ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

{NATURE/TYPE} Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fenoflox 100 mg/ml Solution for Injection for cattle and pigs
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Enrofloxacin 100 mg
n-butanol 30 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100ml, 250ml

5. TARGET SPECIES

Cattle, Pigs,

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intravenous or subcutaneous injection in cattle. Intramuscular injection in pigs.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle:

Intravenous: Meat and offal: 5 days.

Milk: 3 days.

Subcutaneous: Meat and offal: 12 days.

Milk: 4 days.

Pigs:

Meat and offal: 13 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

Shelf-life after first opening the immediate packaging: 28 days.

Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

After first opening the immediate packaging: do not store above 25°C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland.

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

BN:

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

{NATURE/TYPE} Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fenoflox 100 mg/ml Solution for Injection for cattle and pigs
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Enrofloxacin 100 mg
n-butanol 30 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100ml, 250ml

5. TARGET SPECIES

Cattle, Pigs,

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IV or SC injection in cattle. IM injection in pigs.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle:

IV: Meat and offal: 5 days.

Milk: 3 days.

SC: Meat and offal: 12 days.

Milk: 4 days.

Pigs:

Meat and offal: 13 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

Shelf-life after first opening the immediate packaging: 28 days.

Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

After first opening the immediate packaging: do not store above 25°C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland.

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

BN:

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Fenoflox 100 mg/ml Solution for Injection for cattle and pigs
Enrofloxacin

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland

Manufacturer for the batch release:
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland
and
Labiana Life Sciences, c/ Venus, 26. Can Parellada Industrial, 08228 Terrassa . Barcelona, Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fenoflox 100 mg/ml Solution for Injection for cattle and pigs

Enrofloxacin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:
Active substance:
Enrofloxacin 100mg
Excipient:
n-butanol 30mg
A clear light yellow solution, free from particulate matter.

4. INDICATION(S)

Treatment of bacterial infections caused by strains susceptible to enrofloxacin.

Cattle
Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma* spp.
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.

Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis* in cattle less than 2 years old.

Pigs
Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mycoplasma* spp. and *Actinobacillus pleuropneumoniae.*
Treatment of infections of the urinary tract caused by enrofloxacin susceptible strains of *Escherichia coli.*
Treatment of post-partum dysgalactiae syndrome, PDS (MMA syndrome) caused by enrofloxacin susceptible strains of *Escherichia coli* and *Klebsiella* spp.
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.

5. CONTRAINDICATIONS

Do not use for prophylaxis.
Do not use when resistance / cross resistance to (Fluoro)quinolones is known to occur. Do not use in the case of known hypersensitivity to fluoroquinolones or to any of the excipients
Do not use in animals with seizures.
Do not use in growing horses because of possible deleterious damage on articular cartilage.

6. ADVERSE REACTIONS

Local tissue reactions may occasionally occur at the injection site. Normal sterile precautions should be taken. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, Pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intravenous, subcutaneous or intramuscular use.
Repeated injections should be made at different injection sites.

Cattle

5 mg of enrofloxacin/kg body weight (bw), corresponding to 1 ml/20 kg bw, once daily for 3-5 days.
Acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis* in cattle less than 2 years old*:* 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily for 5 days.
The product can be administered by slow intravenous or subcutaneous administration.
Not more than 10 ml should be administered at one subcutaneous injection site.

Pigs

2.5 mg of enrofloxacin/kg bw, corresponding to 0.5 ml/20 kg bw, once daily by intramuscular injection for 3 days.
Alimentary tract infection or septicaemia caused by *Escherichia coli:* 5 mg of enrofloxacin/kg bw, corresponding to 1.0 ml/20 kg bw, once daily by intramuscular injection for 3 days.
In pigs, the injection should be made in the neck at the ear base.
Not more than 3 ml should be administered at one intramuscular injection site.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

10. WITHDRAWAL PERIOD

Cattle:
Following intravenous injection:
Meat and offal: 5 days.
Milk: 3 days.
Following subcutaneous injection:
Meat and offal: 12 days.
Milk: 4 days.

Pigs:
Meat and offal: 13 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children
Do not store above 25°C.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial label after "EXP". The expiry date refers to the last day of that month.
Shelf-life after first broaching the vial: 28 days
After first opening the immediate packaging: do not store above 25°C.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

Special Precautions for use in animals
Do not exceed the recommended dosage.
Repeat injections should be made at different sites.
The safety of the product has not been established in pigs or calves when administered by the intravenous route and use of this route of administration is not recommended in these animal groups.
Enrofloxacin should be used with caution in epileptic animals or animals affected by renal dysfunction.
In cattle, gastrointestinal disturbances may occasionally occur.
Official and local antimicrobial policies should be taken into account when the product is used.
Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials.
Whenever possible, fluoroquinolones should only be used based on susceptibility testing.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.
Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg bw during 14 days.

Use during pregnancy and lactation.
There is no restriction on the use of this product during pregnancy and lactation.

Interactions
Antagonistic effects due to concurrent administration of macrolides, and tetracyclines may occur.
Enrofloxacin may interfere with the metabolism of theophylline, decreasing theophylline clearance resulting in increased plasma levels of theophylline.

Incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Overdose:
Do not exceed the recommended dose.
In accidental overdose (lethargy, anorexia) there is no antidote and treatment should be symptomatic.
No signs of over dosage were observed in pigs following administration of the product at five times the recommended therapeutic dose.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
The product is an alkaline solution. Wash any splashes from skin and eyes immediately with water.

Do not eat, drink or smoke whilst using the product. Direct contact with the skin should be avoided because of sensitisation, contact dermatitis and possible hypersensitivity reactions. Wear gloves.
Care should be taken to avoid accidental self-injection. In case of accidental injection, seek medical advice immediately and show the package leaflet or the label to the physician

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes: 100ml and 250ml.
No of containers in a carton:
1 x 100 ml, 5 x 100 ml, 10 x 100 ml, 12 x 100 ml, 15 x 100 ml, 20 x 100 ml
1 x 250 ml, 5 x 250 ml, 10 x 250 ml, 12 x 250 ml, 15 x 250 ml, 20 x 250 ml.

Not all pack sizes may be marketed.