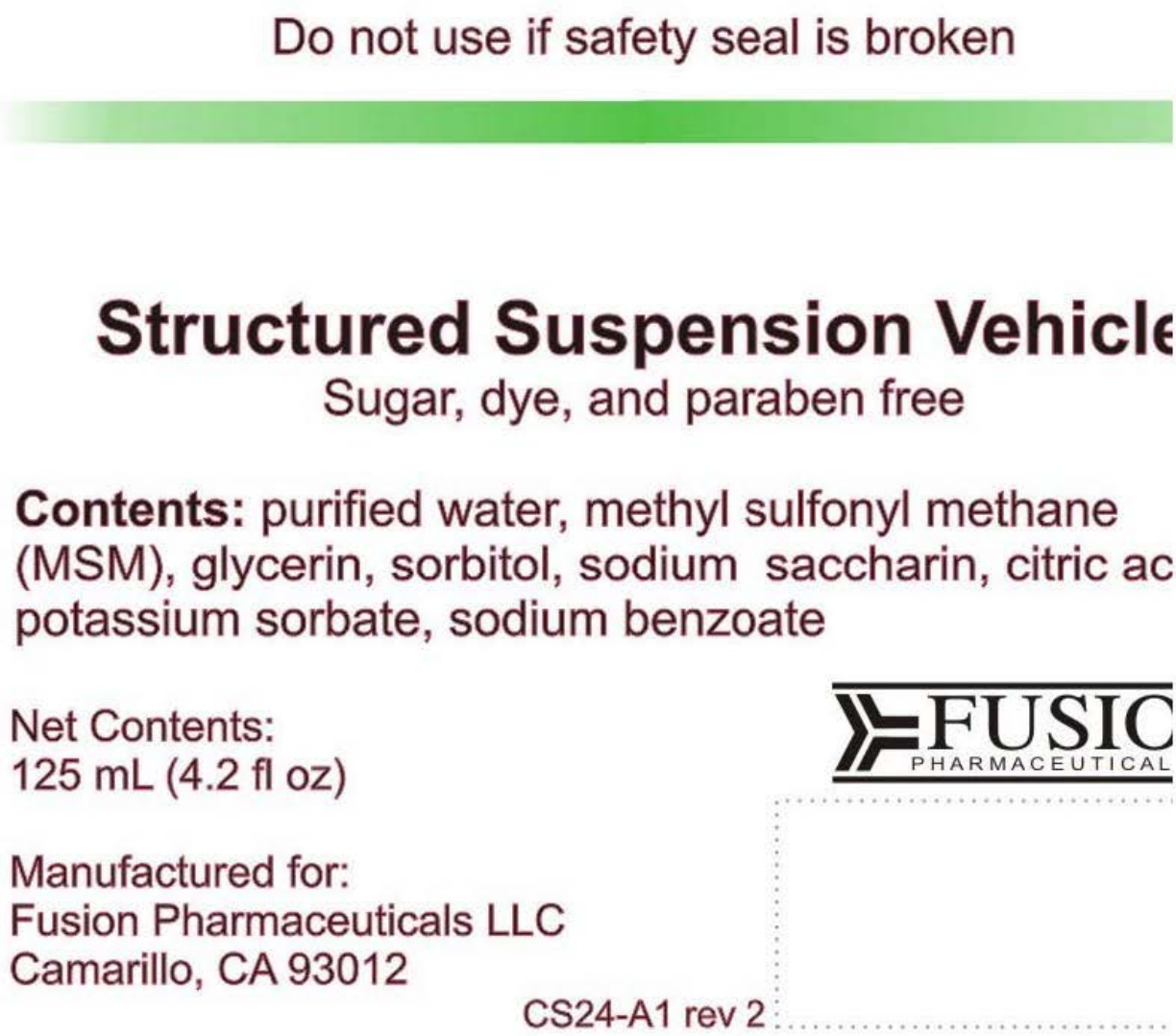
TABRADOL- cyclobenzaprine hydrochloride
Fusion Pharmaceuticals LLC

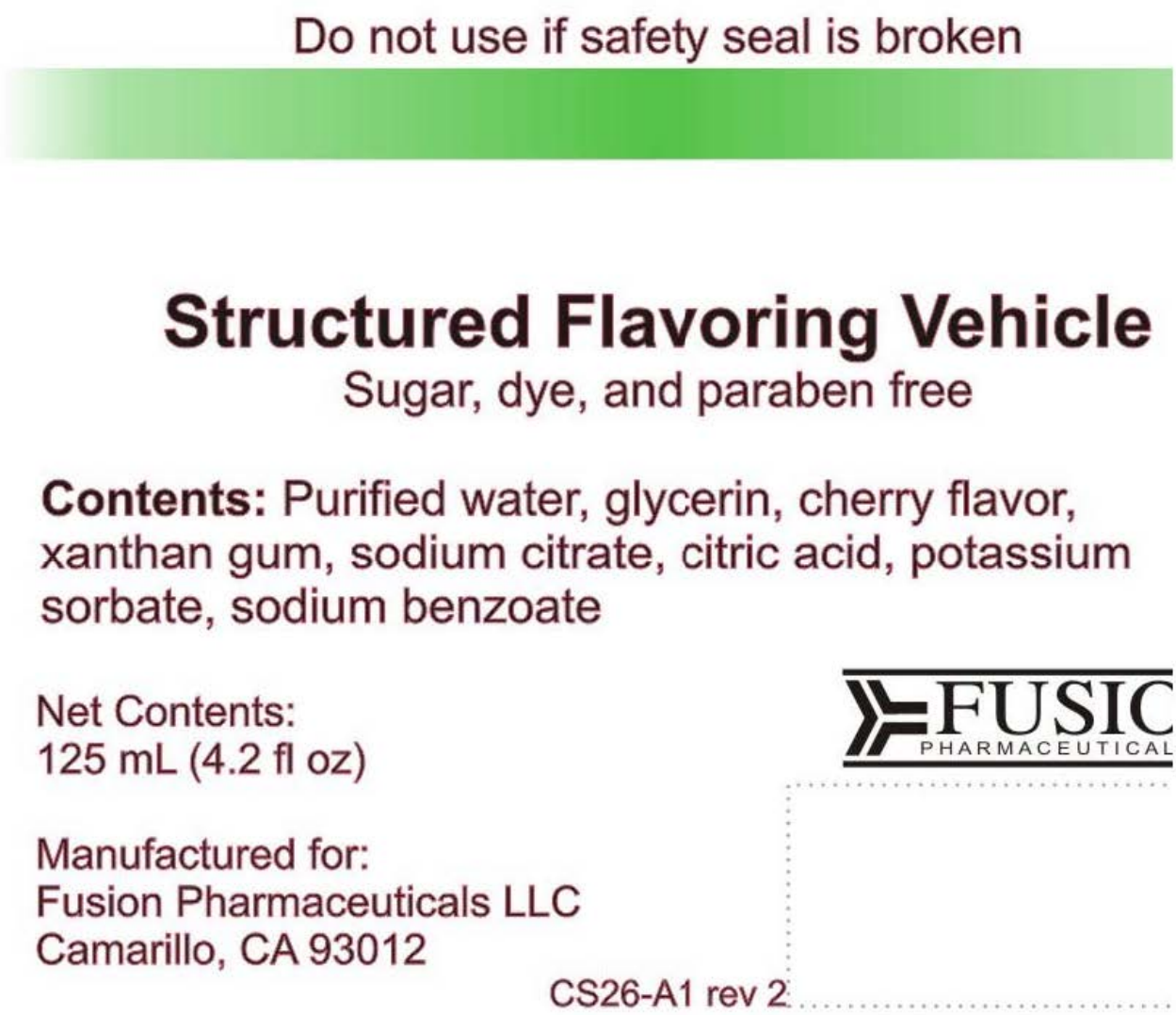
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

TABRADOL

Suspension Label



Flavor Label



Instructions Insert

NDC 43093-101-01

Rx only

FusePaq™

TABRADOL™

(cyclobenzaprine hydrochloride 1 mg/mL, in oral suspension with MSM - kit)

FusePaq™ kits provide a convenient approach to rapidly prepare prescription medications, as all components are pre-measured. This kit is manufactured according to US FDA current Good Manufacturing Practice (cGMP).

Description:

Instructions Insert

When prepared according to directions, this kit makes 250 mL of an oral suspension containing 1 mg/mL cyclobenzaprine hydrochloride with MSM.

Contents:

- 0.25 g cyclobenzaprine hydrochloride, USP
- 250 mL bottle containing 125 mL flavor vehicle (purified water, glycerin, cherry flavor, xanthan gum, sodium citrate, citric acid, potassium sorbate, sodium benzoate)
- 125 mL bottle containing 125 mL suspension vehicle (purified water, methyl sulfonyl methane [MSM], glycerin, sorbitol, sodium saccharin, citric acid, potassium sorbate, sodium benzoate)
- Bottle adaptor for oral syringe
- Oral syringe
- Instructions

Instructions for the Pharmacist

1 Remove and Inspect the Contents of the Kit

Ensure that the safety seals are present and intact on the cyclobenzaprine hydrochloride, flavor, and suspension vehicle bottles. If the seals are not intact, do not use the kit.

2 Prepare for Combining

Wear gloves and eye protection during compounding operations. Remove the seals from the flavor and suspension bottles. Break the perforated seal and remove the cap from the cyclobenzaprine hydrochloride bottle.

3 Transfer Cyclobenzaprine Hydrochloride to the Flavor Bottle

Flip the tip up on the suspension bottle cap. Squeeze suspension into the cyclobenzaprine hydrochloride bottle until at least half full. Cap the cyclobenzaprine hydrochloride bottle and shake well several times. Ensure that the cyclobenzaprine hydrochloride powder has been completely dissolved. Empty the contents into the flavor bottle. Cap the flavor bottle and shake well. Again fill the cyclobenzaprine hydrochloride bottle with liquid suspension vehicle, then cap and shake bottle. Transfer contents to flavor bottle. Repeat the rinsing of the cyclobenzaprine hydrochloride bottle with suspension one last time. Transfer the remaining suspension vehicle into the flavor bottle.

4 Complete the Combining Process

Press the oral syringe adaptor into the flavor bottle. Recap the flavor bottle which now contains the cyclobenzaprine hydrochloride, suspension, and flavor. Shake well by inverting repeatedly several times.

5 Re-label the Resulting Final Suspension

Label the resulting final suspension per the pharmacy's standard practice. Remove or obscure the flavor vehicle label, since the label is no longer accurate once final suspension is completed.

Store the unused kit at room temperature of 15-30C (59-86F). Once prepared, store the mixed suspension between 15-30C (59-86F). The resulting final suspension is stable for at least eight weeks based upon real-time and accelerated stability studies. Each lot of suspension vehicle and flavor vehicle is tested to meet microbial limits per USP Microbial Limit Test 61. In addition, the suspension vehicle and flavor vehicle formulations have each passed the USP 51 Antimicrobial Effectiveness Test.

An oral syringe is provided in the kit and may be used to facilitate accurate delivery of the suspension.

U.S. Patents Pending

Manufactured by:
Fusion Pharmaceuticals LLC
768 Calle Plano
Camarillo, CA 93012

NDC 43093-101-01 **Rx only**

FusePaq™ TABRADOL™

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- Bottle adaptor for oral syringe
- Oral syringe
- Instructions

Instructions for the Pharmacist

1 Remove and Inspect the Contents of the Kit

Ensure that the safety seals are present and intact on the cyclobenzaprine hydrochloride, flavor, and suspension vehicle bottles. If the seals are not intact, do not

NDC 43093-101-01 **Rx only**

FusePaq™ TABRADOL™

(cyclobenzaprine hydrochloride 1 mg/mL, in oral suspension with MSM - kit)

Instructions for the Pharmacist (continued)

3 Transfer Cyclobenzaprine Hydrochloride to the Flavor Bottle

Flip the tip up on the suspension bottle cap. Squeeze suspension into the cyclobenzaprine hydrochloride bottle until at least half full. Cap the cyclobenzaprine hydrochloride bottle and shake well several times. Ensure that the cyclobenzaprine hydrochloride powder has been completely dissolved. Empty the contents into the flavor bottle. Cap the flavor bottle and shake well. Again fill the cyclobenzaprine hydrochloride bottle with liquid suspension vehicle, then cap and shake bottle. Transfer contents to flavor bottle. Repeat the rinsing of the cyclobenzaprine hydrochloride bottle with suspension one last time. Transfer the remaining suspension vehicle into the flavor bottle.

4 Complete the Combining Process

Press the oral syringe adaptor into the flavor bottle. Recap the flavor bottle, which now contains the cyclobenzaprine hydrochloride, suspension, and flavor. Shake well by inverting repeatedly several times.

5 Re-label the Resulting Final Suspension

Label the resulting final suspension per the pharmacy's standard practice. Remove or obscure the flavor vehicle label, since the label is no longer accurate once the resulting final suspension is completed.

Store the unused kit at room temperature of 15-30°C (59-86°F). Once prepared, store the mixed suspension between 15-30°C (59-86°F). The resulting final suspension is stable for at least eight weeks based upon real-time and accelerated stability studies. Each lot of suspension vehicle and flavor vehicle is tested to meet microbial limits per USP Microbial Limit Test <61>. In addition, the suspension vehicle and flavor vehicle formulations have each passed the USP <51> Antimicrobial Effectiveness Test.

Do not use if safety seal is broken

Cyclobenzaprine Hydrochloride

1-Propanamine, 3-(5H-dibenzo[a,d]cyclohepten-5-ylidene)-
N,N-dimethyl-, hydrochloride

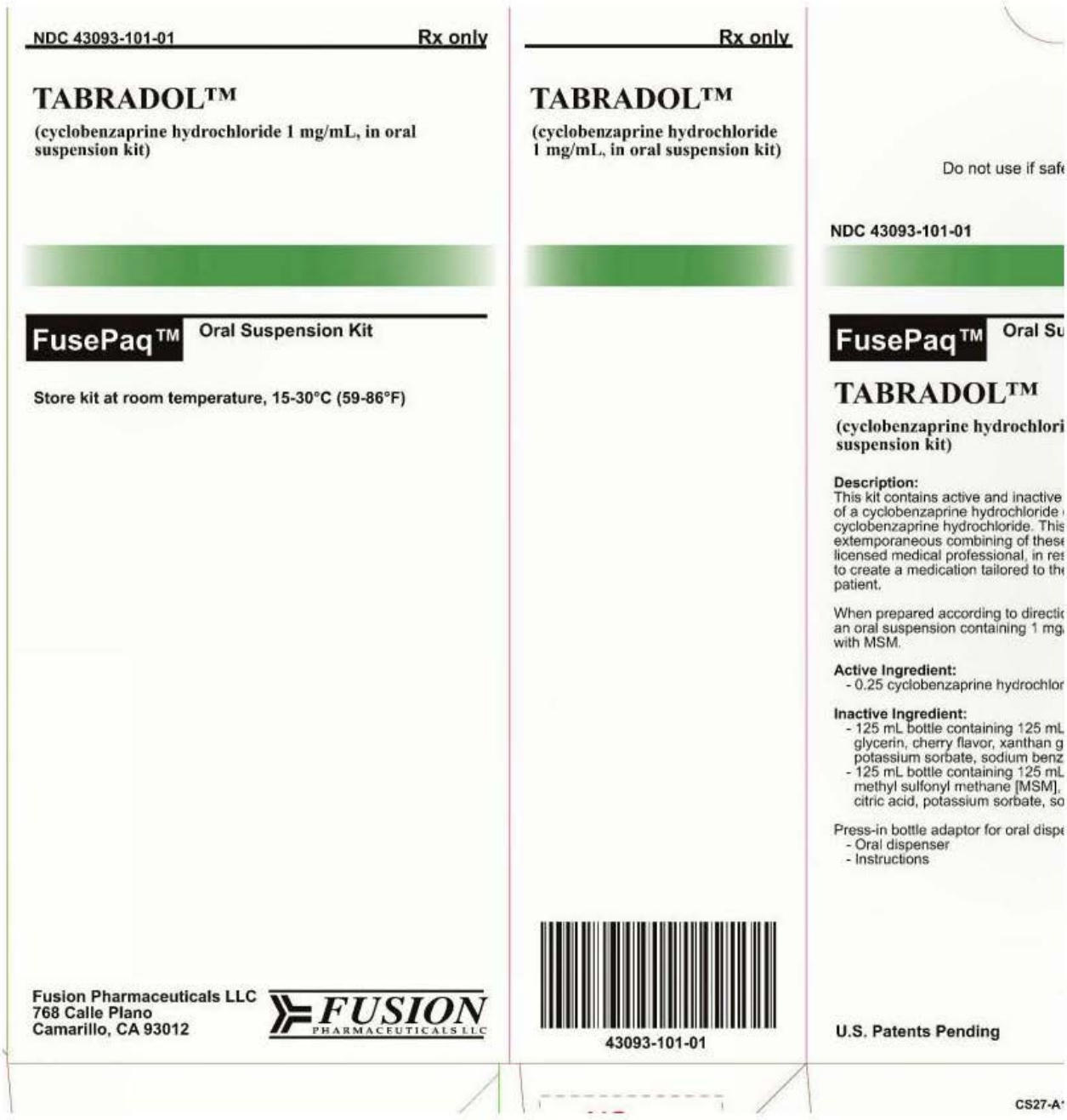
Rx Only

CAS #6202-23-9
Net contents 0.25 g

Repackaged by:
Fusion Pharmaceuticals, LLC
Camarillo, CA 93012

CS22-A1 rev 3

Principal Display Panel



NDC 43093-101-01 Rx only

TABRADOL™

(cyclobenzaprine hydrochloride 1 mg/mL, in oral suspension kit)

FusePaq™ Oral Suspension Kit

Store kit at room temperature, 15-30°C (59-86°F)

Fusion Pharmaceuticals LLC
768 Calle Plano
Camarillo, CA 93012

FUSION PHARMACEUTICALS LLC

Rx only

TABRADOL™

(cyclobenzaprine hydrochloride 1 mg/mL, in oral suspension kit)

43093-101-01

Do not use if saf

NDC 43093-101-01

FusePaq™ Oral Su

TABRADOL™

(cyclobenzaprine hydrochlori suspension kit)

Description:
This kit contains active and inactive
of a cyclobenzaprine hydrochloride
cyclobenzaprine hydrochloride. This
extemporaneous combining of these
licensed medical professional, in res
to create a medication tailored to the
patient.

When prepared according to directio
an oral suspension containing 1 mg
with MSM.

Active Ingredient:
- 0.25 cyclobenzaprine hydrochlor

Inactive Ingredient:
- 125 mL bottle containing 125 mL
glycerin, cherry flavor, xanthan g
potassium sorbate, sodium benz
- 125 mL bottle containing 125 mL
methyl sulfonyl methane [MSM],
citric acid, potassium sorbate, so

Press-in bottle adaptor for oral dispe
- Oral dispenser
- Instructions

U.S. Patents Pending

CS27-A

TABRADOL

cyclobenzaprine hydrochloride kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:43093-101

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:43093-101-01	1 in 1 KIT; Type 0: Not a Combination Product		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE, GLASS	0.28 g
Part 2	1 BOTTLE, PLASTIC	125 mL
Part 3	1 BOTTLE, PLASTIC	125 mL

Part 1 of 3

CYCLOBENZAPRINE HYDROCHLORIDE

cyclobenzaprine hydrochloride powder, for suspension

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CYCLOBENZAPRINE HYDROCHLORIDE (UNII: 0VE05JYS2P) (CYCLOBENZAPRINE - UNII:69O5WQQ5TI)	CYCLOBENZAPRINE HYDROCHLORIDE	0.28 g in 0.28 g

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		0.25 g in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/17/2009	

Part 2 of 3

STRUCTURED SUSPENSION VEHICLE

suspension liquid

Product Information

Route of Administration	ORAL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		125 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/17/2009	

Part 3 of 3

STRUCTURED FLAVORING VEHICLE

flavor liquid

Product Information

Route of Administration	ORAL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

GLYCERIN (UNII: PDC6A3C0OX)	
CHERRY (UNII: BUC5I9595W)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		125 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/17/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/17/2009	

Labeler - Fusion Pharmaceuticals LLC (021420944)

Establishment

Name	Address	ID/FEI	Business Operations
Fusion Pharmaceuticals LLC		021420944	manufacture(43093-101)

Revised: 1/2016 Fusion Pharmaceuticals LLC