C · R · L · P

THE CENTER FOR REPRODUCTIVE LAW & POLICY

01 AUG -8 A9:51

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August 7, 2001

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 10-61
5630 Fishers Lane
Rockville MD 20857

Docket No. 001P-0075/CP 1

To Whom It May Concern:

On February 14, 2001, the Center for Reproductive Law & Policy submitted a petition on behalf of seventy-six organizations, pursuant to 21 C.F.R. § 10.30 (1999), to request that the Food and Drug Administration (FDA) switch two FDA-approved emergency contraceptive drugs and any equivalent new drugs from prescription to over-the-counter (OTC) status. We write to provide supplemental materials in support of the petition (Docket No. 001P-0075/CP 1), including a document establishing that Belgium provides emergency contraception OTC and a list of additional petitioners.

A copy of the Belgium document is attached in its original form along with a translation. The document is a Marketing Authorization showing that Norlevo, an emergency contraceptive drug, is registered by the Belgian Minister of Public Health as deliverable without prescription. This is in addition to Norway, which already provides emergency contraceptive drugs OTC. *See Citizen's Petition*, February 14, 2001 (Dec'l. of Grimes and Raymond at ¶ 9). A list of new petitioners is also attached.

Thank you for your time and consideration.

Sincerely,

Simon Heller

Simon Heller
Director, Domestic Program

01P-0075

SUP1

Réservé à l'Administration :

V

ENREGISTREMENT

(AUTORISATION DE MISE SUR LE MARCHE)

En application de l'A.R. du 3 Juillet 1969 relatif à l'enregistrement des médicaments, le Ministre de la Santé publique a décidé d'accorder à :

Laboratoires IRA PHARMA
Rue Frédérick Lemaître, 19
F - 75020 PARIS

[redacted]

PIETTE INTERNATIONAL
Groot Bijgaardenstraat, 128
1620 - DROGENBOS

sous le n° 2536 IE 1 F 3

l'enregistrement du médicament tel que caractérisé au verso de la présente.
La mise sur le marché de ce médicament est subordonnée aux conditions suivantes :

A cette attestation d'enregistrement sont joints les textes de notices tels qu'ils ont été acceptés lors de l'enregistrement. Les textes de notices qui sont rédigés dans une autre langue que la langue française doivent constituer une traduction exacte et complète du document joint en annexe.
FR/H/146/01

CET ENREGISTREMENT EST VALABLE JUSQU'AU
10/07/2006 o.k.

A ce jour, le mode légal de délivrance au public de ce médicament est le suivant :

- délivrance libre :
- ~~prescription médicale~~ : Art.6, alinea 3 loi 25.03.1964. Art. 7 A.R. 03.07.1969.

Toute modification aux indications qui composent le verso du présent document le rend nul.

A Bruxelles, le
11 -06- 2001

L'INSPECTEUR GENERAL

COMPOSITION QUALITATIVE (D.C.I. ou à défaut, dénomination usuelle + surdosage éventuel en principes actifs)	COMPOSITION QUANTITATIVE	REFERENCES DES NORMES ANALYTIQUES
PRINCIPE ACTIF :		
Lévonorgestrel	750 µg	Ph. Eur. 1998, n° 926
AUTRES COMPOSANTS :		
Lactose monohydraté		
Amidon de maïs		
Povidone		
Silice colloïdale anhydre		
Stéarate de magnésium		
Normes analytiques pour les principes actifs en %	95 - 105 %	

- dénomination et forme pharmaceutique : Norlevo, comprimés
- voie(s) d'administration ; voie orale
- dosage et présentations : 750 µg/comp. sous blister PVC/PE/PVDC/Alu, boîte de 2 et boîtes de 10, 20, 50 et 100 comprimés à usage hospitalier
- durée de validité : 2 ans
- précautions particulières de conservation : température ne dépassant pas 30°C

- nom et adresse du ou des fabricants intervenant dans le processus de fabrication avec indication des étapes auxquelles ils interviennent :

Titulaire :
Laboratoire HRA-Pharma
Rue Frédérick Lemaître, 19
75020 Paris - FRANCE

Fabricant :
Laboratoires Cassenne Osny
Rue de Pontoise, 17
95520 Osny - FRANCE

Importateur :
Laboratoires Piette International SA
Groot-Bijgaardenstraat, 128
1620 Drogenbos - BELGIQUE

For administrative use only:

REGISTRATION

(PERMIT TO SELL)

In enforcement of the A.R. of July 3, 1969 regarding the registration of medications, the Minister of Public Health has decided to grant to:

Laboratoires HRA PHARMA
Rue Frédéric Lemaître, 19
R - 75020 PARIS

PIETTE INTERNATIONAL
Groot Bijgaardenstraat, 12B
1620 - DROGENBOS

Under number 2536 IE I F 3

registration of the medication as is described on the reverse of this document.
The sale of this medication is subject to the following conditions:

Attached to this registration certificate is the text of the warning label as it was approved at the time of registration. If the text of the warning label is translated into a language other than French, the translation must be an exact and complete translation of the document attached herewith in the annex.
FR/H/146/01

THIS PERMIT
IS EFFECTIVE UNTIL
10/07/2005 O.K.

As of today, the legal method of distribution of this medication to the public is the following:

- unrestricted distribution

- ~~medical prescription~~ Art. 6, alinea 3 law 25.03.1964
Art. 7 A.R. 03.07.1969

Any alteration of the notices included on the reverse of this document will render the document void.

Brussels, this day
11-06-2001

CHIEF INSPECTOR

QUALITATIVE COMPOSITION (D.C.I. or if not available, usual designation and possible additional amount of active ingredients)	QUANTITATIVE COMPOSITION	RECOMMENDATIONS FOR ANALYTICAL STANDARDS
Active ingredient: Levonorgestrel	750 µg	Ph. Eur. 1998, # 926
Other components: Lactose monohydrate Corn starch Povidone Anhydrous silica colloid Magnesium stearate		

Analytical standards of active ingredients, in percentages	95 – 105%
- designation and pharmaceutical form:	Norlevo, tablets
- method of administration:	oral method
- dosage and appearance:	750 µg/tablet. Under packaging PVC/PE/PVDC/Alu, bottle of 2 and bottles of 10, 20, 50 and 100 tablets for hospital use
- length of validity	2 years
- specific precautions for preservation:	temperature not to exceed 30°C

- name and address of all intermediate manufacturers involved in the manufacturing process and information regarding the stage at which the manufacturer participated:

Patent holder:
Laboratoire HRA-Pharma
Rue Frédérick Lemaître, 19
75020 Paris – FRANCE

Manufacturer:
Laboratoires Casseime Osay
Rue de Pontoise, 17
95520 Osay – FRANCE

Importer:
Laboratoires Piette International SA
Groot-Bijgaardenstraat, 128
1620 Drogenbos – BELGIQUE

Post- February 14th Petitioners

Juneau Pro-Choice Coalition

National Women's Law Center

Oregon Medical Association

Religious Coalition for Reproductive Choice

Robert Sterling Clark Foundation

Society for Adolescent Medicine

Zero Population Growth, Inc.

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