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[Home \(index.cfm\)](#) | [Previous Page](#)

New Drug Application (NDA): 010187

Company: NOVARTIS

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- [Medication Guide](#)
(http://www.accessdata.fda.gov/drugsatfda_docs/label/2017/010187s087lbl.pdf#page=11)
- [Other Important Information from FDA](#)
(<http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm283449.htm>)

Products on NDA 010187



CSVExcelPrint

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
RITALIN	METHYLPHENIDATE HYDROCHLORIDE	5MG	TABLET;ORAL	Prescription	AB	Yes	No
RITALIN	METHYLPHENIDATE HYDROCHLORIDE	10MG	TABLET;ORAL	Prescription	AB	Yes	No
RITALIN	METHYLPHENIDATE HYDROCHLORIDE	20MG	TABLET;ORAL	Prescription	AB	Yes	Yes

Showing 1 to 3 of 3 entries

[Approval Date\(s\) and History, Letters, Labels, Reviews for NDA 010187](#)



Original Approvals or Tentative Approvals**CSVExcelPrint**

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes
12/05/1955	ORIG-1	Approval	Type 3 - New Dosage Form	STANDARD		Label is not available on this site.

Showing 1 to 1 of 1 entries

Supplements**CSVExcelPrint**

Action Date	Submission	Submission Classification	Letters, Reviews, Labels, Patient Package Insert
01/04/2017	SUPPL-87	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/014201Orig1s001.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/014201Orig1s001.pdf)
05/27/2016	SUPPL-84	Manufacturing (CMC)	
10/02/2015	SUPPL-81	Manufacturing (CMC)	
04/17/2015	SUPPL-80	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/041720Orig1s001.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/041720Orig1s001.pdf)
07/14/2014	SUPPL-78	Manufacturing (CMC)	

Action Date	Submission	Submission Classification	Letter (PDF)
02/07/2014	SUPPL-76	Manufacturing (CMC)	
12/13/2013	SUPPL-77	Labeling- Medication Guide, Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/041821Orig1s001.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/041821Orig1s001.pdf)
10/25/2013	SUPPL-75	Manufacturing (CMC)	
06/07/2013	SUPPL-74	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/041821Orig1s001.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/041821Orig1s001.pdf)
12/09/2010	SUPPL-73	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/041821Orig1s001.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/041821Orig1s001.pdf)
11/15/2010	SUPPL-72	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/041821Orig1s001.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/041821Orig1s001.pdf)
04/25/2007	SUPPL-69	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/041821Orig1s001.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2007/041821Orig1s001.pdf)
08/08/2006	SUPPL-67	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/041821Orig1s001.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/041821Orig1s001.pdf)
08/08/2006	SUPPL-66	Labeling	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/041821Orig1s001.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/041821Orig1s001.pdf)
05/21/2004	SUPPL-58	Labeling	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/041821Orig1s001.pdf)
05/21/2004	SUPPL-57	Labeling	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/041821Orig1s001.pdf)

Action Date	Submission	Submission Classification	Letter (PDF)
06/12/2002	SUPPL-62	Manufacturing (CMC)-Control	
05/29/2002	SUPPL-61	Manufacturing (CMC)	
01/11/2002	SUPPL-60	Labeling	Letter (PDF) (https://www.accessdata.fda.gov/drugs)
08/15/2001	SUPPL-59	Manufacturing (CMC)-Control	
01/11/2000	SUPPL-56	Manufacturing (CMC)	
04/13/1999	SUPPL-55	Manufacturing (CMC) -Packaging	
11/24/1998	SUPPL-54	Manufacturing (CMC)	
09/17/1998	SUPPL-53	Manufacturing (CMC)	

Action Date	Submission	Submission Classification	Le P
08/12/1998	SUPPL-52	Manufacturing (CMC)-Control	
04/24/1998	SUPPL-51	Manufacturing (CMC)-Control	
02/20/1998	SUPPL-50	Labeling	
07/09/1997	SUPPL-48	Labeling	
07/09/1997	SUPPL-46	Labeling	
07/09/1997	SUPPL-42	Labeling	
07/09/1997	SUPPL-39	Labeling	
12/15/1995	SUPPL-47	Labeling	

Action Date	Submission	Submission Classification	Le P
06/01/1995	SUPPL-45	Manufacturing (CMC)-Control	
08/19/1994	SUPPL-44	Manufacturing (CMC)	
05/31/1994	SUPPL-43	Manufacturing (CMC)-Control	
03/07/1994	SUPPL-41	Manufacturing (CMC)-Control	
03/09/1990	SUPPL-40	Manufacturing (CMC)	
12/08/1987	SUPPL-38	Manufacturing (CMC)-Control	
01/21/1986	SUPPL-37	Labeling	
10/10/1985	SUPPL-34	Manufacturing (CMC)-Control	

Action Date	Submission	Submission Classification	Le P
03/13/1985	SUPPL-36	Manufacturing (CMC)-Control	
02/18/1981	SUPPL-32	Labeling	
03/06/1980	SUPPL-31	Manufacturing (CMC) -Formulation	
02/15/1980	SUPPL-30	Manufacturing (CMC) -Formulation	
10/12/1979	SUPPL-26	Manufacturing (CMC)-Control	
09/09/1975	SUPPL-28	Manufacturing (CMC)-Control	
09/09/1975	SUPPL-25	Manufacturing (CMC)-Control	
09/09/1975	SUPPL-24	Manufacturing (CMC)-Control	

Action Date	Submission	Submission Classification	Le P
09/09/1975	SUPPL-23	Manufacturing (CMC)-Control	
02/21/1975	SUPPL-21	Manufacturing (CMC)-Control	
Showing 1 to 50 of 50 entries			

Labels for NDA 010187**Therapeutic Equivalents for NDA 010187**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 10-187/S-057, S-058

NDA 18-029/S-028, S-029

Novartis Pharmaceuticals Corporation
Attention: Mara Stiles
Associate Director, Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936-1080

Dear Ms. Stiles:

Please refer to your supplemental new drug applications dated January 28, 2000, (S-057 and S-028) and March 10, 2000, (S-058 and S-029) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ritalin (methylphenidate HCL) Tablets and Ritalin SR (methylphenidate HCL) Sustained Release Tablets.

We acknowledge receipt of your amendments dated March 20, 2002, November 26, 2002, and March 21, 2003.

We also refer to our December 14, 2001 and November 19, 2002, approvable letters for these labeling supplements. Your submission of March 21, 2003 constituted a complete response to our November 19, 2002 action letter.

These supplements provide for updates to the "Precautions" section of labeling to include:

1. The addition of statements to the "Carcinogenesis/Mutagenesis/Impairment of Fertility" section.
2. The addition of a pregnancy statement.
3. Addition of statements to the "Pediatric Use" section.

We have completed our review of these applications, as amended and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

In addition we refer to the telephone conversation between you and Richardae Taylor of this Division on March 15, 2004, in which you informed the Division of typographical errors in the submitted labeling text for the above supplements. The errors consisted of the use of the term (b)(4)----- instead of Ritalin in the following sections of labeling, *Pregnancy Category C*, *Nursing Mothers*, and *Pediatric Use*. We remind you of your commitment to submit FPL which corrects these errors and replaces the term (b)(4)----- with Ritalin.

The final printed labeling (FPL) must be identical to the package insert submitted on March 21, 2003 including the labeling changes discussed above. Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more

NDA 10-187/S-057, S-058

NDA 18-029/S-028, S-029

Page 2

than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplements NDA 10-187/S-057, S-058 and NDA 18-029/S-028, S-029." Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Richardae C. Taylor, Pharm.D., Regulatory Health Project Manager, at (301) 594-5793.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Russell Katz
5/21/04 10:02:35 AM

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