

Labels & labeling

An over view

(Certainly not an exhaustive one.)

DRUG includes

Section 3 (b) of D&C Act 1940.

- (i)* all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the **diagnosis, treatment, mitigation or prevention** of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

- (ii)* such substances (other than food) intended to **affect the structure** or any **function** of human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;

contd.,

DRUG includes- contd.,

- iii)* all substances intended for use as components of a drug including empty gelatin capsules; and
- (iv)* such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette after consultation with the Board.

COSMETIC

Section 3(aaa) of D&C Act 1940

“cosmetic” means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the **human body** or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic

Statutes / competent Authorities

- The D & C Act, 1940 and Rules 1945,
- The DMR (OA) Act, 1954 and Rules 1955,
- DPCO, 1995 made under section 3 of EC Act 1955,
- The SoWM (pc) Rules 1976,
- B S I – specifications & standards,
- Drugs Controller General of India,
- State Drugs Control Administrations,
- (Regulations of importing countries) etc.,

Label & misbranded

- The term *Label* is **not defined** in the D & C Act, 1940 and Rules, 1945.

But, its important to know that

- A drug / cosmetic is deemed to be **Misbranded**
 - if it is not labelled in the prescribed manner. (17(b), 17-C(b))
 - if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular. 17(c),
 - if the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular. 17-C (c),

Prohibition . . .

- No person shall himself or by any other person on his behalf manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute any drug / cosmetic which is
Misbranded
- No person shall sell or distribute, any drug (including a patent / proprietary medicine) unless it is **labelled** in accordance with the Rules.
- No person shall sell or distribute any cosmetic unless the cosmetic, if of Indian origin, is manufactured by a licensed manufacturer and is **labelled** and packed in accordance with the Rules
- No person shall alter, obliterate or deface any inscription or mark made or recorded by the manufacturer on the container, label or wrapper of any drug (excepting done at instance, direction or with the permission of the L.A.)

Penal provisions.

Sl.No	Name of The statute	Penalty in years (mandatory)	Fine in Rupees, not less than (mandatory)	Relevant Section of law
1.	D&C Act1940 & Rules	one to two years	Rs.20,000/-	27(d)
2.	DMROA Act 1954& Rules	0.5 to 1 year	Or with fine, Or with both	7
3.	DPCO 1995 (E.C.Act 1955)	0.25 to 7 years	fine	7(1)a(ii)
4.	SoWM (pc) Rules 1976	- - - -	Rs.2,000/-	Rule 39

Penal provisions – contd., -

Who shall be the accused ?

Proprietor of the organization

If, a partnership or a company –

- every partner / director
- every person responsible to the day to day affairs of the organization
- every person who was in charge when the offence was committed, including the **employees**
- the company, as well.

Label – why?

- Label is
 - a bridge between the producer and consumer,
 - Identification of the product, its contents, dosage form,
 - name and address of producer – to contact, if needed
 - cautions & warnings,
 - directions for use,
 - batch number, date of manufacture, date of expiry,
 - storage conditions,
 - maximum retail price,
 - and insures against counterfeiting/ spurious products,

Label - defined

- Label means any written, printed or graphic matter on the immediate package and on every other covering in which the package is placed or packed and includes any written, printed or graphic matter accompanying the insecticide. - (***Insecticides Act, 1968.***)
- Label means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, graphic, perforated, stamped or impressed on or attached to container, cover, lid or crown of any food package and includes a product insert.- (***The Food Safety & Standards Act, 2006***)

Label - defined

- Label means any written, marked, stamped, printed or graphic matter affixed to, or appearing upon any commodity (package) or packing containing any commodity.- (***The S o W&M Act 1976 and The Cigarette and other tobacco products etc., Act 2003***)
- Label means a display of written, marked, stamped, printed or graphic matter affixed to, or appearing upon any container. – (***Infants Milk Substitutes etc., Act 1992***)

Label – Pharmacopoeia-defines

- Label means any printed packaging material, including package inserts that provide information on the article .
- (*I.P. 2007*)
- When the term LABEL is used in Pharmacopoeia, the labelling statement may appear on the container, the package, a leaflet accompanying the package, or a certificate of analysis accompanying the article, as decided by the competent authority.- (*Ph.Eur,2009*)
- The term LABELLING designates all labels and other written, printed or graphic matter upon an immediate container of an article or upon, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term label designates that part of labelling upon the immediate container. – (*U.S.P, 30*)

Label - defined

- A **label** is a piece of paper, polymer, cloth, metal, or other material affixed to a container or article, on which is printed a legend, information concerning the product, addresses, etc. A label may also be printed directly on the container or article. (Wikipedia, the free encyclopedia)
- FDA has asserted that oral statements by sales representatives , speeches in CME programs and lectures are “labeling”
 - Never litigated

Therefore

- Label means a display of any printed, written in indelible ink, marked, stamped, stencilled, embossed, etched, perforated, graphic, pictorial or other descriptive matter appearing on a piece of paper, polymer, cloth or other material, or on the immediate container, cover, lid, crown and includes a product insert / leaflet that provide information on the article, affixed to, or appear on ,or accompanying any commodity, as decided by the Competent Authority or the Statutes, as the case may be.

(synopsis of sum total of all the definitions)

Contents of a label.

- If, targeted for export –
- Regulations of the importing country shall be adhered to and shall contain the following minimum details :
 - name of the drug,
 - batch / lot number,
 - date of expiry, if any,
 - manufacturing license number,
 - name & address of the manufacturer /(code number)*

* (if not classified under Sch-F/F1, X, Blood products and ND & PS)

Contents of a label.

- The name of the drug
(proper name, conspicuously, and brand name, if any)
- inclusion of the letters, I.P, NFI,B.P,USP,INN, or descriptive of the true nature or origin (generic name)
- The Net Contents,
- The contents of active ingredients,
- The name & address of the manufacturer,
- Batch Number/ B.No./ Batch/ Lot No./Lot,
- Manufacturing licence number- M.L./ Mfg.Lic.No.
- Date of manufacture & the date of expiry of potency,

Contents of a label. (contd.,)

- “Import licence” number, if of sch - c /c1 & imported,
- “Physician's sample – Not to be sold”,
- Percentage of Alcohol, if not less than 3%,
- Red vertical line - of not less than 1mm thickness,
(falling under schedule G,H,X, narcotic analgesics, hypnotics, sedatives, tranquilizers, corticosteroids, hormones, hypoglycemics, antimicrobials, antiepileptics, anticancer drugs)

(Exceptions – Vet. drugs, external use, ophthalmic preparations, ear drops, sterile sutures, surgical dressings, preparations for parenteral use)
- Mechanical contraceptives + Schedule R.

Contents of a label. (contd.,)-Medicines

Schedule G drug –

“Caution: it is dangerous to take this preparation except under medical supervision”

- conspicuously printed, - surrounded by a line, -no other words.
(exception topical / external preparations.)

Schedule H drug -

- Rx on the left top corner conspicuously

Schedule H drug – warning: to be sold by retail on the prescription of a Registered Medical Practitioner only

Contents of a label. (contd.,)

Medicines.

- Schedule H drug – falling under NDPS Act, 1985
 - NRx ,in red colour ,on the left top corner ,conspicuously
- Schedule H drug – warning: to be sold by retail on the prescription of a Registered Medical Practitioner only

Schedule H drug – specified in Schedule X

XRx ,in red colour ,on the left top corner, conspicuously

Schedule X drug – warning: to be sold by retail on the prescription of a Registered Medical Practitioner only.

* if it is a bulk packing - only XRx in red colour, displayed conspicuously

Contents of a label. (contd.,)

Medicines.

- Liniment, lotion etc., - "For external use only."
- Contains industrial methylated spirit (for human use),
- declare the fact & -"For external use only."
- If for veterinary use – “ Not for human use ;
for animal treatment only ”
Names of the approved colours added, if any.
- Non sterile surgical ligatures & sutures –
- “non sterile surgical ligature (suture) – not to be used
for operations upon the human body unless efficiently
sterilised.”

Contents of a label. (contd.,)

- Directions & guide lines — Pharmacopoeia
- Directions & guide lines - D & C Rules
- Directions & guide lines - SoW&M (PC) Rules
- Directions & guide lines - BIS specifications
- Directions & guide lines - DCG (I), SLAs

Contents of a label. (cosmetics)

- If, targeted for export –
- Regulations of the importing country shall be adhered to
- Shall contain name & address of the manufacturer (code number - if requested by the consignee)

- If targeted for sale or consumption in India
 - shall be manufactured by a licensed manufacturer,
 - shall be labeled as prescribed,
 - shall not contain misleading / false claims

Contents of a label. (cosmetics)

- Shall be labeled on inner and outer label
 - name of the cosmetic,
 - name and address of the manufacturer (if the container is so small the name and principal place of business)
 - Use before ,
 - Net contents (On outer label),
 - Adequate directions for use, warning, caution or special directions, names and quantities of hazardous / poisonous materials added --(where hazard exists)

Contents of a label. (cosmetics) contd.,

- Batch number, preceded by “B”,
- Manufacturing license number –
preceded by “M”,
- List of ingredients of more than or equal to 1%, in the order of addition, in descending order (exemption to less than 60ml / 30 g), preceded by the words
“INGREDIENTS”
- Schedule- S, r.w. BSI specifications, if any
(directions issued by licensing authority)

Contents of a label. (cosmetics) contd.,

- Toothpaste containing fluoride
 - content of fluoride in ppm (shall not be more than 1000 ppm)
 - date of expiry on tube and cartoon.

Note :-Medicated toothpastes are drugs.

- Hair dyes containing dyes, colours, pigments – shall bear a caution (R-149)

Contents of a label. (cosmetics) contd., Hair dyes containing dyes, colours

- “**Caution**—This product contains ingredients which may cause skin irritation in certain cases and so a preliminary test according to the accompanying direction should first be made. This product should not be used for dyeing the eye-lashes or eye-brows as such a use may cause blindness”.
- Each package shall also contain instructions in English and *local languages* on the following lines for carrying out the test:

“This preparation may cause serious inflammation of the skin in some cases and so a preliminary test should always be carried out to determine whether or not special sensitivity exists. To make the test, cleanse a small area of skin behind the ear or upon the inner surface of the forearm, using either soap and water or alcohol. Apply a small quantity of the hair dye as prepared for use to the area and allow it to dry. After twenty-four hours, wash the area gently with soap and water. If no irritation or inflammation is apparent, it may be assumed that no hypersensitivity to the dye exists. The test should, however, be carried out before each and every application. This preparation should on no account be used for dyeing eye-brows or eye-lashes as severe inflammation of the eye or even blindness may result”.

Your comments please – 1.

PIOPOD G 2

10 x 10 TABLETS

Mfg. Lic. No. : MNB/05/101

Batch No. : AF-8003

Mfg. Date : AUG. 2008
उत्पादन की तिथि

Exp. Date : JUL. 2010
समाप्ति की तिथि

Max. Retail Price Rs. 88.85

अधिकतम खुदरा मूल्य रु.
per strip of 10 tablets
१० गोली प्रति पत्रा
Inclusive of all taxes
सभी कर सहित

पायोपोड जी २

१० X १० टेबलेट्स

PIOPOD G 2

10 x 10 TABLETS

Each uncoated tablet contains :
Pioglitazone Hydrochloride
equivalent to Pioglitazone 15 mg
Glimepiride U.S.P. 2 mg
Excipients q.s.
Dosage : As directed by the Physician

KEEP IN A COOL & DRY PLACE
PROTECT FROM LIGHT
Keep out of reach of children

Schedule 'H' Drug
Warning : To be sold by retail on the
prescription of a Registered Medical
Practitioner only

Caution : It is dangerous to take this
preparation except under Medical
Supervision

SP2

Rx
Pioglitazone Hydrochloride &
Glimepiride Tablets

PIOPOD G 2

10 STRIPS OF 10 TABLETS EACH



Marketed by :
TORRENT PHARMACEUTICALS LTD.
Indrad-382 721, Dist. Mehsana, INDIA.
Manufactured by :
Acme Formulation Pvt. Ltd.
Ropar Road, Nalagarh, Dist. Solan H.P.-174101

Your comments please-2

Rx

Risperidone And Trihexyphenidyl Hcl
Tablets

DON PLUSTM
डान प्लसTM

Crescent

DON PLUS डान प्लसTM

2 X 5 X 10 Tablets

Each film coated tablet contains :

Risperidone 3 mg.
Trihexyphenidyl Hcl. I.P. 2 mg.
COLOUR : Red-Iron Oxide & Titanium Oxide
DOSAGE : As directed by the Psychiatrist.
STORAGE : Store between 15° C to 30° C
in dry place, protect from light.
Keep medicine away from reach
of the children.

WARNING : To be sold by retail on the
prescription of a Psychiatrist only.

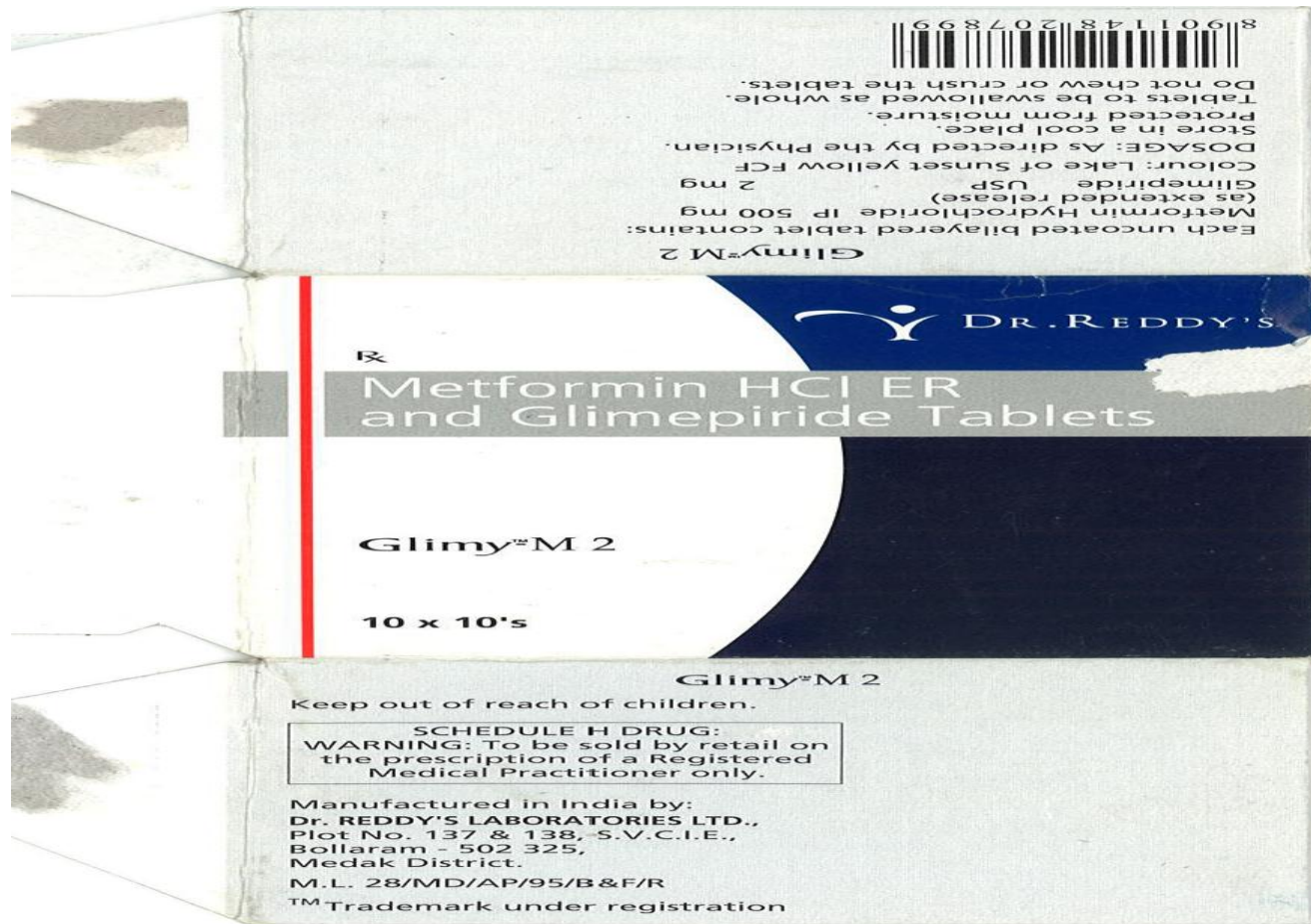
Mfg. Lic. No: MNB/01/47 & MB/01/46
Batch No. : **DP-6010**
Date of Mfg : **01/2008**
उत्पादन की तिथि : **01/2008**
Date of Exp. : **12/2009**
समाप्ति की तिथि : **12/2009**
M.R.P. Rs. : **34.55**
Incl of all Taxes Per Blister of 10 tablets
अधिकतम खुदरा मूल्य सभी कर सहित प्रति 10 गोलीयां

Marketed by:

Crescent
THERAPEUTICS LIMITED
Crescent Towers, H.No: 4-7-11/4/B,
Raghavendra Nagar, Nacharam,
Hyderabad - 500 076.
(TM) Trade Mark Pending
Mfd by: MISSION LABORATORIES
190-B, HPSIDC, Baddi-173205 (H.P.)

DON PLUS डान प्लसTM

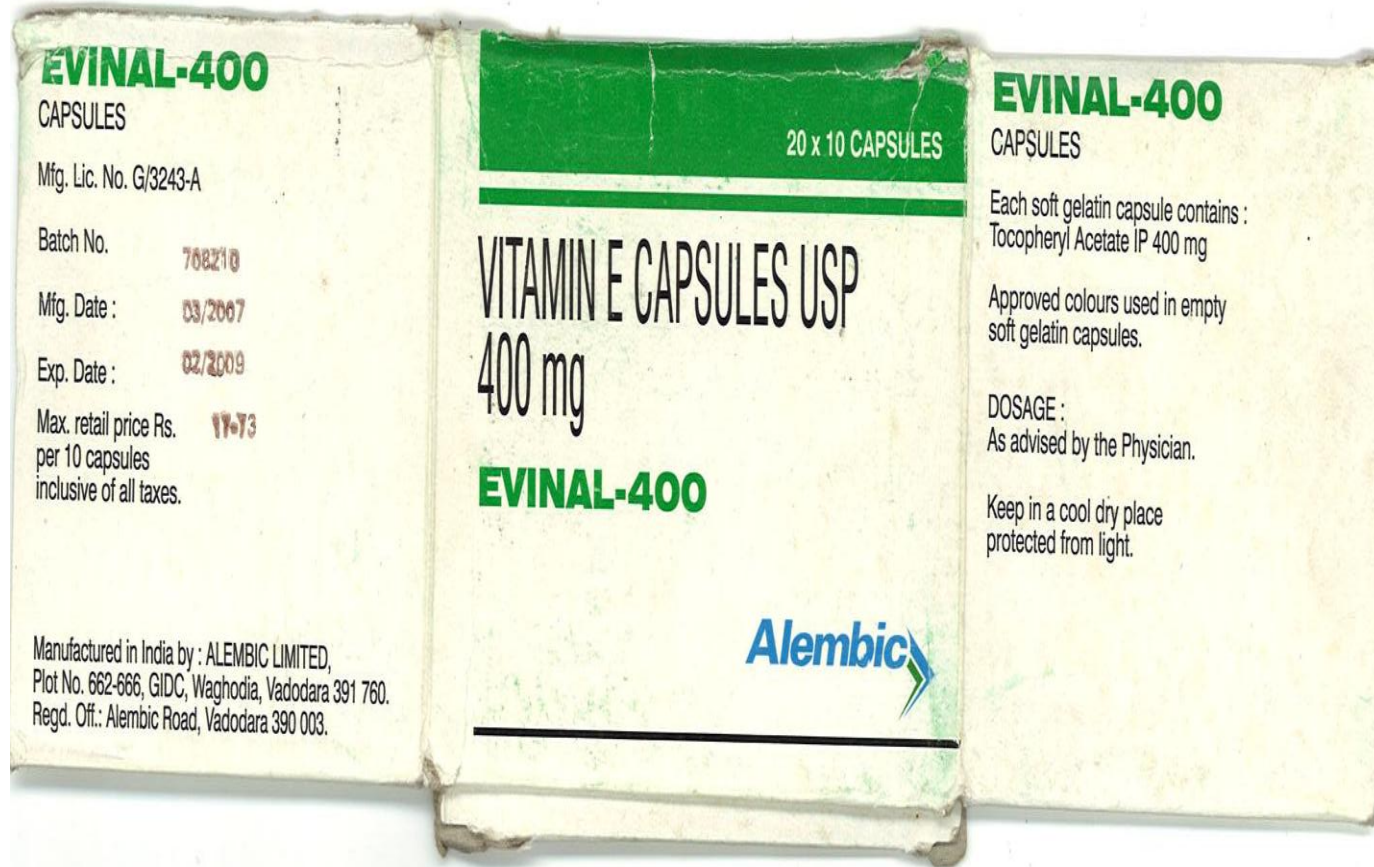
Your comments please – 3.



Your comments please -4.



Your comments please – 5.



Your comments please – 6.



Your comments please – 7.



Thank you all

and

let me try to ANSWER your

?

misleading: ?

- Factors that make claims misleading:
 - – Lack of adequate basis for comparative claims
 - – Reliance on inadequate studies
 - – Manipulation of data, statistical analysis
 - – Lack of sufficient emphasis on adverse effect information
- – Promotion of uses beyond approved NDA