SUMADAN XLT- sulfacetamide sodium, sulfur, avobenzone, octinoxate, and octisalate
Medimetriks Pharmaceuticals Inc.

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.

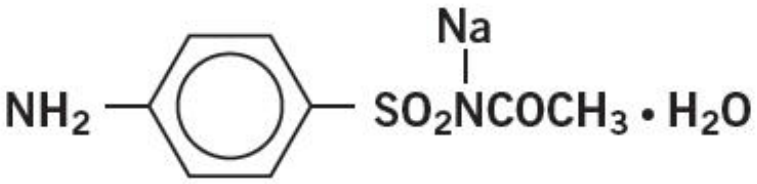
Sumadan®
(Sodium Sulfacetamide 9% & Sulfur 4.5%)
WASH
In a Moisturizing
Novasome® Vehicle

R_x Only

DESCRIPTION

Sodium sulfacetamide is a sulfonamide with antibacterial activity while sulfur acts as a keratolytic agent. Chemically sodium sulfacetamide is N-[(4-aminophenyl) sulfonyl]-acetamide, monosodium salt, monohydrate.

The structural formula is:



Each mL of **Sumadan® (sodium sulfacetamide 9% & sulfur 4.5%) Wash** contains 90 mg of sodium sulfacetamide and 45 mg of sulfur in a formulation consisting of: butylated hydroxytoluene, C12-15 alkyl benzoate, caprylyl glycol, cetyl alcohol, cholesterol, chrysanthemum dendranthema, dimethicone, disodium oleamido MIPA sulfosuccinate, edetate disodium, ethylene brassilate, glyceryl stearate, hexylene glycol, lemon oil, magnesium aluminum silicate, magnesium chloride, magnesium nitrate, methylchloroisothiazolinone, methylisothiazolinone, niacinamide, nonoxynol-20, octoxynol-5, purified water, PEG-100 stearate, phenoxyethanol, propylene glycol, sodium cocoyl isotheionite, sodium methyl cocoyl taurate, sodium thiosulfate, stearyl alcohol, xanthan gum.

CLINICAL PHARMACOLOGY

The most widely accepted mechanism of action of sulfonamides is the Woods-Fildes theory, which is based on the fact that sulfonamides act as competitive antagonists to para-aminobenzoic acid (PABA), an essential component for bacterial growth. While absorption through intact skin has not been determined, sodium sulfacetamide is readily absorbed from the gastrointestinal tract when taken orally and excreted in the urine, largely unchanged. The biological half-life has variously been reported as 7 to 12.8 hours. The exact mode of action of sulfur in the treatment of acne is unknown, but it has been reported that it inhibits the growth of Propionibacterium acnes and the formation of free fatty acids.

INDICATIONS

Sumadan® (sodium sulfacetamide 9% & sulfur 4.5%) Wash is indicated for the topical control of

acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS

Sumadan® (sodium sulfacetamide 9% & sulfur 4.5%) Wash are contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. **Sumadan® (sodium sulfacetamide 9% & sulfur 4.5%) Wash** is not to be used by patients with kidney disease.

WARNINGS

Although rare, sensitivity to sodium sulfacetamide may occur. Therefore, caution and careful supervision should be observed when prescribing this drug for patients who may be prone to hypersensitivity to topical sulfonamides. Systemic toxic reactions such as agranulocytosis, acute hemolytic anemia, purpura hemorrhagica, drug fever, jaundice, and contact dermatitis indicate hypersensitivity to sulfonamides. Particular caution should be employed if areas of denuded or abraded skin are involved.

FOR EXTERNAL USE ONLY. Keep away from eyes. Keep out of reach of children. Keep container tightly closed.

PRECAUTIONS

General

If irritation develops, use of the product should be discontinued and appropriate therapy instituted. Patients should be carefully observed for possible local irritation or sensitization during long-term therapy. The object of this therapy is to achieve desquamation without irritation, but sodium sulfacetamide and sulfur can cause reddening and scaling of the epidermis. These side effects are not unusual in the treatment of acne vulgaris, but patients should be cautioned about the possibility.

Information for Patients

Avoid contact with eyes, eyelids, lips and mucous membranes. If accidental contact occurs, rinse with water. If excessive irritation develops, discontinue use and consult your physician.

Carcinogenesis, Mutagenesis and Impairment of Fertility

Long-term studies in animals have not been performed to evaluate carcinogenic potential.

PREGNANCY

Category C

Animal reproduction studies have not been conducted with **Sumadan® (sodium sulfacetamide 9% & sulfur 4.5%) Wash**. It is also not known whether **Sumadan® (sodium sulfacetamide 9% & sulfur 4.5%) Wash** can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. **Sumadan® (sodium sulfacetamide 9% & sulfur 4.5%) Wash** should be given to a pregnant woman only if clearly needed.

NURSING MOTHERS

It is not known whether sodium sulfacetamide is excreted in the human milk following topical use of **Sumadan® (sodium sulfacetamide 9% & sulfur 4.5%) Wash**. However, small amounts of orally administered sulfonamides have been reported to be eliminated in human milk. In view of this and because many drugs are excreted in human milk, caution should be exercised when **Sumadan® (sodium sulfacetamide 9% & sulfur 4.5%) Wash** is administered to a nursing woman.

PEDIATRIC USE

Safety and effectiveness in children under the age of 12 have not been established.

ADVERSE REACTIONS

Although rare, sodium sulfacetamide may cause local irritation.

DOSAGE AND ADMINISTRATION

Apply **Sumadan® (sodium sulfacetamide 9% & sulfur 4.5%) Wash** once or twice daily to affected areas, or as directed by your physician. Wet skin and liberally apply to areas to be cleansed. Massage gently into skin for 10-20 seconds, working into a full lather, rinse thoroughly and pat dry. If drying occurs, it may be controlled by rinsing off **Sumadan® (sodium sulfacetamide 9% & sulfur 4.5%) Wash** sooner or using less often.

HOW SUPPLIED

Sumadan® (sodium sulfacetamide 9% & sulfur 4.5%) Wash is available in a Net wt. 16 oz. (454 g) bottle, NDC 43538-190-16.

Sumadan® KIT contents one unit of **Sumadan® Wash**, Net wt. 16 oz. (454 g) and one unit of Rehyla® Wash, 16 oz. bottle, NDC 43538-191-16.

Sumadan® XLT contents one unit of **Sumadan® Wash**, Net wt. 16 oz. (454 g) bottle and one unit of Niseko® Sunscreen, 3 oz. tube, NDC 43538-192-16.

Store at controlled room temperature 15°-30° C (59°-86° F). Protect from freezing.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

To report **SUSPECTED ADVERSE REACTIONS**, contact Medimetriks Pharmaceuticals, Inc., at 1-973-882-7512 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Manufactured for:

MEDIMETRIKS
PHARMACEUTICALS, INC.

383 Route 46 West
Fairfield, NJ 07004-2402 USA

www.medimetriks.com

IP022-R3
Rev. 10/17

PRINCIPAL DISPLAY PANEL - Kit Carton

NDC 43538-192-16

R_x Only
Sumadan®
(Sodium Sulfacetamide 9% & Sulfur 4.5%)
XLT

KIT CONTENTS:

1 - Sumadan® (Sodium Sulfacetamide 9% & Sulfur 4.5%) Wash (Net Wt. 16 oz.)

1 - Niseko® Sunscreen Broad Spectrum SPF 25 (Net Wt. 3 oz.)

MEDIMETRIKS
PHARMACEUTICALS, INC.

NDC 43538-192-16

Rx Only

Sumadan®

(Sodium Sulfacetamide 9% & Sulfur 4.5%)

XLT

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NDC 43538-192-16

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XLT

KIT CONTENTS:

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(Sodium Sulfacetamide 9% & Sulfur 4.5%)
Wash (Net Wt. 16 oz.)

1 - Niseko® Sunscreen
Broad Spectrum SPF 25 (Net Wt. 3 oz.)

℞ Only

Sumadan®

(Sodium Sulfacetamide 9% & Sulfur 4.5%)

WASH

In a Moisturizing Novasome® Vehicle

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

Keep out of reach of children. Keep bottle tightly closed.

Store at controlled room temperature 15°-30°C (59°-86°F). Protect from freezing.

niseko®

SUNSCREEN

Broad Spectrum SPF 25

For external use only. Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Store at controlled room temperature 15°-30°C (59°-86°F). Protect from freezing.

Medimetriks Pharmaceuticals guarantees that this product was manufactured with the highest pharmaceutical control standards, the most desirable ingredients, under strict demands for quality and safety, ensuring batch-to-batch quality and use-to-use consistency.

MEDIMETRIKS PHARMACEUTICALS, INC.

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NDC 43538-192-16

Rx Only

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(Sodium Sulfacetamide 9% & Sulfur 4.5%)

XLT

KIT CONTENTS:

1 - Sumadan®
(Sodium Sulfacetamide 9% & Sulfur 4.5%) Wash (Net Wt. 16 oz.)

1 - Niseko® Sunscreen
Broad Spectrum SPF 25 (Net Wt. 3 oz.)

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(Sodium Sulfacetamide 9% & Sulfur 4.5%)

WASH In a Moisturizing Novasome® Vehicle

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Manufactured for:
Medimetriks Pharmaceuticals, Inc.
383 Route 46 West, Fairfield, NJ 07004-2402 USA
Made in USA

niseko®

SUNSCREEN
Broad Spectrum SPF 25

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NDC 43538-192-16

Rx Only

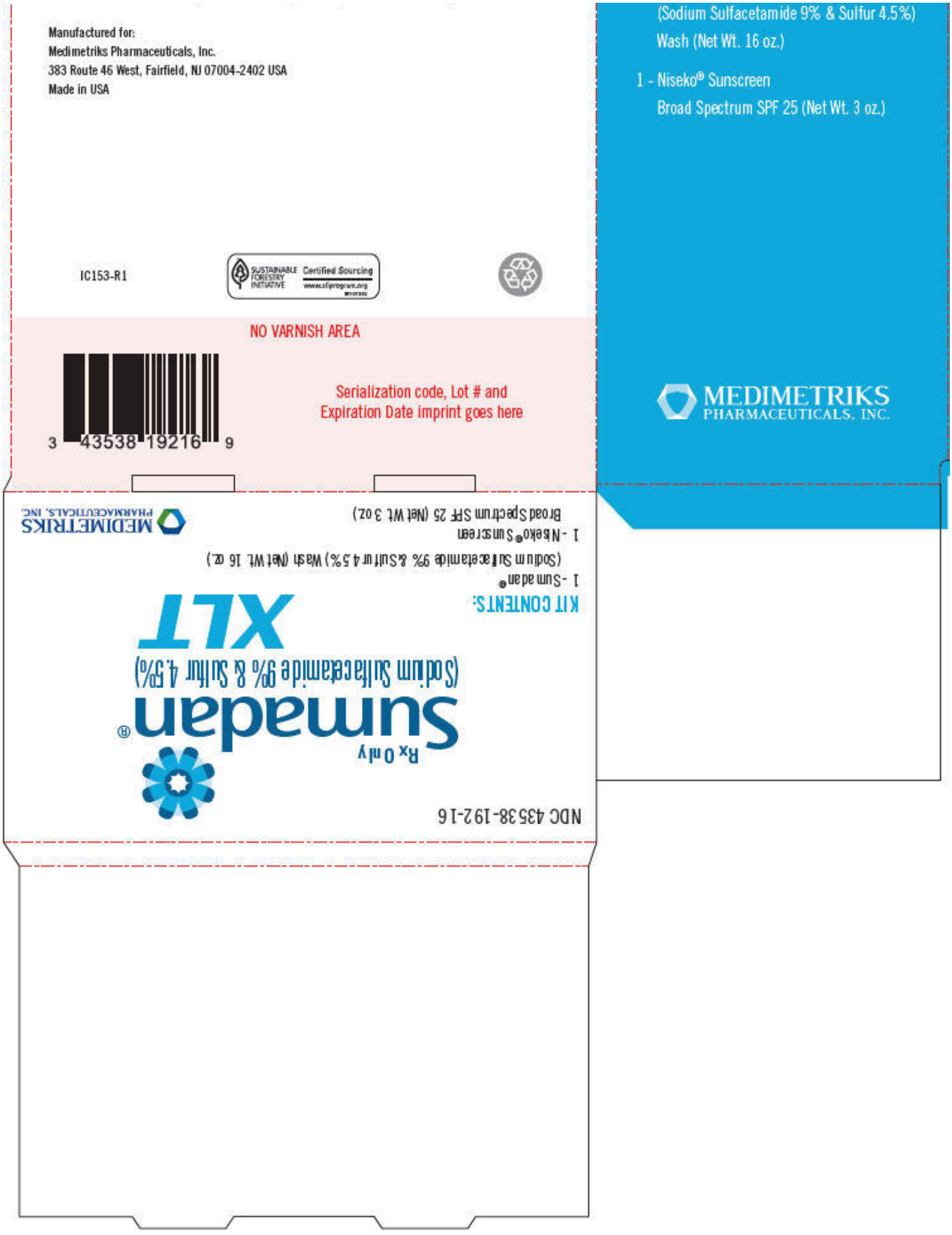
Sumadan®

(Sodium Sulfacetamide 9% & Sulfur 4.5%)

XLT

KIT CONTENTS:

1 - Sumadan®



SUMADAN XLT

sulfacetamide sodium, sulfur, avobenzone, octinoxate, and octisalate kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:43538-192

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:43538-192-16	1 in 1 CARTON	12/01/2013	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE, PUMP	454 g
Part 2	1 TUBE	85 g

Part 1 of 2

SUMADAN WASH

sulfacetamide sodium and sulfur cream

Product Information	
Item Code (Source)	NDC:43538-190
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
sulfacetamide sodium (UNII: 4NRT660KJQ) (sulfacetamide - UNII:4965G3J0F5)	sulfacetamide sodium	90 mg in 1 g
sulfur (UNII: 70FD1KFU70) (sulfur - UNII:70FD1KFU70)	sulfur	45 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
caprylyl glycol (UNII: 00YIU5438U)	
cholesterol (UNII: 97C5T2UQ7J)	
dimethicone (UNII: 92RU3N3Y1O)	
disodium oleamido MIPA-sulfosuccinate (UNII: 0MBZ20845F)	
edetate disodium (UNII: 7FLD91C86K)	
glyceryl monostearate (UNII: 230OU9XXE4)	
hexylene glycol (UNII: KEH0A3F75J)	
lemon oil (UNII: I9GRO824LL)	
magnesium aluminum silicate (UNII: 6M3P64V0NC)	
magnesium chloride (UNII: 02F3473H9O)	

magnesium nitrate (UNII: 77CBG3UN78)	
methylchloroisothiazolinone (UNII: DEL7T5QRPN)	
methylisothiazolinone (UNII: 229D0E1QFA)	
niacinamide (UNII: 25X51I8RD4)	
nonoxynol-20 (UNII: 60ZT1XYO5N)	
octoxynol-5 (UNII: TJ327E1R1V)	
water (UNII: 059QF0KO0R)	
PEG-100 stearate (UNII: YD01N1999R)	
phenoxyethanol (UNII: HIE492ZZ3T)	
propylene glycol (UNII: 6DC9Q167V3)	
sodium methyl cocoyl taurate (UNII: JVL98CG53G)	
sodium thiosulfate (UNII: HX1032V43M)	
stearyl alcohol (UNII: 2KR89I4H1Y)	
xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics			
Color	YELLOW	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43538-190-16	454 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		06/01/2011	

Part 2 of 2

NISEKO SUNSCREEN SPF 25

avobenzone, octinoxate, and octisalate cream

Product Information	
Item Code (Source)	NDC:43538-290
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

avobenzone (UNII: G63QQF2NOX) (avobenzone - UNII:G63QQF2NOX)	avobenzone	30 mg in 1 g
octinoxate (UNII: 4Y5P7MUD51) (octinoxate - UNII:4Y5P7MUD51)	octinoxate	75 mg in 1 g
octisalate (UNII: 4X49Y0596W) (octisalate - UNII:4X49Y0596W)	octisalate	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
butyloctyl salicylate (UNII: 2EH13UN8D3)	
glyceryl stearate SE (UNII: FCZ5MH785I)	
isododecane (UNII: A8289P68Y2)	
glycerin (UNII: PDC6A3C0OX)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetyl alcohol (UNII: 936JST6JCN)	
dihexadecyl phosphate (UNII: 2V6E5WN99N)	
ceteth-10 phosphate (UNII: 4E05O5N49G)	
cholesterol (UNII: 97C5T2UQ7J)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
edetate disodium (UNII: 7FLD91C86K)	
methylparaben (UNII: A2I8C7HI9T)	
phenoxyethanol (UNII: HIE492ZZ3T)	
xanthan gum (UNII: TTV12P4NEE)	
green tea leaf (UNII: W2ZU1RY8B0)	
C13-14 isoparaffin (UNII: E4F12ROE70)	
laureth-7 (UNII: Z95S6G8201)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43538-290-03	85 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	11/15/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

UNAPPROVED DRUG OTHER		12/01/2013	

Labeler - Medimetriks Pharmaceuticals Inc. (019903816)

Establishment

Name	Address	ID/FEI	Business Operations
IGI Laboratories		011036910	MANUFACTURE(43538-192)

Revised: 12/2017 Medimetriks Pharmaceuticals Inc.