CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75288

ADMINISTRATIVE DOCUMENTS

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

ANDA Number: **75-288** Date of Submission: **October 16, 1998**

Applicant's Name: **SCS Pharmaceuticals**

Proprietary Name: **Low-Ogestrel®-21 and Low-Ogestrel®-28**

Established Name: **Norgestrel and Ethinyl Estradiol Tablets USP, 0.3 mg/0.03 mg - 21 and 28 day cycles**

Labeling Deficiencies:

1. BLISTER CARD (21 day and 28 day)

   a. Revise the established name to read as follows:

      Norgestrel and Ethinyl Estradiol Tablets USP, 0.3 mg/0.03 mg

   b. Relocate the following sentence from the back panel to the front panel on your 28 day package:

      TAKE ALL WHITE TABLETS BEFORE TAKING ANY PEACH TABLETS.

2. CARTON (6 x 21 and 6 x 28)

   a. Revise the established name to read as follows:

      Norgestrel and Ethinyl Estradiol Tablets USP, 0.3 mg/0.03 mg

   b. Include the following statement on your carton:

      This product (like all oral contraceptives) is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

3. INSERT

   a. GENERAL COMMENT

i. We acknowledge your comments regarding the labeling submitted being identical in format and content to the "Searle Norinyl 1+35" product labeling (revised July 15, 1993). However, the most recent labeling was approved August 30, 1995; Revised April 1995.. Therefore, you must revise your labeling to be in accord with the latest approved labeling for Norinyl 1+35.

b. PHYSICIAN LABELING

i. TITLE

We encourage the inclusion of "℞ only" in this section.

ii. DESCRIPTION

Revise the first two paragraphs to read as follows:

Low-Ogestrel® 0.3/30-21 Tablets(Norgestrel and Ethinyl Estradiol Tablets, USP) provide an oral contraceptive regimen consisting of 21 white tablets.

Low-Ogestrel® 0.3/30-21 Tablets (Norgestrel and Ethinyl Estradiol Tablets, USP) provide an oral contraceptive regimen consisting of 21 white tablets followed by 7 peach tablets.

iii. INDICATIONS AND USAGE

Low-Ogestrel® (Norgestrel and Ethinyl Estradiol Tablets USP) tablets are indicated...

c. DETAILED PATIENT PACKAGE INSERT

i. Satisfactory in draft.

d. BRIEF PATIENT PACKAGE INSERT

i. Satisfactory in draft.

Please revise your blister card labels, carton, and physician insert labeling, as instructed above, and submit

12 copies of final printed blister card labels, along with 12 copies each of final printed carton, physician insert, detailed patient insert, and brief summary insert labeling.

Please note that we reserve 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.

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

Robert L. West, M.S., R.Ph.
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

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

Do you have 12 Final Printed Labels and Labeling? Yes No
If no, list why:

Blister Card Label:

Carton Labeling:

Professional Package Insert Labeling:

Detailed Patient Package Insert Labeling:

Brief Patient Package Insert Labeling:

Revisions needed post-approval:

BASIS OF APPROVAL:

Was this approval based upon a petition? No

What is the RLD on the 356(h) form: Lo-Ovral

NDA Number: 17-612 and 17-617

NDA Drug Name: Lo-Ovral

NDA Firm: Wyeth Ayerst

Date of Approval of NDA Insert and supplement #: The Labeling review was based on the approved labeling of Norinyl 1+35, Approved August 30, 1995; Revised April 1995.
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: Norinyl labels in file folder.

Basis of Approval for the Carton Labeling: Norinyl labeling in file folder.

Other Comments:

This is common practice for an NDA holder to utilize their labeling and not the labeling of the RLD for the inserts. They can keep their product line uniform. This practice has been in existence since the Kent Johnson era.

REVIEW OF PROFESSIONAL LABELING CHECK LIST

Established Name	Yes	No	N.A.
Different name than on acceptance to file letter?		X	
Is this product a USP item? If so, USP supplement in which verification was assured. USP 23	X		
Is this name different than that used in the Orange Book? ethinyl estradiol listed first.	X		
If not USP, has the product name been proposed in the PF?			X
Error Prevention Analysis			
Has the firm proposed a proprietary name? If yes, complete this subsection.	X		
Do you find the name objectionable? List reasons in FTR, if so. Consider: Misleading? Sounds or looks like another name? USAN stem present? Prefix or Suffix present?	X		
Has the name been forwarded to the Labeling and Nomenclature Committee? If so, what were the recommendations? If the name was unacceptable, has the firm been notified? Forwarded March 6, 1998.	X		
Packaging			
Is this a new packaging configuration, never been approved by an ANDA or NDA? If yes, describe in FTR.		X	
Is this package size mismatched with the recommended dosage? If yes, the Poison Prevention Act may require a CRC. See comment to the firm regarding the day 1 start.	X		
Does the package proposed have any safety and/or regulatory concerns?		X	
If IV product packaged in syringe, could there be adverse patient outcome if given by direct IV injection?			X
Conflict between the DOSAGE AND ADMINISTRATION and INDICATIONS sections and the packaging configuration?		X	
Is the strength and/or concentration of the product unsupported by the insert labeling?		X	
Is the color of the container (i.e. the color of the cap of a mydriatic ophthalmic) or cap incorrect?			X
Individual cartons required? Issues for FTR: Innovator individually cartoned? Light sensitive product which might require cartoning? Must the package insert accompany the product?	X		
Are there any other safety concerns?		X	
Labeling			
Is the name of the drug unclear in print or lacking in prominence? (Name should be the most prominent information on the label).		X	
Has applicant failed to clearly differentiate multiple product strengths?			X
Is the corporate logo larger than 1/3 container label? (No regulation - see ASHP guidelines)		X	
Labeling (continued)	**Yes**	**No**	**N.A.**
Does RLD make special differentiation for this label? (i.e., Pediatric strength vs Adult; Oral Solution vs Concentrate, Warning Statements that might be in red for the NDA)		X	
Is the Manufactured by/Distributor statement incorrect or falsely inconsistent between labels and labeling? Is "Jointly Manufactured by...", statement needed?		X	

Failure to describe solid oral dosage form identifying markings in HOW SUPPLIED?		X	
Has the firm failed to adequately support compatibility or stability claims which appear in the insert labeling? Note: Chemist should confirm the data has been adequately supported.		X	
Scoring: Describe scoring configuration of RLD and applicant (page #) in the FTR			
Is the scoring configuration different than the RLD?		X	
Has the firm failed to describe the scoring in the HOW SUPPLIED section?		X	
Inactive Ingredients: (FTR: List page # in application where inactives are listed)			
Does the product contain alcohol? If so, has the accuracy of the statement been confirmed?		X	
Do any of the inactives differ in concentration for this route of administration?		X	
Any adverse effects anticipated from inactives (i.e., benzyl alcohol in neonates)?		X	
Is there a discrepancy in inactives between DESCRIPTION and the composition statement? No composition statement sent for the inert tablets.	X		
Has the term "other ingredients" been used to protect a trade secret? If so, is claim supported?		X	
Failure to list the coloring agents if the composition statement lists e.g., Opacode, Opaspray?		X	
Failure to list gelatin, coloring agents, antimicrobials for capsules in DESCRIPTION?			X
Failure to list dyes in imprinting inks? (Coloring agents e.g., iron oxides need not be listed)		X	
USP Issues: (FTR: List USP/NDA/ANDA dispensing/storage recommendations)			
Do container recommendations fail to meet or exceed USP/NDA recommendations? If so, are the recommendations supported and is the difference acceptable?		X	
Does USP have labeling recommendations? If any, does ANDA meet them?		X	
Is the product light sensitive? If so, is NDA and/or ANDA in a light resistant container?		X	
Failure of DESCRIPTION to meet USP Description and Solubility information? If so, USP information should be used. However, only include solvents appearing in innovator labeling. See note to firm.	X		
Bioequivalence Issues: (Compare bioeqivalency values: insert to study. List Cmax, Tmax, T ½ and date study acceptable)			
Insert labeling references a food effect or a no-effect? If so, was a food study done?		X	
Has CLINICAL PHARMACOLOGY been modified? If so, briefly detail where/why.		X	
Patent/Exclusivity Issues?: FTR: Check the Orange Book edition or cumulative supplement for verification of the latest Patent or Exclusivity. List expiration date for all patents, exclusivities, etc. or if none, please state.		X	

*****NOTES/QUESTIONS TO THE CHEMIST:*****

FOR THE RECORD:

1. Review based on the labeling of the listed drug (Norinyl; Approved August 30, 1995; Revised April 1995).

2. Patent/ Exclusivities:

   There are no patents or exclusivities that pertain to this drug product.

3. Storage/Dispensing Conditions:

   NDA: No storage or dispensing information.

   ANDA: Store at controlled room temperature 15° and 25°C (59° - 77°F).

   USP: Preserve in well-closed containers.

4. Scoring:

   NDA: NOT scored
   ANDA: NOT scored

5. Product Line:

   The innovator markets their product in 21 or 28 day packs in cartons containing 6 packs. The 21 day pack allows for a Same day or Sunday start and the 28 allows for a Sunday start only.

   The applicant proposes to market their product in 21 and 28 days packs in cartons containing 6 packs. The firm proposes both packs to have a 21 or 28 day start.

6. The tablet imprintings have been accurately described in the HOW SUPPLIED section as required by 21 CFR 206,et al. (Imprinting of Solid Oral Dosage Form Products for Human Use; Final Rule, effective 9/13/95). See page 768, Vol. 1.3.

7. Inactive Ingredients:

   The listing of inactive ingredients in the DESCRIPTION section of the package insert appears to be consistent with the listing of inactive ingredients found in the statement of components and composition appearing on page 648, Vol. 1.1. There was no components/composition statement submitted for the insert tablets. See note to firm and note to chemist.

8. All manufacturing will be performed by Searle and Co. No outside firms are utilized. See pages 750 and 746, Vol. 1.3.

9. Container/Closure:

   This product will be packaged in Aluminum foil PVC/PE/Aclar Blister Film. See page 821, Vol. 1.3.

10. The firm submitted draft labeling based on NDA labeling that has not been approved by the Agency yet. The firm was instructed to submit labeling that was in accord with the latest approved labeling of April 1994.

Date of Review: **November 17, 1998**

Date of Submission: **October 16, 1998**

Reviewer: /S/ **Date:** 1-5-99

Team Leader: /S/ **Date:** 1-11-99

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cc:

ANDA 75-288
DUP/DIVISION FILE
HFD-613/TWatkins/JGrace (no cc)

Review

Orig
1.1

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

ANDA Number: **75-288** Date of Submission: **December 24, 1997**

Applicant's Name: **SCS Pharmaceuticals**

Proprietary Name: **Low-Ogestrel®-21 and Low-Ogestrel®-28**

Established Name: **Norgestrel and Ethinyl Estradiol Tablets USP, 0.3 mg/0.03 mg - 21 and 28 day cycles**

Labeling Deficiencies:

1. BLISTER CARD (21 day and 28 day)

   a. Revise the established name to read as follows:

      Norgestrel and Ethinyl Estradiol Tablets USP, 0.3 mg/0.03 mg

   b. Replace the "CAUTION: Federal law..." statement with the symbol "Rx only" or "℞ only". We refer you to the Guidance For Industry, "Implementation of Section 126, Elimination of Certain Labeling Requirements...", at the internet site, **http://www.fda.gov/cder/guidance/index.htm** for guidance.

   c. Revise the temperature storage recommendations to read as follows:

      Store between 15° - 25°...

   d. We note you have preprinted the days of the week on your foil blister. There is no mention of the use of alternate date stickers. Therefore, this blister configuration allows only for a Sunday Start only. What plan do you have for "Day 1" starters? Please comment and/or revise.

3. CARTON (6 x 21 and 6 x 28)

   a. How many "Detailed" and "Brief Summary" inserts

will accompany each carton?

b. Include the established name in conjunction with the proprietary name as described in comment b under BLISTER CARD.

c. Include the product strength in conjunction with the established name.

d. See comments a and b under BLISTER CARD?

4. INSERT

a. GENERAL COMMENT

i. We acknowledge your comments regarding the labeling submitted being identical in format and content to the "Searle Demulen product labeling not yet approved by the Division of Reproductive and Urologic Drug Products". We find this unacceptable. The Office of Generic Drugs cannot utilize labeling that has not be approved by the Agency. Therefore, you must revise your labeling to be in accord with the latest approved labeling for Demulen (Approved April 20, 1994; Revised July 15, 1993).

ii. The requirements of 21 CFR 201.10(g) must be met. The established name must appear in certain sections in association with the proprietary name. Please revise your labeling accordingly.

b. PHYSICIAN LABELING

i. TITLE

See GENERAL COMMENT under regarding the proposed proprietary name.

ii. DESCRIPTION

A) Revise the first four paragraphs to read as follows:

Low-Ogestrel® 0.3/30-21 Tablets(Norgestrel and Ethinyl Estradiol Tablets, USP) provide an oral contraceptive regimen consisting of 21 white tablets.

Low-Ogestrel® 0.3/30-21 Tablets (Norgestrel and Ethinyl Estradiol Tablets, USP) provide an oral contraceptive regimen consisting of 21 white tablets followed by 7 peach tablets.

Each white tablet, for oral administration, contains 0.3 mg of norgestrel and 0.03 mg of ethinyl estradiol and the following inactive ingredients...

Each inactive peach tablet, for oral administration, in the 28 day regimen contains the following inactive ingredients...

ii. Include the molecular weight and molecular formula of each active ingredient.

iii. Include the Chemical solubilities as listed in USP 23 for each active ingredient.

iv. We note you have not submitted a components and composition statement for the inert peach tablets. Please revise accordingly.

iii. INDICATIONS AND USAGE

Low-Ogestrel® (Norgestrel and Ethinyl Estradiol Tablets USP) tablets are indicated...

iv. DOSAGE AND ADMINISTRATION

Schedule #2, Day 1 start - The instructions do not allow for a day 1 start for the 28 day regimen. Please comment and/or revise.

v. REFERENCES

See GENERAL COMMENT i under INSERT.

c. DETAILED PATIENT PACKAGE INSERT

See GENERAL COMMENTS i and ii under INSERT.

d. BRIEF PATIENT PACKAGE INSERT

See GENERAL COMMENTS i and ii under INSERT.

Please revise your blister card labels, carton, physician, detailed patient and brief patient insert labeling, as instructed above, and submit draft labels and labeling.

Please note that we reserve 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.

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

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

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

Do you have 12 Final Printed Labels and Labeling? Yes No
If no, list why:

Blister Card Label:

Carton Labeling:

Professional Package Insert Labeling:

Detailed Patient Package Insert Labeling:

Brief Patient Package Insert Labeling:

Revisions needed post-approval:

BASIS OF APPROVAL:

Was this approval based upon a petition? No

What is the RLD on the 356(h) form: Lo-Ovral

NDA Number: 17-612 and 17-617

NDA Drug Name: Lo-Ovral

NDA Firm: Wyeth Ayerst

Date of Approval of NDA Insert and supplement #: The Labeling review was based on the approved labeling of Demulen, Approved April 20, 1994; Revised July 15, 1993.
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: Demulen labels in file folder.

Basis of Approval for the Carton Labeling: Demulen labeling in file folder.

Other Comments:

This is common practice for an NDA holder to utilize their labeling and not the labeling of the RLD for the inserts. They can keep their product line uniform. This practice has been in existence since the Kent Johnson era.

REVIEW OF PROFESSIONAL LABELING CHECK LIST

Established Name	Yes	No	N.A.
Different name than on acceptance to file letter?		X	
Is this product a USP item? If so, USP supplement in which verification was assured. USP 23	X		
Is this name different than that used in the Orange Book? ethinyl estradiol listed first.	X		
If not USP, has the product name been proposed in the PF?			X
Error Prevention Analysis			
Has the firm proposed a proprietary name? If yes, complete this subsection.	X		
Do you find the name objectionable? List reasons in FTR, if so. Consider: Misleading? Sounds or looks like another name? USAN stem present? Prefix or Suffix present?	X		
Has the name been forwarded to the Labeling and Nomenclature Committee? If so, what were the recommendations? If the name was unacceptable, has the firm been notified? Forwarded March 6, 1998.	X		
Packaging			
Is this a new packaging configuration, never been approved by an ANDA or NDA? If yes, describe in FTR.		X	
Is this package size mismatched with the recommended dosage? If yes, the Poison Prevention Act may require a CRC. See comment to the firm regarding the day 1 start.	X		
Does the package proposed have any safety and/or regulatory concerns?		X	
If IV product packaged in syringe, could there be adverse patient outcome if given by direct IV injection?			X
Conflict between the DOSAGE AND ADMINISTRATION and INDICATIONS sections and the packaging configuration?		X	
Is the strength and/or concentration of the product unsupported by the insert labeling?		X	
Is the color of the container (i.e. the color of the cap of a mydriatic ophthalmic) or cap incorrect?			X
Individual cartons required? Issues for FTR: Innovator individually cartoned? Light sensitive product which might require cartoning? Must the package insert accompany the product?	X		
Are there any other safety concerns?		X	
Labeling			
Is the name of the drug unclear in print or lacking in prominence? (Name should be the most prominent information on the label).		X	
Has applicant failed to clearly differentiate multiple product strengths?			X
Is the corporate logo larger than 1/3 container label? (No regulation - see ASHP guidelines)		X	

Labeling (continued)	Yes	No	N.A.
Does RLD make special differentiation for this label? (i.e., Pediatric strength vs Adult; Oral Solution vs Concentrate, Warning Statements that might be in red for the NDA)		X	
Is the Manufactured by/Distributor statement incorrect or falsely inconsistent between labels and labeling? Is "Jointly Manufactured by...", statement needed?		X	
Failure to describe solid oral dosage form identifying markings in HOW SUPPLIED?		X	
Has the firm failed to adequately support compatibility or stability claims which appear in the insert labeling? Note: Chemist should confirm the data has been adequately supported.		X	
Scoring: Describe scoring configuration of RLD and applicant (page #) in the FTR-			
Is the scoring configuration different than the RLD?		X	
Has the firm failed to describe the scoring in the HOW SUPPLIED section?		X	
Inactive Ingredients: (FTR: List page # in application where inactives are listed)			
Does the product contain alcohol? If so, has the accuracy of the statement been confirmed?		X	
Do any of the inactives differ in concentration for this route of administration?		X	
Any adverse effects anticipated from inactives (i.e., benzyl alcohol in neonates)?		X	
Is there a discrepancy in inactives between DESCRIPTION and the composition statement? No composition statement sent for the inert tablets.	X		
Has the term "other ingredients" been used to protect a trade secret? If so, is claim supported?		X	
Failure to list the coloring agents if the composition statement lists e.g., Opacode, Opaspray?		X	
Failure to list gelatin, coloring agents, antimicrobials for capsules in DESCRIPTION?			X
Failure to list dyes in imprinting inks? (Coloring agents e.g., iron oxides need not be listed)		X	
USP Issues: (FTR: List USP/NDA/ANDA dispensing/storage recommendations)			
Do container recommendations fail to meet or exceed USP/NDA recommendations? If so, are the recommendations supported and is the difference acceptable?		X	
Does USP have labeling recommendations? If any, does ANDA meet them?		X	
Is the product light sensitive? If so, is NDA and/or ANDA in a light resistant container?		X	
Failure of DESCRIPTION to meet USP Description and Solubility information? If so, USP information should be used. However, only include solvents appearing in innovator labeling. See note to firm.	X		
Bioequivalence Issues: (Compare bioeqivalency values: insert to study. List Cmax, Tmax, T 1/2 and date study acceptable)			
Insert labeling references a food effect or a no-effect? If so, was a food study done?		X	
Has CLINICAL PHARMACOLOGY been modified? If so, briefly detail where/why.		X	
Patent/Exclusivity Issues?: FTR: Check the Orange Book edition or cumulative supplement for verification of the latest Patent or Exclusivity. List expiration date for all patents, exclusivities, etc. or if none, please state.		X	

*****NOTES/QUESTIONS TO THE CHEMIST:*****

1. See comment b iv. under INSERT. Do you concur? NO!

they DO have C&C. Statement in the application P.1121 on V.A.1.c

bc

FOR THE RECORD:

1. Review based on the labeling of the listed drug (Demulen; Approved April 20, 1994, Revised July 15, 1993).

2. Patent/ Exclusivities:

   There are no patents or exclusivities that pertain to this drug product.

3. Storage/Dispensing Conditions:

   NDA: No storage or dispensing information.

   ANDA: Store at controlled room temperature 15° and 25°C (59° - 77°F).

   USP: Preserve in well-closed containers.

4. Scoring:

   NDA: NOT scored
   ANDA: NOT scored

5. Product Line:

   The innovator markets their product in 21 or 28 day packs in cartons containing 6 packs. The 21 day pack allows for a Same day or Sunday start and the 28 allows for a Sunday start only.

   The applicant proposes to market their product in 21 and 28 days packs in cartons containing 6 packs. The firm proposes both packs to have a 21 or 28 day start.

6. The tablet imprintings have been accurately described in the HOW SUPPLIED section as required by 21 CFR 206,et al. (Imprinting of Solid Oral Dosage Form Products for Human Use; Final Rule, effective 9/13/95). See page 768, Vol. 1.3.

7. Inactive Ingredients:

   The listing of inactive ingredients in the DESCRIPTION section of the package insert appears to be consistent with the listing of inactive ingredients found in the statement of components and composition appearing on page 648, Vol. 1.1. There was no components/composition statement submitted for the

insert tablets. See note to firm and note to chemist.

8. All manufacturing will be performed by Searle and Co. No outside firms are utilized. See pages 750 and 746, Vol. 1.3.

9. Container/Closure:

   This product will be packaged in Aluminum foil PVC/PE/Aclar Blister Film. See page 821, Vol. 1.3.

10. The firm submitted draft labeling based on NDA labeling that has not been approved by the Agency yet. The firm was instructed to submit labeling that was in accord with the latest approved labeling of April 1994.

Date of Review: March 5, 1998

Date of Submission: December 24, 1997

Reviewer: /S/ **Date:** 3/26/98

Team Leader: /S/ **Date:** 3/27/98

cc:

ANDA 75-288
DUP/DIVISION FILE
HFD-613/CHolquist/JGrace (no cc)

Review

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

Date: 11-Jun-1999 03:42pm EDT
From: Michael Smela
SMELA
Dept: HFD-625 MPN2 E236
Tel No: 301-827-5848 FAX 301-594-0180

TO: Denise Huie (HUIED)
TO: Teresa Watkins (WATKINST)

CC: John Grace (GRACEJ)
CC: Pat Beers-Block (BEERSBLOCKP)
CC: Bing Cai (CAIB)

Subject: ANDA 75288

Denise...I am closing this application for Norgestrel/Ethinyl Estradiol of SCS. CMC, Bio, and EER are OK. Labeling review of the 5/27/99 facsimile amendment is pending.

Please add to the approval matrix. The EER expires June 26 so we may need a FUR.

Teresa: Please let Bing know as soon as the labeling is OK so we may prepare the approval package.

Mike

RECORD OF TELEPHONE CONVERSATION
Office of Generic Drugs
Division of Chemistry I
Branch 2 HFD-625

FROM: Bing Cai/Michael J. Smela, Jr. DATE:6/10/99

NAME/TITLE OF INDIVIDUAL(S): Doranne Frano, Associate Director
FIRM: Searle
PRODUCT NAME: Norgestrel and Ethinyl Estradiol Tablets
TEL #: 847-982-7691
Reference: 75-288

Notes of Conversation:

Michael and Bing phoned in regard to their proposed stability protocol submitted in the amendment date 05/27/99.

In their revised stability protocol, Searle indicated that they would not perform any stability testing at 13 and 39 weeks for their annual production batches. The firm was informed that this is not acceptable based on OGD's current policy.

The firm was asked to commit that the stability samples will be tested at all time stations, including 13 and 39 weeks time stations for their annual batches. However, they may remove some of these test stations by providing us a supplement after the approval of this ANDA and they have obtained enough stability data.

Ms. Frano said she could submit a Fax/Tele amendment today (with a fax copy to Bing Cai) and agreed to clarify this issue.

SIGNATURE OF OGD REPRESENTATIVES: /S/ /S/ 6/10/99

Location of Electronic Copy:
V:\FIRMSNZ\SEARLE\TELECONS\061099.bbc.DOC