

12/2004

Attachment A

Sample Professional Label

Title Page

Trade name of product

Common name of product, if any: e.g. lidocaine transdermal delivery system

Prescription symbol or statement. (Suggest holding out for right to use Rx symbol, per drug regs)

Contents of Professional Labeling

1. Combination Product Description: short description of combo product. e.g., the XXX drug x delivery system is composed of an implantable reservoir, pump, controller and associated firmware/software, and a specific formulation of drug x. Drawing or photo of product could be helpful. Sizes or doses in which product is available should be described.

1.1 Device Component Description: A brief description of the device component of the product, state material of composition and how provided (assembled, kit, single unit, single use). Drawing if useful.

1.2 Drug Component Description

1.2.1 Drug substance(s): this is a description of the chemistry of the drug, its chemical formula, structural formula, IUPAC name, NDC number, etc.

1.2.2 Recipients/matrices: any additional chemical substances employed to make the drug compatible with the system as a whole. E.g., special formulation, special drug containing/eluting matrix, etc.

1.2.3 Drug component formulation: actual amount of drug in product, amounts of any other excipients matrices involved in providing the drug activity. Total amount of drug present in acceptable units (weight or potency units, depending) should be given. If a delivery system, rate of drug delivery (using same quantity units) should be given. Amounts of excipients should be given.

Note Clinical Pharmacology will be addressed in a later section.

2. Indications: State the disease conditions, expected effect of product, expected patient populations, e.g., “for the treatment of acute conjunctivitis caused by gram negative aerobic organisms in patients between 16 and 25 years of age.”

3. Contraindications: Self explanatory: Under what circumstance should the product not be used because the risk of use outweighs the benefit.

4. Warnings: Describes serious hazards of using the product, serious adverse effects. e.g., warnings about sharps, sterility maintenance of product if required (“discard if package damaged”), allergy to components.

5. Precautions:

5.1 General Precautions: Special care to be exercised by users of the product to ensure safe use.

5.2 Specific Patient precautions, if any (e.g., driving, use of alcohol, interactions with OTC drugs).

5.3 Laboratory tests required or recommended to follow course of treatment.

5.4 Use in conjunction with other procedures or other prescription products.

5.5 Special Populations (not all may be needed for any one particular product):

5.5.1 Pregnancy

5.5.2 Lactation

5.5.3 Gender

5.5.4 Ethnicity

5.5.5 Pediatric use (pediatric assessment now required for NDA products unless waived or deferred)

5.5.6 Geriatric Use

5.6 Particular precautions relating to device component, if any.

5.7 Known Drug Interactions with product (drug or device component, if any).

5.8 Application, insertion, placement of product: if internal or patient-contact. (Ignore for extracorporeal product)

5.9 Removal of product (if required)

5.10 Post-Procedure precautions, if any

6. Drug Information:

This is the traditional drug information package, straight out of 21 CFR 201.57

6.1 Mechanism of Action

6.2 Pharmacokinetics

6.3 Drug Interactions (if this has already been handled in Section 5.8, do not repeat).

6.4 Carcinogenicity, Genotoxicity and Reproductive Toxicology

6.5 Pregnancy (this should expand on any precautions for pregnant women in 5.6).

6.6 Lactation (see above)

6.7 Other precautions that need expanding, if any.

7. Overview of Clinical Studies: (with product or product prototype, if relevant). This is a short summary which will be expanded upon in 9.

8. Adverse Events: (product as a whole)

8.1 Observed Adverse Events

8.2 Potential Adverse Events

9. Clinical Studies: This section usually gives data tables, and stats.

10. Individualization of Treatment: Carry vary size of unit, dosage, duration of delivery? State and describe.

11. Patient Counseling Information: For products for which no patient package insert is required, a section on any important information patient should have before, during or after treatment. This section is essentially a patient information brochure, or can refer to one, which is offered to the patient prior to treatment.

12. How Supplied: Product as a whole, describe package, sterility, single use or more, virtual (for use only with brand x product), kit, or integrated combination product, and state storage conditions.

13. Operators Instructions: will vary depending on type of combination product. The following is simply a suggestion for the type of information that might be found in this section, which is in fact an IFU manual.

13.1 Inspection of Product prior to unpacking, or upon receipt at place of use.

13.2 Materials Required (not included in Product Package)

13.3 Preparation of patient, suite, or other environment prior to use of product.

13.3.1 Packaging removal and inspection of product.

13.3.2 Assembly or preparation of combination product after unpacking.

13.3.3 Administration of product, which may include: application of product, implantation of product, etc.

13.3.4 Termination of treatment with product, which may include removal, detachment from patient or appliance, etc. If this is a permanent implant with a limited term elution function, it might be a good idea to suggest procedures for determining if the elution has ceased.

13.4 Observations and procedures during treatment with product.

13.5 Troubleshooting: telephone # of service function.

14. In Vitro Information: If there are in vitro tests or studies that are relevant to the product function, describe them and describe expected results for lab tests.

15. Reuse Precaution Statement: if a single use product.

16. Warranties.

17. Seller, Manufacturer Information.