO: ANDA 73-416

As part of a project to try to move applications that have been pending for over 400 days, firms are being contacted to determine where there is active interest or requesting withdrawal. In many cases the deficiencies have been outstanding for 3 years or move. In those cases, recommendation is made for withdrawal and resubmission rather than expending resources to answer old deficiencies.

I spoke to George Nolan. Expects to respond within 30 days.

REVIEW OF PROFESSIONAL LABELING #3

ORIGINAL AMENDMENT

DRAFT

DATE OF REVIEW: December 11, 1995

ANDA #: 73-416

NAME OF FIRM: Becton Dickinson AcuteCare

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

DATE OF SUBMISSION: 5/30/95 and 6/28/95

COMMENTS:

Container:

We note that there are discrepancies between your container label and carton labeling in the description of your product and in the WARNINGS section. Except for the revision to carton labeling requested below, please revise your container label to be consistent with your carton labeling.

Carton:

Revise to include the word "antiseptic" in your product labeling as seen in labeling of the listed drug.

RECOMMENDATIONS:

1. Inform the firm of the above comments.

2. Request the firm revise their container label and carton labeling, then prepare and submit final printed labeling. Should further information become available relating to the safety and efficacy of this product, you may be asked to further revise your labeling prior to approval.

FOR THE RECORD:

1. Review based on the labeling for ANDA 72-525, approved 10/24/89 and NDA 17-768 approved 6/13/89.

Note: The revised WARNINGS statement approved 8/25/89 for all chlorhexidine gluconate topical products does not appear on the label of ANDA 72-525. Firm has been requested to revise their label to be consistent with carton labeling which has this WARNING.

2. Trade Name

   a. A discussion was held among CHoppes, JGrace, JWhite, and LGolson about the legal right of Becton Dickinson (BD) to refer to Hibiclens® in its product description. We believe the letter from ICI dated May 17, 1989, provides this authorization. It appears that BD purchases Hibiclens® from and incorporates in into their sponge/brush.

   b. As with the Hibiclens®, Becton Dickinson refers to chlorhexidine gluconate as Hibitane® as the trademarked active ingredient in the description of their product.

3. We also discussed whether or not this authorization also allows BD to make claims about their product that other generic firms cannot make without performing independent studies and testing (i.e., describing Hibiclens® as an antiseptic). We decided that BD could make such claims since it appears in the approved labeling of the listed drug.

4. Patent/ Exclusivities: None

5. Storage Conditions:

   NDA - Avoid excessive heat above (104°F)

   ANDA - Avoid excessive heat above 40°C (104°F)

6. Inactive Ingredients:

   The listing of inactive ingredients in the DESCRIPTION section of the package labeling is consistent with the listing of inactive ingredients found in the DESCRIPTION section of the Hibiclens® labeling.

Lillie Golson

cc: ANDA 73-416
Dup/Division File 1/16/96 CHoppes 4/19/96
HFD-613/LGolson/JWhite/CHoppes (no cc:)
HFD-600/RF

Review

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 73-416 Date of Submission: January 19, 1998 (Amendment)

Applicant's Name: Becton Dickinson Division

Established Name: Chlorhexidine Gluconate 4% Scrub-Brush/Sponge

Proprietary Name: E-Z SCRUB® 106

Labeling Deficiencies:

1. CONTAINER

   a. General Comment

      Revise to include the established name, in alphabetical order, of **EACH** inactive ingredient contained in your product. (Please see Section 412 of Title IV of the FDA Modernization Act of 1997).

   b. Principal display panel

      i. "Antiseptic" rather than "antispectic" (spelling)

      ii. Revise the storage temperature range to read, "...15-30°C (59-86°F)." (Delete "[See USP]")

   c. Directions for Use

      Revise to combine the first two sentences of Direction #2 so that it appears as:
      Use nail cleaner and then apply...

2. CARTON

   a. See CONTAINER comments.

   b. WARNINGS

      Revise the fifth sentence to read,
      IF THIS PRODUCT SHOULD...

Please revise your labels and labeling, as instructed above, and submit in final print.

Please note that the Agency reserves the right to request further changes in your labels and/or labeling based upon changes in the approved labeling of the listed drug or upon further review of the application prior to approval.

Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

NOTES/QUESTIONS TO THE CHEMIST:

Firm changed its storage temperature recommendation from
to
Do you concur with this change? (Note: BD has been asked to revise the range to 15-30°C (59-86°F))

FOR THE RECORD:

1. Review based on the labeling for ANDA 72-525, approved 10/24/89 and NDA 17-768 approved 6/13/89.

Note: The revised WARNINGS statement approved 8/25/89 for all chlorhexidine gluconate topical products does not appear on the label of ANDA 72-525. Firm has revised their label accordingly.

2. Trade Name

   a. A discussion was held among CHoppes, JGrace, JWhite, and LGolson about the legal right of Becton Dickinson (BD) to refer to Hibiclens® in its product description. We believe the letter from dated May 17, 1989, provides this authorization. It appears that BD purchases Hibiclens® from and incorporates in into their sponge/brush.

   b. As with the Hibiclens®, Becton Dickinson refers to chlorhexidine gluconate as Hibitane® as the trademarked active ingredient in the description of their product.

3. We also discussed whether or not this authorization also allows BD to make claims about their product that other generic firms cannot make without performing independent studies and testing (i.e., describing Hibiclens® as an antiseptic). We decided that BD could make such claims since it appears in the approved labeling of the listed drug.

4. Patent/ Exclusivities: None

5. Storage Conditions:

NDA - Avoid excessive heat above (104°F)

ANDA - Store at CRT, [See USP].
NOTE: BD changed their storage recommendation from that of the RLD to that listed above. They have been asked to revise the temperature range to 15-30°C (59-86°F) and to delete "[See USP]".

6. Inactive Ingredients:

The listing of inactive ingredients in the DESCRIPTION section of the package labeling is consistent with the listing of inactive ingredients found in the DESCRIPTION section of the Hibiclens® labeling.

7. Bio waiver was granted May 28, 1997.

Date of Review:
January 26, 1998

Date of Submission:
January 15, 1998

Primary Reviewer:
/S/

Date:
1/28/98

Team Leader:
/S/

Date:
1/28/98

cc:
ANDA: 73-416
DUP/DIVISION FILE
HFD-613/LGolson/JGrace (no cc)

Review

File

RECORD OF TELEPHONE CONVERSATION

Mr. Nichols called to say that he was referred to me by Maureen Dillon Parker (HFD-520). He said his firm manufactures 20% Chlorhexidine Gluconate and Becton Dickinson Company would like to use the concentrate to manufacture a 4% product. They want to know what to do to get approval to do so. I asked him whether has a DMF for the 20% CHG and whether Becton has a drug application. He responded yes to both questions. I told him that his company should give a letter of authorization to the DMF and Becton should file an amendment/supplement to their drug application proposing to employ the use of the I told him they should make an exhibit batch and run an accelerated stability study on the batch. The submission should include the batch record, the COA, and the stability data. I told him the Becton Reg. Affairs people should know what to do. He asked if I could send our policy for such submissions to him. I referred him to the Agency's InterNet Web site. He asked whether he could call me back on a conference call with the Becton people. I told him if he had to call again it would best to call Dr. Paul Schwartz who is the Team Leader for Chlorhexidine Gluconate products.

DATE
July 22, 1998

APPLICATION NUMBER
73-416

IND NUMBER

TELECON

INITIATED BY **MADE**
XX APPLICANT/ SPONSOR _ BY TELE.
_ FDA _ IN PERSON

PRODUCT NAME
Chlorhexidine Gluconate

FIRM NAME

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD
H. J. Nichols

TELEPHONE NUMBER

SIGNATURE
/S/
7/22/98

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 73-416

Date of Submission: October 5, 1998
(Minor Amendment)

Applicant's Name: Becton Dickinson Division

Established Name: Chlorhexidine Gluconate 4% Scrub-Brush/Sponge

Proprietary Name: E-Z SCRUB® 106

Spoke w Mr. Nolan 10/22/98 and requested these changes. The labeling set was draft and I explained that we need true color...
[signature]

Labeling Deficiencies:

1. GENERAL COMMENT:

   For computer generated labeling to be acceptable as final print, they must be of true color, size, and clarity. Please submit 12 copies of final printed container labels and carton labeling which meet these criteria.

2. CONTAINER

   See GENERAL COMMENT.

3. CARTON (30 units)

   a. See GENERAL COMMENT.

   b. WARNINGS

      Revise the fifth sentence to read,
      IF THIS...

Please revise your labels and labeling, as instructed above, and submit in final print.

Please note that the Agency reserves the right to request further changes in your labels and/or labeling based upon

changes in the approved labeling of the listed drug or upon further review of the application prior to approval.

_____

Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

NOTES/QUESTIONS TO THE CHEMIST:

1. Please verify that the listing of inactive ingredients on the container label and carton labeling is correct. Correct. 11/30/98 Gil Kang

2. Firm changed its storage temperature recommendation from "Avoid excessive heat above 40°C (104°F)" to "Store at CRT, 20-25°C (60-77°F)". Do you concur with this change? (Note: BD has been asked to revise the range to 15-30°C (59-86°F))

No. Gil Kang 11/30/98

FOR THE RECORD:

1. Review based on the labeling for ANDA 72-525, approved 10/24/89 and NDA 17-768 approved 6/13/89.

Note: The revised WARNINGS statement approved 8/25/89 for all chlorhexidine gluconate topical products does not appear on the label of ANDA 72-525. Firm has revised their label accordingly.

2. Trade Name

   a. A discussion was held among CHoppes, JGrace, JWhite, and LGolson about the legal right of Becton Dickinson (BD) to refer to Hibiclens® in its product description. We believe the letter from ICI dated May 17, 1989, provides this authorization. It appears that BD purchases Hibiclens® from ICI and incorporates in into their sponge/brush.

   b. As with the Hibiclens®, Becton Dickinson refers to chlorhexidine gluconate as Hibitane® as the trademarked active ingredient in the description of their product.

3. We also discussed whether or not this authorization also allows BD to make claims about their product that other generic firms cannot make without performing independent studies and testing (i.e., describing Hibiclens® as an antiseptic). We decided that BD could make such claims since it appears in the approved labeling of the listed drug.

4. Patent/ Exclusivities: None

5. Storage Conditions:

NDA - Avoid excessive heat above (104°F)

ANDA - Store at CRT, 20-25°C (68-77°F) [See USP].
NOTE: BD changed their storage recommendation from that of the RLD to that listed above. They have been asked to revise the temperature range to 15-30°C (59-86°F) and to delete "[See USP]".

6. Inactive Ingredients:

The listing of inactive ingredients in the DESCRIPTION section of the package labeling is consistent with the listing of inactive ingredients found in the DESCRIPTION section of the Hibiclens® labeling.

7. Bio waiver was granted May 28, 1997.

8. Since this is a minor amendment, Mr. Nolan will be telephoned regarding this review.

Date of Review:
October 21, 1998

Date of Submission:
October 5, 1998 (Minor Amendment)

Primary Reviewer:

Date:
10/21/98

Team Leader:

Date:
10/23/98

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cc:

ANDA: 73-416
DUP/DIVISION FILE
HFD-613/LGolson/JGrace (no cc)
ldg/10/21/98/X:\NEW\FIRMSAM\BECTON\LTRS&REV\73416NA3.L
Review

APPROVAL SUMMARY

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 73-416 Date of Submission: November 2, 1998 (Amendment)

Applicant's Name: Becton Dickinson Division

Proprietary Name: E-Z SCRUB® 106

Established Name: Chlorhexidine Gluconate 4% Scrub-Brush/Sponge

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APPROVAL SUMMARY (List the package size, strength(s), and date of submission for approval):

Do you have 12 Final Printed Labels and Labeling? Yes

Container Labels: Satisfactory as of November 2, 1998 submission

Carton Labeling: (30 units) – Satisfactory as of November 2, 1998 submission

BASIS OF APPROVAL:

Was this approval based upon a petition? No

What is the RLD on the 356(h) form: 4% Chlorhexidine Gluconate Topical

NDA Number: 17-768 and ANDA 72-525

NDA Drug Name: Chlorhexidine Gluconate Topical, 4%

NDA Firm: Zeneca Pharmaceutical

Date of Approval of NDA : June 13,1989 and ANDA October 24, 1989

Has this been verified by the MIS system for the NDA? Yes

Was this approval based upon an OGD labeling guidance? No

Basis of Approval for the Container Labels: Side-by-side comparison

Basis of Approval for the Carton Labeling: Side-by-side comparison

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FOR THE RECORD:

1. Review based on the labeling for ANDA 72-525, approved 10/24/89 and NDA 17-768 approved 6/13/89.

Note: The revised WARNINGS statement approved 8/25/89 for all chlorhexidine gluconate topical products does not appear on the label of ANDA 72-525. Firm has revised their label accordingly.

2. Trade Name

   a. A discussion was held among CHoppes, JGrace, JWhite, and LGolson about the legal right of Becton Dickinson (BD) to refer to Hibiclens7 in its product description. We believe the letter from ICI dated May 17, 1989, provides this authorization. It appears that BD purchases Hibiclens7 from ICI and incorporates in into their sponge/brush.

   b. As with the Hibiclens7, Becton Dickinson refers to chlorhexidine gluconate as Hibitane7 as the trademarked active ingredient in the description of their product.

3. We also discussed whether or not this authorization also allows BD to make claims about their product that other generic firms cannot make without performing independent studies and testing (i.e., describing Hibiclens7 as an antiseptic). We decided that BD could make such claims since it appears in the approved labeling of the listed drug.

4. Patent/ Exclusivities: None

5. Storage Conditions:

   NDA - Avoid excessive heat above (104EF)

   ANDA - Store at CRT, 20-25EC (68-77EF) [See USP].
   NOTE: BD changed their storage recommendation from that of the RLD to that listed above. They have been asked to revise the temperature range to 15-30EC (59-86EF) and to delete A[See USP]@.

6. Inactive Ingredients:

   The listing of inactive ingredients in the DESCRIPTION section of the package labeling is consistent with the listing of inactive ingredients found in the DESCRIPTION section of the Hibiclens7 labeling.

7. Bio ~~waiver was granted May 28, 1997.~~ study found acceptable 3/3/99

Date of Review:
February 17, 2000

Date of Submission:
November 2, 1998 (Amendment)

Primary Reviewer:
/S/

Date:
2/17/00

Secondary Reviewer:

Date:

Team Leader:
/S/

Date:
2/22/2000

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cc: ANDA:
DUP/DIVISION FILE
HFD-613// (no cc)
V:\FIRMSAM\BECTON\LTRS&REV\73416ap.l
Review

Patent and Exclusivity Search Results from query on 018423 001.

Patent Data

There are no unexpired patents for this product in the Orange Book Database.

[Note: Title I of the 1984 Amendments does not apply to drug products submitted or approved under the former Section 507 of the Federal Food, Drug and Cosmetic Act (antibiotic products). Drug products of this category will not have patents listed.]

Exclusivity Data

There is no unexpired exclusivity for this product.

Thank you for searching the Electronic Orange Book

Patent and Exclusivity Terms

Return to Electronic Orange Book Home Page

BD Medical Systems
9450 South State Street
Sandy, Utah 84070
tel: 801 565 2300
fax: 801 565 2740
www.bd.com

BD
Indispensable to human health

Debarment Certification Statement

RE: **ANDA 73-416, E-Z SCRUB® (Chlorhexidine Gluconate Scrub-Brush/Sponge) 4%**

This is a certification that Becton Dickinson did not and will not use in any capacity the services of any person debarred under subsection (a) or (b) [section 306 (a) or (b)], in connection with this application. [Section 306(k)(1) of the GDEA (21 U.S.C. 335a (k)(1).]

Jane Stickel
Name

2/22/00
Date

Director Regulatory Affairs
Title

E L E C T R O N I C M A I L M E S S A G E

Date: 22-Jun-1995 02:46pm EDT
From: Albert Sheldon
SHELDON
Dept: HFD-520 PKLN 12B17
Tel No: 301-443-0335 FAX 301-443-5803

'O: James Chaney (CHANEYJ)
'O: Jason Gross (GROSSJ)

'C: David Bostwick (BOSTWICK)

ubject: ANDA 73-416; Deseret Medical Scrub/Sponge brush

James or Jason,

A cursory review of the data submitted by Deseret Medical in ANDA 70-416 for the study performed by has been performed. The data looks satisfactory upon first pass but this may be expected in lieu of the fact that one of the FDA district offices has received reports from persons working at stating that data is being fabricated by during the performance of the studies. The facility was inspected but we have not received a clear answer stating whether we will or will not accept data from this facility.

In the interim, there is some information that we can obtain from the sponsor that will give us greater assurance that the information that we are reviewing is at least derived from a complete database.

Therefore, I would recommend that we request the following information:

1. I want all treatment (test and control product) raw data records and calculations generated during the conduct of this study.

2. I want the raw data for validation of the neutralization studies that were performed for the test and control products used in this study. The data should include an analysis of the validation test results.

3. I want to see a CV of all of the persons involved in performing this study or that had an part in performing this study. A description of what their function was in this study should also be provided.

4. I want photocopies of the subject screening information records including the raw data used to screen subjects for inclusion in the study.

5. I want photocopies of the Informed Consent records of all participants taking part in this study. Include a listing of the Institutional Review Board members, their CV and their function at

6. I want photocopies of the Log of Samples for the products used in this study as well as a description regarding assurances that the correct products are tested.

7. The sponsor should state whether the photocopies provide are actual copies of raw data sheets or are copies of other photocopies. If they are copies of other photocopies, then we need to know why photocopies of original raw data sheets are not being provided.

I do not know whether data was fabricated for this study. It is my understanding that the scientific investigations staff did an inspection of the facility and they had difficulty tracking the products tested by because places their own labels and code numbers on products being tested. A link between the product code numbers provided by and the results given to the sponsor could not be performed. The reason for asking for the other information is self-evident.

Perhaps Mr. D. Bostwick has further comments that he would like to make.

Electronic Mail Message

Sensitivity: COMPANY CONFIDENTIAL

Date: 03-Mar-2000 05:42pm
From: DSI Bioequivalence
DSIBE
Dept: HFD-340 MPN1 115
Tel No: 301-827-5460

TO: Pat Beers-Block (BEERSBLOCKP)

Subject: RE:

There have not been more recent bioequivalence inspections at The Clinical Investigations Branch (now Good Clinical Practices Branches I and II) also arranged for one or more audits there, about which I believe Carolanne Currier provided some information to you, in response to the note (below).

Sensitivity: COMPANY CONFIDENTIAL

Date: 22-Jul-1999 08:58am EST
From: DSI Bioequivalence
DSIBE
Dept: HFD-340 MPN1 115
Tel No: 301-827-5460

... Patricia Nguyen (NGUYENP)
CC: Jennifer Fan (FANJE)
CC: Elaine Hu (HUE)
CC: Jacqueline O'Shaughnessy (OSHAUGHNESSY)
CC: Carol-Anne Currier (CURRIER)

Subject: RE: Clinical Site

>Subject: Clinical Site-
>
>Good Morning,
>
>We would like to know if you have any inspectional history on a
>clinical site -

There are several companies with similar or identical names. One in was previously known as when BE studies for 3 ANDAs were inspected in 9/92. Can you please provide more information to identify the site?

Printed by Pat Beers-Block

Electronic Mail Message

Sensitivity: COMPANY CONFIDENTIAL

Date: 03-Mar-2000 03:04pm
From: Pat Beers-Block
BEERSBLOCKP
Dept: HFD-640 MPN2 E260
Tel No: 301-827-5844 FAX 301-594-0183

TO: DSI Bioequivalence (DSIBE)

Subject:

Dear DSI folks,

We have inspection history for (from the 6/96 inspection and DSI's recommendation that the facility was acceptable in 10/96). Do you have any more recent inspectional informaiton that we should consider as we prepare to approve an application whose BE study was conducted at this site? thanks in advance.

E L E C T R O N I C M A I L M E S S A G E

Sensitivity: COMPANY CONFIDENTIAL

Date: 08-Mar-2000 12:25pm EST
From: Pat Beers-Block
BEERSBLOCKP
Dept: HFD-640 MPN2 E260
Tel No: 301-827-5849 FAX 301-443-3839

TO: Eda Howard * (HOWARDE)

Subject: 73-416

Eda,

BD Acute Care left me a phone message stating that they faxed 3/356h forms in for ANDA 73-416. Have you seen these faxes yet? If so, could someone from your staff let me know and I'd be glad to pick them up.

thanks much, pb2