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APPLICATION NUMBER:
74-926

BIOEQUIVALENCE

NOV 15 1996

Miconazole Nitrate Dual Pack (200 mg/2%)
ANDA: 74-926
Reviewer: A.P.Patel
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NMC Laboratories
Glendale, NY
Submitted:
July 15, 1996

Review of a waiver request

Introduction:

Miconazole is used in the treatment of vaginal yeast infections and relief from irritation associated with yeast infection.

Objective:

NMC Laboratories Inc. has applied for a waiver of clinical studies for their products, Miconazole 200 mg suppositories and Miconazole 2% Vaginal Cream packaged as Miconazole Nitrate Dual Pack. The reference listed product is Monistat® 3 combination Pack manufactured by Ortho Pharmaceutical Corporation.

Comments:

1. The firm cites that Miconazole Nitrate Vaginal Suppositories, USP 200 mg submitted to FDA on Feb. 12, 1991 (ANDA# 74-508 and clinical study #900155) and FDA approved it on Nov. 19, 1993.
2. Miconazole Nitrate External Vulvar Cream 2% has been submitted for review to the FDA on May 21, 1993 (ANDA# 74-164 and clinical study # 91021). The application was approved on March 29, 1996.
3. The dual pack is a combination of approved products manufactured by NMC Laboratories and deemed to be bioequivalent to reference listed product Monistat® 3 combination Pack manufactured by Ortho Pharmaceutical Corporation.
4. Composition of suppositories and vaginal cream is shown in Table 1.


Deficiency: None

Recommendation:

The Division of Bioequivalence finds the application submitted by NMC Laboratories, Inc. for Miconazole Nitrate Dual Pack acceptable. Miconazole Nitrate Dual Pack contains an approved Miconazole Nitrate Vaginal Suppositories, USP 200 mg product (ANDA# 74-508) and an approved Miconazole Nitrate External Vulvar Cream 2% product (ANDA# 74-164). The Division of Bioequivalence deems Miconazole Nitrate Dual Pack manufactured by NMC Laboratories, Inc. bioequivalent to the reference

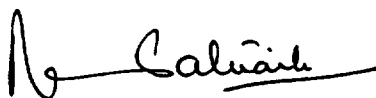
listed product Monistat® 3 combination Pack manufactured by Ortho Pharmaceutical Corporation.

The firm should be informed of the above recommendation.

 11/14/96

A.P. Patel
Division of Bioequivalence
Review Branch III

RD INITIALED RMhatre
FT INITIALED RMhatre Ramakant M. Mhatre Date: 11/14/96
Ramakant M. Mhatre, Ph.D.
Chief, Branch III
Division of Bioequivalence

Concur:  Date: 11/15/96

Rabindra Patnaik, Ph.D.
Acting Director
Division of Bioequivalence

cc: A
: File.

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Table 1

Test Product vaginal Cream Formulation

INGREDIENT	AMOUNT/GRAM	% W/W
Miconazole nitrate, USP (micronized)	0.02 g	
mineral oil,		
pegoxol		
peglicol		
benzoic acid,		
butylated hydroxyanisole.		
purified water,		11.0

Test Product Vaginal Suppository Formulation

INGREDIENT	AMOUNT/Unit
Miconazole nitrate,	200 mg
Vegetable Oil, :	
Vegetable Oil, '	