LABELLING

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FDA Labelling Template

ACKNOWLEDGEMENT

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PARTICULARS TO APPEAR ON THE <OUTER PACKAGING> <AND> <THE IMMEDIATE PACKAGING>
(outer packaging or, where there is no outer packaging on the immediate packaging
{NATURE/TYPE}

1. NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form}
{Active substance(s)}

2. STATEMENT OF ACTIVE SUBSTANCE(S)

3. LIST OF EXCIPIENTS

List of excipients of known safety concern (eg; lactose, gluten, metabisulfites, parabens, ethanol, tartrazine) should be stated on the secondary product label. http://www.ema.europa.eu/docs/en.....

4. PHARMACEUTICAL FORM AND CONTENTS

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

[For terms on Batch number and Expiry date see Appendix 3 (ref. Appendix IV)]

9. SPECIAL STORAGE CONDITIONS

[For storage conditions statements see Appendix 3 (ref. Appendix III)]

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE <MANUFACTURER> HOLDER

{Name and Location Address}
<{tel}>
<{fax}>
<{e-mail}>

13. BATCH NUMBER

[For terms on Batch number and Expiry date see appendix 3 (ref. Appendix IV)]

14. <ADVICE ON> GENERAL CLASSIFICATION FOR SUPPLY

<Medicinal product subject to medical prescription.>
<Medicinal product not subject to medical prescription.>

15. DIRECTIONS FOR USE

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}

1. NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form}
{Active substance(s)}

2. NAME OF THE MANUFACTURER

{Name}

3. EXPIRY DATE

[For terms on Batch number and Expiry date see appendix 3 (ref. Appendix IV)]

4. BATCH NUMBER

[For terms on Batch number and Expiry date see appendix 3 (ref. Appendix IV)]

5. OTHER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
(Applicable to containers less than or equal to 10ml capacity that are marketed in an outer pack such as a carton where the outer pack bears all the required information)
{NATURE/TYPE}

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

{(Invented) name strength pharmaceutical form}
{Active substance(s)}
{Route of administration}

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

[For terms on Batch number and Expiry date see appendix 3 (ref. Appendix IV)]

4. BATCH NUMBER

[For terms on Batch number and Expiry date see appendix 3 (ref. Appendix IV)]

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

6. OTHER