# CENTER FOR DRUG EVALUATION AND RESEARCH

## APPLICATION NUMBER: NDA 20-701

## CORRESPONDENCE

NDA 20-701

NOV 25 1996

Columbia Research Laboratories, Inc.
Attention: Howard Levine, Pharm. D.
Vice President
100 No. Village Avenue
Rockville Centre, NY 11570

Dear Dr Levine:

Please refer to your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug and Cosmetic Act for Crinone® (progesterone gel).

This is to notify you that your application has been accepted for review as of July 31, 1996, and has been filed as of September 29, 1996, under section 505(b) of the Act in accordance with 21 CFR 314.101(a).

Should you have any questions, please contact:

Diane Moore
Consumer Safety Officer
Telephone: (301)827-4260

Sincerely,

Heidi Jolson MD 11/25/96
Heidi M. Jolson, M.D., M.P.H.
Acting Deputy Director
Division of Reproductive and Urologic Drug Products (HFD-580)
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Original NDA 20-701
HFD-580/Div. Files
HFD-580/LRarick/HJolson

drafted: dm/10.4.96/n20701.fl

Concurrence:
LPauls 10.10.96/HJolson 10.17.96

GENERAL CORRESPONDENCE (GC) (NDA 20-701)

NDA 20-701

AUG 5 1996

Columbia Research Laboratories, Inc.
Attention: Howard Levine, Pharm. D.
Vice President
100 No. Village Avenue
Rockville Centre, NY 11570

Dear Dr. Levine:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

| | |
|---|---|
| Name of Drug Product: | Crinone® (progesterone gel) |
| Therapeutic Classification: | Standard |
| Date of Application: | July 23, 1996 |
| Date of Receipt: | July 31, 1996 |
| Our Reference Number: | 20-701 |

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on September 29, 1996, in accordance with 21 CFR 314.101(a).

Should you have any questions, please contact:

Diane Moore
Consumer Safety Officer
Telephone: (301) 827-4260

Dm 8/5/96

Co. Corres

ORIGINAL

COLUMBIA
RESEARCH
LABORATORIES, INC.

June 30, 1997

NEW CORRESP

Lisa Rarick, M.D., Director
Division of Reproductive & Urologic Drug Products (HFD-580)
Food and Drug Administration
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, MD 20857

RE: NDA 20-701
CRINONE® (progesterone gel)

Dear Dr. Rarick:

Pursuant to Section 505 of the Federal Food, Drug and Cosmetic Act and in reference to 21 CFR 314.50(d)(5)(vi)(b), on February 28, 1997 a Safety Update (Section 9) was submitted to New Drug Application #20-701 for CRINONE® (progesterone gel), that was originally submitted on July 23, 1996.

Subsequent to the filing of February 28, 1997, no new safety data has become available for CRINONE® (progesterone gel). CRINONE® (progesterone gel) has not been marketed in any other country to date, therefore no additional safety information is available from that source.

If there are any overall questions concerning this application, please contact the undersigned at (516) 766-2660.

Yours truly,

Howard Levine, Pharm.D.
Vice President
Columbia Research Laboratories, Inc.

REVIEWS COMPLETED

CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO

CSO INITIALS DATE


30 No. Village Avenue
Rockville Centre, NY 11570

TEL: (516) 766-2647
FAX: (516) 766-2673

ORIGINAL

NEW CORRESP

COLUMBIA
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June 12, 1997

Diane Moore, CSO
Division of Reproductive and Urologic Drug Products (HFD-580)
Food & Drug Administration
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, MD 20857


RE: NDA 20-701
CRINONE® (progesterone gel)

Dear Ms. Moore:

As requested, please find enclosed a diskette which contains two files in WordPerfect 6.1 format.

These files are as follows: 20-701.lab (secondary amenorrhea alone) and 701&756.lab (combined ART and secondary amenorrhea indications).

If there are any questions, please contact the me at (516) 766-2660.

Yours truly,

Howard Levine, Pharm.D.
Vice President
Columbia Research Laboratories, Inc.

Enclosed

| REVIEWS COMPLETED | |
|---|---|
| CSO ACTION: ☐ LETTER ☐ N.A.I. ☐ MEMO | |
| CSO INITIALS | DATE |

100 No. Village Avenue
Rockville Centre, NY 11570

TEL: (516) 766-2647
FAX: (516) 766-2873

ORIGINAL

COLUMBIA
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LABORATORIES, INC.

April 19, 1997

ORIG AMENDMENT

Food & Drug Administration
Center for Drug Evaluation and Research
Documents and Records Section
12420 Parklawn Drive
Rockville, MD 20852

| REVIEWS COMPLETED | |
|---|---|
| CSO ACTION: ☐ LETTER ☐ N.A.I. ☐ MEMO | |
| CSO INITIALS | DATE |

**Attention:** Lisa Rarick, M.D., Director
Division of Reproductive and Urologic Drug Products

Noted
For Chemistry
Review
5/6/97

**RE:** Amendment to NDA 20-701
CRINONE® (progesterone gel)
Response to FDA Request

Dear Dr. Rarick:

We reference our NDA 20-701 for CRINONE® (progesterone gel) submitted on July 31, 1996 to support the use of CRINONE® in the treatment of secondary amenorrhea and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as fibroids or uterine cancer. In response to the request of Dr. Mitra for a MSDS for progesterone and concerning the Environmental Assessment section of the submission, we are amending the application with the following information and enclosures:

1. MSDS sheet for progesterone as provided by the suppler.

2. Concerning Disposal of Returned/Damaged Goods - As stated in the Environmental Assessment, all Crinone® manufacturing occurs outside the United States. Section 3.12.4E (Disposal Sites) and referenced appendices describe the disposal method during manufacture, as well as that associated with patient use. Drug product returned to Columbia Laboratories after entry into the United States will be disposed of in a solid waste management system. Columbia Laboratories is in the process of identifying a site for return in the United States.

3. Page 229 of Section 3.12, with the appropriate signature.

If there are any questions concerning this submission, please contact the undersigned at (516) 766-2660.

Yours truly,

Howard Levine, Pharm.D.
Vice President
Columbia Research Laboratories, Inc.

CENTER FOR DRUG
REC'D
MAY 0 1 1997

Attachments

0 No. Village Avenue
ckville Centre, NY 11570

L: (516) 766-2847
X: (516) 766-2873

COLUMBIA
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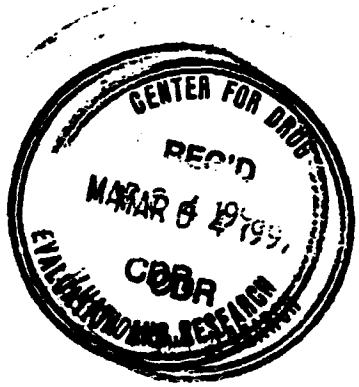
# ORIGINAL




February 28, 1997

Food & Drug Administration
Center for Drug Evaluation and Research
Documents and Records Section
12420 Parklawn Drive
Rockville, MD 20852

ORIG AMENDMENT

**Attention:** Diane Moore, Consumer Safety Officer
Division of Reproductive and Urologic Drug Products

**RE:** Amendment to NDA 20-701
CRINONE® (progesterone gel)
Response to FDA Request

Dear Ms. Moore:

We reference our NDA 20-701 for CRINONE® (progesterone gel) submitted on July 31, 1996 to support the use of CRINONE® in the treatment of secondary amenorrhea and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as fibroids or uterine cancer. In response to your request, we are amending the application with the enclosed information:

- Draft labeling , consisting of 4 boxes each of the 4% (six applicator package), 8% (six applicator package) and 8% (eighteen applicator package),
- Draft labeling, consisting of the 4 copies of the printing on the flow wrapper for the 4% and 8% applicators,
- Sample of the aluminum flow wrapper material (without printing).

If there are any questions concerning this submission, please contact the undersigned at (516) 766-2660.

Yours truly,

REVIEWS COMPLETED
CSO ACTION
☐ LETTER ☐ N.A.I. ☐ MEMO
DATE


Howard Levine, Pharm.D.
Vice President
Columbia Research Laboratories, Inc.

Attachments

00 No. Village Avenue
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February 28, 1997

ORIGINAL

**NDA 20-701 SECTION 9 - SAFETY UPDATE**

ORIG AMENDMENT

Lisa Rarick, M.D., Director
Division of Reproductive & Urologic Drug Products (HFD-580)
Food and Drug Administration
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, MD 20857

**RE:** NDA 20-701 Section 9 - Safety Update
CRINONE® (progesterone gel)

Dear Dr. Rarick:

Pursuant to Section 505 of the Federal Food, Drug and Cosmetic Act and in reference to 21 CFR 314.50(d)(5)(vi)(b), we submit in duplicate, this Safety Update (Section 9) to New Drug Application #20-701 for CRINONE® (progesterone gel), that was originally submitted on July 23, 1996. Because there are two active NDAs for the same product, this document also contains the safety update for NDA #20-756 (CRINONE®) that was originally submitted on November 13, 1996. Please note that this document is also being submitted to NDA 20-756.

Attachment 1 to this letter is a disk containing WordPerfect® files for the text of the Safety Update and the accompanying documentation.

Attachment 2 to this letter is a disk containing the original and SAS® analysis data sets for the database and the accompanying documentation. Only those subjects from COL1620-007US who were enrolled in the study and completed or withdrew from the study after 15 June 1996 are included in the database.

Please be advised that material and data contained in this submission are confidential. The legal protection of such confidential material is hereby claimed under applicable provisions of 18 U.S.C., Section 1905 or 21 U.S.C., Section 331(J).

If there are any overall questions concerning this application, please contact the undersigned at (516) 766-2660.

Yours truly,

Howard Levine, Pharm.D.
Vice President
Columbia Research Laboratories, Inc.

Attachments

REVIEWS COMPLETED

CSO ACTION:
☐ LETTER ☐ ☐ MEMO

CSO INITIALS DATE

CENTER FOR DRUG EVALUATION AND RESEARCH
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FEB 28 1997
HFD-580

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EL: (516) 766-2847
AX: (516) 766-2873

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LABORATORIES, INC.

| REVIEWS COMPLETED | |
|---|---|
| CSO ACTION: ☐ LETTER ☐ N.A.I. ☐ MEMO | |
| CSO INITIALS | DATE |

ORIGINAL

February 17, 1997

**AMENDMENT TO A PENDING NDA - RESPONSE TO FDA REQUEST**

ORIG AMENDMENT

Food & Drug Administration
Center for Drug Evaluation and Research
Division of Reproductive and Urologic Drug Products (HFD-580)
5600 Fisher Lane
Rockville, MD 20857

**Attention:** Gary Barnette, PK Reviewer
Division of Reproductive and Urologic Drug Products

**RE:** Amendment to NDA #20-701
CRINONE® (progesterone gel)
Response to FDA Request

Dear Dr. Barnette:

We reference our NDA 20-701 for CRINONE® (progesterone gel) submitted on July 23, 1996 to support the use of CRINONE® in women with secondary amenorrhea. In response to your request, we are amending the application with the enclosed information:

- Dissolution data in hard copy and electronic form for specified batches
- Diskette containing the package insert for this application and the 20-756 NDA which was filed to support the use of CRINONE® in women undergoing advanced reproductive technology (ART) procedures.
- Diskette containing excel files for the 10 PK studies; data documentation consisting of the contents and printout of these files; hard copies of the PK summaries prepared for each study report. Please note that the assay data for study 005323 will be forthcoming shortly under separate cover.
- Diskette containing the text of the HPB Section from NDA 20-701, for your reference (WordPerfect 6.1 format).

If there are any questions concerning this submission, please contact the undersigned at (516) 766-2660.

Yours truly,

Howard Levine, Pharm.D.
Vice President
Columbia Research Laboratories, Inc.

Enc.

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FEB 18 1997
HFD-580
EVALUATION AND RESEARCH

00 No. Village Avenue
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Desk Copy

COLUMBIA
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November 13, 1996

Food & Drug Administration
Center for Drug Evaluation & Research
Division of Endocrine and Reproductive Drug Products (HFD-580)
5600 Fisher Lane
Rockville, Maryland 20854


**Attention:** Lisa Rarick, M.D.
Director, Endocrine and Reproductive Drug Products

**RE:** Amendment to NDA 20-701 CRINONE® (progesterone gel)

Dear Dr. Rarick:

We reference our NDA 20-701 for CRINONE® (progesterone gel) submitted July 23, 1996. At this time, we are amending the application to provide updated information in regard to the person responsible for the quality control (QC) of CRINONE® and to correct information on the batch number information, compendial references and stability information, included in that original submission.

To that end, the following documentation is attached:

| DOCUMENT | PAGE NUMBER(S) | PURPOSE |
|---|---|---|
| CMC Section 3.8.1.3 | 1-2 | Update Responsible Head of QC to Dr. J.A. Farooqi of Jensa House. This is due to a personal change at Jensa House. |
| Table of Clinical Studies* | 3 | Change the batch numbers for COL1620-007US from PS1741 and PS1743 to PS2141 and PS2143, respectively. Change batch numbers for COL1620-FO2 from PS1730, PS1733 & PS1738 to PS1730, PS1733, PS2138 & PS2143, respectively. |
| NDA Summary CMC Section Table C | 4-6 | Same reason |
| CMC Section 3.10.5 | 7-10 | Same reason |

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| | | |
|---|---|---|
| NDA Summary CMC Section Table B | 11 | To correct the compendial references for Progesterone, Glycerin, Sodium Hydroxide, & Purified Water to include Ph. Eur. 2nd Edition and for Sorbic Acid compendial reference change from USP to USNF. Or European Pharmacopia specification. |
| CMC Section | 12 | Same reason |
| CMC Section 3.4.1 | 13 | Same reason |
| CMC Section 3.9 Attachment 1 | 14-15 | To correct the stability data for the 2 month time point. The original data provided in NDA 20-701 was that for the filled applications of Batch #2H02, not the bulk gel. |

* This table studies appeared in NDA 20-701 in the NDA Summary ,the Clinical Data Section Summary, the Statistical Data Section Summary, the ISE and the ISS.

Please note that the pages containing correct information are marked at the top with "revised 06 November 1996".

This information is being provided for clarification and as such does not represent a major amendment to NDA 20-701.

If you have any questions or if you require further information, please contact the undersigned at (515) 766-2660.

Yours Truly,

Howard Levine, Pharm. D.
Vice President
Columbia Laboratories

Attachments
Desk Copy

00 No. Village Avenue
ockville Centre, NY 11570

EL: (516) 766-2847
AX: (516) 766-2873

COLUMBIA
RESEARCH
LABORATORIES, INC.

July 23, 1996


**ORIGINAL NDA SUBMISSION**

Food & Drug Administration
Center for Drug Evaluation and Research
Documents and Records Section
12420 Parklawn Drive
Rockville, MD 20852

**Attention:** Lisa Rarick, M.D.
Acting Director, Division of Reproductive and Endocrine Drug Products

**RE:** Original NDA Submission #20-701
CRINONE® (progesterone gel)

Dear Dr. Rarick:

Pursuant to Section 505 of the Federal Food, Drug and Cosmetic Act and in reference to 21 CFR 314, we submit in duplicate, this original New Drug Application #20-701 for CRINONE® (progesterone gel).

This application was the topic for discussion at several meetings held between Columbia Research Laboratories and the Division of Metabolism and Endocrine Drug Products (now, Reproductive and Endocrine Drug Products), the most important of these on December 20, 1993 and on October 13, 1995. The agreements reached at these meetings are delineated in Attachment 1, entitled "Summary of Prior Agreements with the Division of Metabolism and Endocrine Drug Products."

In addition, a discussion was held with Phill Price, M.D., Medical Officer, on July 10, 1996 concerning additional requests in regard to the safety evaluation of the product in relation to laboratory testing and specific urinary adverse events. A response to those requests is provided in Attachment 2.

Attachment 3 to the Clinical and Archive copy of this letter are 4 disks containing WordPerfect® files for the NDA Summary, the text portion of the Integrated Summaries of Efficacy and Safety, and the text portions of the final study reports for the three studies conducted in patients with secondary amenorrhea (COL1620-005US, COL1620-009US, COL1620-004US). A copy of the accompanying documentation is provided in all copies of this letter.

Attachment 4 to the Statistical and Archive copy of this letter is a disk containing the SAS® data sets for the Integrated Summary of Efficacy (ISE). A copy of the accompanying documentation is provided in all copies of this letter.


100 No. Village Avenue
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RESEARCH
LABORATORIES, INC.

Please be advised that material and data contained in this submission are confidential. The legal protection of such confidential material is hereby claimed under applicable provisions of 18 U.S.C., Section 1905 or 21 U.S.C., Section 331(J).

If there are any overall questions concerning this application, please contact the undersigned at (516) 766-2660.

Yours truly,

Howard Levine, Pharm.D.
Vice President
Columbia Research Laboratories, Inc.

Attachments

100 No. Village Avenue
Rockville Centre, NY 11570

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FAX: (516) 766-2673

COLUMBIA
RESEARCH
LABORATORIES, INC.

June 30, 1997

Food & Drug Administration
Center for Drug Evaluation and Research
Documents and Records Section
12420 Parklawn Drive
Rockville, MD 20852

**Attention:** Lisa Rarick, M.D., Director
Division of Reproductive and Urologic Drug Products

**RE:** Amendment to NDA 20-701
CRINONE® (progesterone gel)
Response to FDA Comments and Requests

Dear Dr. Rarick:

We reference our NDA 20-756 for CRINONE® (progesterone gel) submitted on November 13, 1996 to support the use of CRINONE® for progesterone supplementation or replacement as part of an ART treatment for infertile women with documented or suspected progesterone deficiency. In response to your comment and requests in your letter of March 25, 1997 concerning the Chemistry, Manufacturing and Controls section of the submission, we are amending the application with the information and enclosures:

Drug Substance

1. The Certificate of Analysis, containing the acceptance specification for progesterone from along with the Certificate of Analysis from is provided in Appendix 1.

2. The reference standard for progesterone used by is the U.S.P. reference standard. uses the reference standard for progesterone. itself uses the U.S.P. reference standard for progesterone. There are no reference standards for the progesterone related substance, Δ14-progesterone. The method for the determination of this substance does not require the preparation of a standard, as the content is calculated against the main progesterone peak. Standards of 6α-hydroxyprogesterone, 6 keto-progesterone, and 6β-hydroxyprogesterone (provided by AKZO Nobel) were used to determine relative response factors used in the development and validation of this method. Representative reference IR spectra for the standard and the standard can be found in Appendix 2.

100 No. Village Avenue
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TEL: (516) 766-2847
FAX: (516) 766-2873

Lisa Rarick, M.D.
June 30, 1997

General Tests and Specifications

1. The Certificates of Analysis containing the acceptance specifications of all excipients are provided in Appendix 3. The sample Certificates of Analysis (included) for Purified Water U.S.P. and Sodium Hydroxide N.F. will be used for these raw materials for all production batches.

2. The source of the sorbic acid reference standard Representative IR spectra for the reference standard and the can be found in Appendix 4.

3. The purified water and sodium hydroxide used in the formulation will comply with U.S.P. and N.F. specifications, respectively.

4. The method for determination of Uniformity of Content in Crinone® applicators can be found in Appendix 5. The test for Content Uniformity is included in the revised release specifications for the product (Appendix 6). As the Method Validation for progesterone content determination has already been provided (NDA 20-701, Volume 1.04, page 305), no additional method validation is included in this submission.

5. The method for preparation of a Composite Sample is provided in Appendix 7. This method is used in preparing the sample for assay of progesterone and related substances.

6. The limit of detection and quantification of Δ14-progesterone, the only identified related substance, is shown in Appendix 8. The other substances listed (6α-hydroxyprogesterone, 6-ketoprogesterone and 6β-hydroxyprogesterone) are degradants, not related substances.

7. The release rate testing is included in the revised specifications (Appendix 6). Release rate testing will be performed on the first three production batches, and on one of each five batches produced. The forecast is to produce 60 batches per year, therefore this testing will be performed approximately monthly on a randomly selected batch. The Method Validation for this testing has previously been submitted (NDA 20-701, Volume 1.04, page 238), therefore it is not included in this submission.

8. The Microbial Limit test will be conducted according to the method described in U.S.P. 23.

Stability

1. In accordance with the ICH Guidelines, the storage conditions and test intervals to be used for the first three production batches is shown in Appendix 9.

2. The sorbic acid is used in this product as an "in-process" preservative, protecting the product from microbes which may be introduced from the raw materials during the manufacturing process. Once the product is formulated, the gel's intrinsic low pH (2.5-3.5) makes it self-preserving. Therefore, it is only of concern to document that there is sufficient sorbic acid present during production and at release of the product to assure that any potential microbial contamination is removed. Due to the rapid degradation of sorbic acid, its concentration declines to below "effective" levels, however preservative efficacy testing shows the product to pass. The specifications will include a limit for sorbic acid upon release ( %), as well as a limit during the stability testing period of %.

Labeling

If there are any questions concerning this submission, please contact the undersigned at (516) 766-2660.

Yours truly,

Howard Levine, Pharm.D.
Vice President
Columbia Research Laboratories, Inc.

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

# APPLICATION TO MARKET A NEW DRUG FOR HUMAN USE OR AN ANTIBIOTIC DRUG FOR HUMAN USE

*(Title 21, Code of Federal Regulations, 314)*

Form Approved: OMB No. 0910-0001
Expiration Date: March 31, 1998
See OMB Statement on Page 3.

FOR FDA USE ONLY

| DATE RECEIVED | DATE FILED |
|---|---|
| | |
| DIVISION ASSIGNED | NDA/ANDA/BLA ASS |
| | |

NOTE: No application may be filed unless a completed application form has been received (21 CFR Part 314).

| NAME OF APPLICANT | DATE OF SUBMISSION |
|---|---|
| Columbia Research Laboratories, Inc. | June 30, 1997 |
| **ADDRESS** (Number, Street, City, State and Zip Code) | **TELEPHONE NO** (Include Area Code) |
| 100 North Village Avenue, Suite 32<br>Rockville Centre, NY 11570 | (516) 766-2660 |
| | **NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER** (If previously issued) |
| | 20-701 |

## DRUG PRODUCT

| ESTABLISHED NAME (e.g., USP/USAN) | PROPRIETARY NAME (If any) |
|---|---|
| progesterone gel | Crinone |

| CODE NAME (If any) | CHEMICAL NAME |
|---|---|
| COL-1620 | |

| DOSAGE FORM | ROUTE OF ADMINISTRATION | STRENGTH(S) |
|---|---|---|
| gel | vaginal | 4%/8% |

**PROPOSED INDICATIONS FOR USE**

Treatment of secondary amenorrhea and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as fibroids or uterine cancer.

**LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS (21 CFR Part 312), NEW DRUG OR ANTIBIOTIC APPLICATIONS (21 CFR Part 314), AND DRUG MASTER FILES (21 CFR 314.420) REFERRED TO IN THIS APPLICATION:**

IND (COL-160, progesterone gel)
DMF

## INFORMATION ON APPLICATION

**TYPE OF APPLICATION (Check one)**

☐ THIS SUBMISSION IS A FULL APPLICATION (21 CFR 314.50) ☐ THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) (21 CFR 314.55)

**IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION**

| NAME OF DRUG | HOLDER OF APPROVED APPLICATION |
|---|---|
| | |

**STATUS OF APPLICATION (Check one)**

☐ PRESUBMISSION ☐ ORIGINAL APPLICATION ☒ AN AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION ☐ SUPPLEMENTAL APPLICATION

**PROPOSED MARKETING STATUS (Check one)**

☒ APPLICATION FOR A PRESCRIPTION DRUG PRODUCT (Rx) ☐ APPLICATION FOR AN OVER-THE-COUNTER PRODUCT (OTC)