CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40306

ADMINISTRATIVE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date DEC 15 1998

From Consumer Safety Officer, Investigations & Preapproval Compliance Branch/DMPQ (HFD-324)

Subject Approve Recommendation, ANDA 40-306 Methylphenidate HCl (ER) Extended Release Tablets, 10 mg

To Pat Beers-Block, Chief
Review Support Branch, HFD-617

Applicant: Medeva Pharmaceuticals CA, Inc.
3501 West Garry Ave.
Santa Ana, CA 92704
CFN 2050088

Division of Manufacturing and Product Quality (HFD-320) has completed review of the Establishment Inspection Report (EIR) of the subject ANDA. The EIR covers an inspection conducted at Medeva's Santa Ana facility from October 5 - 9, 1998. The ANDA identifies this site as a manufacturer of both the active pharmaceutical ingredient and the solid oral dosage form. The site is also identified to perform analytical testing on both.

DMPQ does not concur with the District's recommendation to withhold approval of this ANDA. Our non-concurrence is based on the applicant's satisfactory response to FDA-483 observations 2, 3 and 4. Furthermore, although the first observation has not been corrected to date, we recognize revalidation (which is the subject of the first observation) to be a post approval issue. We also acknowledge that these revalidation efforts, which were conducted on their 20 mg strength (ER) and a 10 mg immediate release dosage form of this product have resulted in several out-of-specification assay results. However, in the absense of any regulatory recommendation, and given the VAI district GMP classification, and the fact that validation is expected to be routinely conducted post approval, DMPQ is unable to support a withhold recommendation.

A copy of the EIR and exhibits are attached for your review. If you have questions, please contact me at (301)-827-0065.

/S/
Randall L. Woods

Attachments - EIR and Exhibits
Applicant's Response

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

ANDA Number: 40-306 Date of Submission: April 10, 1998

Applicant's Name: Medeva Pharmaceuticals, Inc.

Established Name: Methylphenidate Hydrochloride Extended-release Tablets USP, 10 mg

Labeling Deficiencies:

1. CONTAINER - 100's

   a. We encourage you to differentiate your drug product from other strengths by using a boxing and/or contrasting colors, or some other means.

   b. We encourage you to increase the prominence of the statement "Rx only" and relocate to the principal display panel where the established name appears.

   c. USUAL DOSAGE

      It is preferable to use the term "insert" rather than '

2. INSERT

   a. DESCRIPTION

      i. Include the chemical formula.

      ii. Last paragraph:

         ... anhydrous lactose and... [rather than

   b. CLINICAL PHARMACOLOGY

      i. First paragraph, first sentence:

         Methylphenidate is a mild...

      ii. Penultimate and ultimate paragraphs:

         Your proposed statements regarding

pharmacokinetic studies of your drug product were found acceptable by the Division of Bioequivalence. However, we ask that you replace "Ritalin-SR®" with the established name of the drug product.

c. WARNINGS

i. Replace with "methylphenidate" throughout the text.

ii. Fourth paragraph, second sentence:

Relocate so that it begins a new fifth paragraph.

d. ADVERSE REACTIONS - Include the following statement immediately after the last sentence of the first paragraph.

Very rare reports of neuroleptic malignant syndrome (NMS) have been received, and, in most of these, patients were concurrently receiving therapies associated with NMS. In a single report, a ten year old boy who had been taking methylphenidate for approximately 18 months experienced an NMS-like event within 45 minutes of ingesting his first dose of venlafaxine. It is uncertain whether this case represented a drug-drug interaction, a response to either drug alone, or some other cause.

e. OVERDOSAGE (Third paragraph) - Revise the third sentence to read as follows:

Gastric contents may be evacuated by gastric lavage.

f. DOSAGE AND ADMINISTRATION - Children (6 years and over) - First paragraph:

Methylphenidate hydrochloride tablets should...

g. HOW SUPPLIED

We encourage the relocation of "Rx only" to the TITLE section.

Please revise your container labels and package insert labeling, as instructed above, and submit final printed container labels and insert labeling in final print.

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 the last submitted labeling with all differences annotated and explained.

/S/

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

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

ANDA Number: 40-306 Date of Submission: 3/1/99 & 5/20/99

Applicant's Name: Medeva Pharmaceuticals, Inc.

Established Name: Methylphenidate Hydrochloride Extended-release Tablets USP, 10 mg

---

Labeling Deficiencies:

1. GENERAL

   Your proposed proprietary names, Equasym ER, Zyteran ER, Ecuvin ER, Equazin ER, and Equazym ER Tablets, were found to be unacceptable by the CDER Labeling and Nomenclature Committee because they look like and/or sound like names of other products that are currently on the market. Examples of the Committee's findings are: Zyteran ER looks and/or sounds like Cytadren and Zyrtec; Ecuvin ER looks and/or sounds like Ecotrin, Oncovin, and Accutane; Equazin ER looks and/or sounds like Equanil and Equazine M; and Equasym ER looks and/or sounds like Equanil, Equazine and Aquasol.

2. CONTAINER - 100's

   a. Your container labels are difficult to read. Revise your container label to increase readability.

   b. Relocate "R_x only" to appear on the principal display panel.

3. INSERT

   a. DESCRIPTION

      The second sentence of the first paragraph should be revised to read "…is available as extended-release tablets of 10 and 20 mg for…"

   b. PRECAUTIONS (Carcinogenesis/Mutagenesis)

      Separate the last three sentences from the first paragraph to form a new paragraph.

Please revise your container labels and package insert labeling, as instructed above, and submit in draft or in final print using the established name of this product if you prefer.

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 the last submitted labeling with all differences annotated and explained.

/S/

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

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?			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?			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.		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?		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.		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.			

FOR THE RECORD:

1. MODEL LABELING

   Ritalin® - Novartis Pharmaceuticals Corporation; revised , and approved February 20, 1998 (18-029/S-022). FPL was found acceptable on October 26, 1998.

   Also used is the last approved labeling (approved 2/13/98) of the combined package insert for the immediate release tablets and extended-release tablets, 20 mg.

2. This application is to apply for the approval of extended-release tablets, 10 mg. The firm has proposed a combined package insert for their extended-release methylphenidate tablets.

3. The innovator does not market Ritalin-SR® tablets, 10 mg. The Agency has approved the firm's citizen's petition for this new strength.

4. 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 3506 (Volume B 1.12.

5. PATENTS/EXCLUSIVITIES

No pending issue. The firm's statement is accurate.

6. The "description and solubility" of the drug products found in the DESCRIPTION section is consistent with those described in the innovator's insert labeling.

7. STORAGE TEMPERATURE RECOMMENDATIONS COMPARISON

NDA - Do not store above 86°F (30°C). Protect from moisture.

ANDA - Store at controlled room temperature 15°-30°C (59°-86°F). Protect from moisture.

8. DISPENSING STATEMENT COMPARISON

NDA - Dispense in a tight, light-resistant container as defined in USP.

ANDA - Dispense in a tight, light-resistant container with child-resistant closure.

9. PACKAGING CONFIGURATIONS

NDA - 100's
ANDA - 100's

10. CONTAINER/CLOSURE SYSTEM (p.3722, vol.B.1.2)

Container: HDPE
Closure: 100's - Non-CRC

11. The tablet debossing(s) 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).

12. SCORING

NDA - Not available (20 mg is unscored)

ANDA - unscored

13. The firm has included pharmacokinetic data on their product (E-R 10 mg) in the CLINICAL PHARMACOLOGY section. I have referred this information to the bio. reviewer for comment as follows.

The firm has proposed Methylphenidate Extended-release tabletS USP, 10 mg (ANDA 40-306, Medeva Pharmaceuticals, Inc) whereas the RLD, Ritalin-SR® markets only 20 mg strength. The firm has included the following pharmacokinetic data under CLINICAL PHARMACOLOGY section of the package insert. Please review these statements for accuracy and forward your comment to me. Chan

Based on rate of bioavailability ($AUC_{0-\infty}$, T_{max}, and C_{max}), no significant statistical difference was found following single dose administration, in fasting and fed adults, of two 10 mg extended-release methylphenidate HCL tablets, USP or one tablet of Ritalin-SR® 20 mg. The administration of the extended-release methylphenidate HCL, USP, tablets with food, resulted in a greater C_{max} and $AUC_{0-\infty}$ than when administered in a fasting condition.

Pharmacokinetic and statistical analyses for a multiple dose study demonstrated that 3 times daily administration of two 10 mg methylphenidate HCL extended-release tablets, USP, met the requirements for bioequivalence to Ritalin-SR® 20 mg tablets when administered every eight hours. Pharmacokinetic parameters (i.e., $AUC_{0-\infty}$, T_{max}, C_{max}, C_{min}, and C_{av}) demonstrated achievement of steady state following 3 times daily administration of two 10 mg methylphenidate HCL extended-release tablets, USP was confirmed.

Answer: Jahnavi Kharidia in the Div. of Bioequivalency stated that the proposed statements appear acceptable via e-mail on 9/21/98. The e-mail correspondence is filed in the archival jacket.

Date of Review: June 2, 1999
Date of Submission: March 1, and May 20, 1999

Primary Reviewer: Koung Lee KL **Date:** 6/9/99

Team Leader: Charlie Hoppes **Date:** 6/10/99

/S/

cc:
ANDA: 40-306
DUP/DIVISION FILE
HFD-613/KLee/CHoppes (no cc)

Review

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

ANDA Number: 40-306 Date of Submission: 8/13/99

Applicant's Name: Medeva Pharmaceuticals, Inc.

Established Name: Methylphenidate Hydrochloride Extended-release Tablets USP, 10 mg

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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: (100's)

Satisfactory in FPL as of the 8/13/99 submission.

Professional Package Insert Labeling:

Satisfactory in FPL as of the 8/13/99 submission.

Revisions needed post-approval:

1. Add "(see USP)" after the storage temperature statement.

2. WARNINGS (Drug Interactions)

   The first sentence of the last paragraph should read as "…phenobarbital, phenytoin, primidone), phenylbutazone, and tricyclic drugs (imipramine…"

BASIS OF APPROVAL:

- Was this approval based upon a petition? no
- What is the RLD on the 356(h) form: Ritalin SR Sustained Release Tablets
- NDA Number: NDA 18-029
- NDA Drug Name: Methylphenidate Sustained Release Tablets
- NDA Firm: Novartis Pharmaceuticals Corporation
- Date of Approval of NDA Insert & supplement #: S-022, 10/26/98
- 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
- Basis of Approval for the Carton Labeling: N/A
- Other Comments: Package insert is shared with NDA 89-601/S-12.

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?			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
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Is this package size mismatched with the recommended dosage? If yes, the Poison Prevention Act may require a CRC.		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	
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Labeling			
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Answer: Jahnavi Kharidia in the Div. of Bioequivalency stated that the proposed statements appear acceptable via e-mail on 9/21/98. The e-mail correspondence is filed in the archival jacket.

14. The LNC found proposed name, Metadate ER, acceptable on July 13, 1999.

Date of Review: August 25, 1999
Date of Submission: August 13, 1999

Primary Reviewer: Koung Lee /s/ **Date:** 8/26/99

Team Leader: Charlie Hoppes /s/ **Date:** 8/26/99

cc: ANDA: 40-306
DUP/DIVISION FILE
HFD-613/KLee/CHoppes (no cc)

Concur 8/26/1999

Review

Telecon

Date: 042098

Time: 0940 H

ANDA #: 40-306

Firm: Medeva Pharmaceuticals

Drug: Methylphenidate Hydrochloride Extended-release Capsules USP, 10 mg

Participants: Gregg Davis, FDA and Norma Capetti, Medeva

Phone #: 716-274-5826

Agenda:

I called Norma and asked for some additional information and revisions. First, I asked for a RLD container label and a side-by-side labeling comparison. I also asked for any spectra/chromatograph data on the active drug substance. Next, I asked for amy container/closure data they had. Lastly, I asked for a revised √GDEA certification to include a convictions statement.

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

Date: 16-Apr-1998 08:15am EDT
From: Margo Bennett
BENNETTM
Dept: HFD-615 MPN2 113
Tel No: 301-827-5862 FAX 301-594-0174

TO: Rashmikant Patel (PATELR)
TO: Frank Holcombe (HOLCOMBE)
TO: Brenda Arnwine (ARNWINE)

CC: William Rickman (RICKMAN)

Subject: First Generic

Hi,

First generic for Methylphenidate HCl Extended-release Tablets, 10 mg
ANDA 40-306 firm Medeca PHarm. cover letter date 4-10-98 received 4-13-98.
Random V - Brenda Arnwine.

T s,

Margo

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

Date: 01-May-1998 11:11am EDT
From: William Rickman
RICKMAN
Dept: HFD-615 MPN2 113
Tel No: 301-827-5862 FAX 301-594-0174

TO: ELLA S WALKER (ORA) (EWALKER@ORA.FDA.GOV @INTERNET)
TO: ALFRED C KING (ORA) (AKING1@ORA.FDA.GOV @INTERNET)

Subject: RE: Methods Verification

OGD has accepetd for filing ANDA 40-306 for methylphenidate HCl Extended-release Tablets USP, 10 mg from:

Medeva Pharmaceuticals Manufacturing, Inc.
Att: Robert Parker, Ph.D.
755 Jefferson Rd.
P.O. Box 1710
Rochester, NY 14603-1710

Peter

Printed by Robert West

Electronic Mail Message

itivity: COMPANY CONFIDENTIAL

Date: 15-Oct-1999 07:01am
From: Mark Anderson
ANDERSONM
Dept: HFD-640 MPN2 E249
Tel No: 301-827-5787 FAX 301-443-3839

O: Patricia Nguyen (NGUYENP)

:C: Robert West (WESTR)
ubject: Re: DSI audit:Harris Labs

hanks, Patty for quick response!

Mark

>Good Afternoon Mark,
>
>That is correct we cancelled the DSI request due to the good inspection
>of( ) Therefore, no DSI issue to hold up this
>ANDA for approval. Hope this helps.
>
>Thanks,
>Patty
>>
>>
>>
>>
>>

ti/Elaine: We are processing application ANDA 40-306 for
>hylphenidate
>>HCL Extended-release tablets for approval. ( )

(was used for clinical testing and analytical testing. I can
>not
>>determine if site was inspected for this application. However I note
>that as of
>>August 5, 1999 DSI audits of( ) were cancelled (due
>to
>>acceptable inspectional history). Any reason not to approve this
>application
>>based on DSI?
>>Thanks!
>>
>>Mark

Printed by Pat Beers-Block

Electronic Mail Message

Se vity: COMPANY CONFIDENTIAL

Date: 05-Aug-1999 05:57pm
From: Elaine Hu
HUE
Dept: HFD-615 MPN2 118
Tel No: 301-827-5862 FAX 301-594-0181

TO: See Below
Subject: Re: Audits at 7 sites

Good Afternoon,

It was concluded after the Bio Division Directors Meeting held on 8/3/99 with Doug Sporn and Dale Conner, to cancel DSI inspections that have not been started at the following study sites:

Dr. Skelly provided a list of ANDAs that utilized clinical/analytical sites mentioned above and that are pending DSI audits (please see below). The Division of Bioequivalence reviewed this list, and is authorizing the cancellation of all inspection requests listed below.

Please feel free to contact me if you have any further questions.

T you very much for your help,
E
(7-5721)

> Elaine:
>
> The requests for ANDA audit/inspection for which the inspections at the seven sites have not yet begun involve these ANDAs:
>
> ANDA 75-091 Carbidopa+Levodopa (clin+anal)
> ANDA 75-515 Sotalol (anal; The audit of the clinical portion at will proceed.)
> ANDA 75-089 Ticlopidine (clin+anal)
> ANDA 75-624 Enalapril+Hydrochlorthiazide (anal)
> ANDA 75-451 Lovastatin (anal)
> ANDA 75-256 Desogestrel+Ethinyl Estradiol (clin+anal)
> ANDA 75-517 Ursodiol (clin+anal)
> ANDA 75-461 Nizatidine (clin+anal)
> ANDA 75-094 Ranitidine (clin+anal)
>
> none
>
> ANDA 75-273 Ketoconazole (clin)
> ANDA 75-153 Pseudoephedrine (clin)
>
> ANDA 75-640 Hydrochlorthiazide (clin+anal)
> ANDA 75-182 Estradiol transdermal (clin+anal; The audit of the

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

Date: 14-Oct-1999 11:15am EDT
From: Mark Anderson
ANDERSONM
Dept: HFD-640 MPN2 E249
Tel No: 301-827-5787 FAX 301-443-3839

TO: Patricia Nguyen (NGUYENP)

CC: Elaine Hu (HUE)

Subject: DSI audit:

Patti/Elaine: We are processing application ANDA 40-306 for Methylphenidate HCL Extended-release tablets for approval.
was used for clinical testing and analytical testing. I can not determine if site was inspected for this application. However I note that as of August 5, 1999 DSI audits of were cancelled (due to acceptable inspectional history). Any reason not to approve this application based on DSI?
Thanks!

M

Patent and Exclusivity Search Results from query on 018029 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

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Search results from the "Rx" table for query on "018029."

Active Ingredient:	METHYLPHENIDATE HYDROCHLORIDE
Dosage Form;Route:	Tablet, Extended Release; Oral
Proprietary Name:	RITALIN-SR
Applicant:	NOVARTIS
Strength:	20MG
Application Number:	018029
Product Number:	001
Approval Date:	Mar 30, 1982
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	**AB**
Patent and Exclusivity Info for this product:	Click Here

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