CATTLE EPITHELIUM - cattle epithelium injection, solution DOG EPITHELIUM - dog epithelium injection, solution CHICKEN FEATHERS - chicken feathers injection, solution DUCK FEATHERS - duck feathers injection, solution GOOSE FEATHERS - goose feathers injection, solution GERBIL EPITHELIUM - gerbil epithelium injection, solution GOAT EPITHELIUM - goat epithelium injection, solution GUINEA PIG EPITHELIUM - guinea pig epithelium injection, solution HAMSTER EPITHELIUM - hamster epithelium injection, solution HOG EPITHELIUM - hog epithelium injection, solution HORSE EPITHELIUM - horse epithelium injection, solution RABBIT EPITHELIUM - mouse epithelium injection, solution RABBIT EPITHELIUM - rabbit epithelium injection, solution Nelco Laboratories, Inc.

Allergenic Extract

WARNING

Diagnostic and therapeutic allergenic extracts are intended to be administered by a physician who is an allergy specialist and experienced in allergenic diagnostic testing and immunotherapy and the emergency care of anaphylaxis.

This product should not be injected intravenously. Deep subcutaneous routes have been safe. Sensitive patients may experience severe anaphylactic reactions resulting in respiratory obstruction, shock, coma and/or death. **(See Adverse Reactions)**

Serious adverse reactions should be reported to Nelco Laboratories immediately and a report filed to: MedWatch, The FDA Medical Product Problem Reporting Program, at 5600 Fishers Lane, Rockville, Md. 20852-9787, call 1-800-FDA-1088.

Extreme caution should be taken when using allergenic extracts for patients who are taking betablocker medications. In the event of a serious adverse reaction associated with the use of allergenic extracts, patients receiving beta-blockers may not be responsive to epinephrine or inhaled brochodialators.⁽¹⁾(See Precautions)

Allergenic extracts should be used with caution for patients with unstable or steroid-dependent asthma or underlying cardiovascular disease. **(See Contraindications)**

DESCRIPTION

Allergenic extracts are sterile solutions consisting of the extractable components from various biological sources including pollens, inhalants, molds, animal epidermals and insects. Aqueous extracts are prepared using cocas fluid containing NaCl 0.5%, NaHCO3 0.0275%, WFI, preservative 0.4% Phenol. Glycerinated allergenic extracts are prepared with cocas fluid and glycerin to produce a 50% (v/v) allergenic extract. Allergenic Extracts are supplied as concentrations designated as protein nitrogen units (PNU) or weight/volume (w/v) ratio. Standardized extracts are designated in Bioequivalent Allergy Units (BAU) or Allergy Units (AU). *(See product insert for standardized extracts)*

For diagnostic purposes, allergenic extracts are to be administered by prick-puncture or intradermal routes. Allergenic extracts are administered subcutaneously for immunotherapy injections.

CLINICAL PHARMACOLOGY

The pharmacological action of allergenic extracts used diagnostically is based on the liberation of histamine and other substances when the allergen reacts with IgE antibodies attached to the mast cells. When allergenic extracts are used for immunotherapy, the effect is an increase in immunoglobulin G (IgG) and an increased T suppresser lymphocyte which interferes with the allergic response.⁽²⁾ With repeated administration of allergenic extracts changes develop in regards to IgG and IgE production and mediator-releasing cells. The histamine release response is reduced in some patients.

INDICATIONS AND USAGE

Allergenic extracts are indicated for use in diagnostic testing and as part of a treatment regime for allergic disease, as established by allergy history and skin test reactivity.

Allergenic extracts are indicated for the treatment of allergen specific allergic disease for use as hyposensitization or immunotherapy when avoidance of specific allergens can not be attained. The use of allergenic extracts for therapeutic purpose has been established by well-controlled clinical studies. Allergenic extracts may be used as adjunctive therapy along with pharmacotherapy which includes antihistamines, corticosteroids, and cromoglycate, and avoidance measures. Allergenic extracts for therapeutic use should be given using only the allergen selection to which the patient is allergic, has a history of exposure and are likely to be exposed to again.

CONTRAINDICATIONS

Allergenic extracts should not be used if the patient has asthma, cardiovascular disease, emphysema, diabetes, bleeding diathesis or pregnancy, unless a specific diagnosis of type 1 allergic disease is made based on skin testing and the benefits of treatment outweigh the risks of an adverse reaction during testing or treatment. Allergenic extracts are not indicated for use in patients who are not clinically allergic or who are not skin reactive to an allergen. Allergenic extracts should be discontinued or the concentration of potency substantially reduced in patients who experience unacceptable adverse reactions.

WARNINGS

DO NOT INJECT INTRAVENOUSLY.

Epinephrine 1:1000 should be available.

Concentrated extracts must be diluted with sterile diluent prior to first use on a patient for treatment or intradermal testing. All concentrates of glycerinated allergenic extracts have the ability to cause serious local and systemic reactions including death in sensitive patients. Sensitive patients may experience severe anaphylactic reactions resulting in respiratory obstruction, shock, coma and /or death.⁽⁴⁾(*See Adverse Reactions*) An allergenic extract should be temporarily withheld from patients or the dose of the extract adjusted downward if any of the following conditions exist: (1) Severe symptoms of rhinitis and/or asthma (2) Infections or flu accompanied by fever and (3) Exposure to excessive amounts of clinically relevant allergen prior to a scheduled injection. When switching patients to a new lot of the same extract the initial dose should be reduced 3/4 so that 25% of previous dose is administered.

PRECAUTIONS

GENERAL: Epinephrine 1:1000 should be available as well as personnel trained in administering emergency treatment. Allergenic Extracts are not intended for intravenous injections. For safe and effective use of allergenic extracts, sterile diluents, sterile vials, sterile syringes should be used and aseptic precautions observed when making a dilution and/or administering the allergenic extract injection. A sterile tuberculin syringe graduated in 0.1 ml units to measure each dose for the prescribed

dilution should be used. To reduce the risk of an occurrence of adverse reactions, begin with a careful personal history plus a physical exam. Confirm your findings with scratch or intradermal skin testing.

Standardized extracts are those labeled in AU/ml units or BAU/ml units. Standardized extracts are not interchangeable with extracts previously labeled as wt/vol or PNU/ml. Before administering a standardized extract, read the accompanying insert contained with standardized extracts.

Information for Patients: All concentrates of allergenic extracts have the ability to cause serious local and systemic reactions including death in sensitive patients. Patients should be informed of this risk prior to skin testing and immunotherapy. Patients should be instructed to recognize adverse reaction symptoms that may occur and to report all adverse reactions to a physician. Patients should be instructed to remain in the office for 30 minutes during testing using allergenic extracts and at least 30 minutes after therapeutic injections using allergenic extracts.

DRUG INTERACTIONS: Some drugs may affect the reactivity of the skin; patients should be instructed to avoid medications, particularly antihistamines and sympathomimetic drugs, for at least 24 hours prior to skin testing. Antihistamines and Hydroxyzine can significantly inhibit the immediate skin test reactions as they tend to neutralize or antagonize the action of histamine.⁽³⁾ This effect has been primarily documented when testing was performed within 1 to 2 hours after drug ingestion. Partial inhibition of the skin test reaction had been observed for longer periods. Epinephrine injection inhibits the immediate skin test reactions for several hours. Patients on delayed absorption antihistamine tablets should be free of such medication for 48 hours before testing. Patients using Astemizole (Hismanal) may experience prolonged suppression and should be free from such medication for up to 6 to 8 weeks prior to testing. Refer to package insert from an applicable long acting antihistamine manufacturer for additional information.

Extreme caution should be taken when using allergenic extracts on patients who are taking betablockers. Patients on non-selective beta blockers may be more reactive to allergens given for testing or treatment and may be unresponsive to the usual doses of epinephrine used to treat allergic reactions.

Carcinogenesis, mutagenesis, impairment of fertility:

Long term studies in animals have not been conducted with allergenic extracts to determine their potential carcinogenicity, mutagenicity or impairment of fertility.

Pregnancy: Category C: Animal reproduction studies have not been conducted with Allergenic Extracts. It is not known whether allergenic extracts can cause fetal harm when administered to pregnant women or can affect reproduction capacity. Allergenic extracts should be given to pregnant women only if clearly needed.

Nursing Mothers: It is not known whether this drug appears in human milk. Because many drugs are detected in human milk, caution should be exercised when Allergenic Extracts are administered to a nursing woman. There are no current studies on extract components in human milk, or their effect on the nursing infant.

Pediatric Use: Allergenic extracts have been used in children over two years of age.⁽⁵⁾

ADVERSE REACTIONS

Adverse systemic reactions usually occur within minutes and consist primarily of allergic symptoms such as: generalized skin erythema, urticaria, pruritus, angioedema, rhinitis, wheezing, laryngeal edema, itching of nose and throat, breathlessness, dyspnea, coughing, hypotension and marked perspiration. Less commonly, nausea, emesis, abdominal cramps, diarrhea and uterine contractions may occur. Severe reactions may cause anaphylaxis or shock and loss of consciousness and rarely death.

The treatment of systemic allergic reactions is dependent upon the system complex. Antihistamines may offer relief of recurrent urticaria, associated skin reactions and gastrointestinal symptoms. Corticosteroids may provide benefit if symptoms are prolonged or recurrent. **(See Overdose section)**

Local Reactions consisting of erythema, itching, swelling tenderness and sometimes pain may occur at the injection site. These reactions may appear within a few minutes to hours and persist for several days. Local cold applications and oral antihistamines may be effective treatment. For marked and prolonged local reactions the use of antihistamines or anti-inflammatory medications may be dictated. **Serious adverse reactions** should be reported to Nelco Laboratories immediately and a report can be filed to: **MedWatch, The FDA Medical Product Problem Reporting Program, at 5600 Fishers Lane, Rockville, MD 20852-9787, call 1-800-FDA-1088.**

OVERDOSAGE

Overdose can cause both local and systemic reactions. An overdose may be prevented by careful observation and questioning of the patient about the previous injection.

If systemic or anaphylactic reaction, does occur, apply a tourniquet above the site of injection and inject intramuscularly or subcutaneously 0.3 to 0.5ml of 1:1000 Epinephrine Hydrochloride into the opposite arm. The dose may be repeated in 5-10 minutes if necessary. Loosen the tourniquet at least every 10 minutes. The Epinephrine Hydrochloride 1:1000 dose for infants to 2 years is 0.05 to 0.1 ml, for children 2 to 6 years it is 0.15 ml, for children 6-12 years it is 0.2 ml.

Patients unresponsive to Epinephrine may be treated with Theophylline. Studies on asthmatic subjects reveal that plasma concentrations of Theophylline of 5 to 20 μ g/ml are associated with therapeutic effects. Toxicity is particularly apparent at concentrations greater than 20 μ g/ml. A loading dose of Aminophylline of 5.8 mg/kg intravenously followed by 0.9 mg/kg per hour results in plasma concentrations of approximately 10 μ g/ml for patients not previously receiving theophylline. (Mitenko and Ogilive, Nicholoson and Chick, 1973)

Other beta-adrenergic drugs such as Isoproterenol, Isoetharine, or Albuterol may be used by inhalation. The usual dose to relieve broncho-constriction in asthma is 0.5 ml of the 0.5% solution for Isoproterenol HCl. The Albuterol inhaler delivers approximately 90 mcg of Albuterol from the mouthpiece. The usual dosage for adults and children would be two inhalations repeated every 4-6 hours. Isoetharine supplied in the Bronkometer unit delivers approximately 340 mcg Isoetharine. The average dose is one to two inhalations. Respiratory obstruction not responding to parenteral or inhaled bronchodilators may require oxygen, intubation and the use of life support systems.

DOSAGE AND ADMINISTRATION

General Precautions

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permits.

The dosage of allergenic extracts is dependent upon the purpose of the administration. Allergenic extracts can be administered for diagnostic use or for therapeutic use.

When allergenic extracts are administered for diagnostic use, the dosage is dependent upon the method used. Two methods commonly used are scratch testing and intradermal testing. Both types of tests result in a wheal and flare response at the site of the test which usually develops rapidly and may be read in 20-30 minutes.

Diagnostic Use: Scratch Testing Method

Scratch testing is considered a simple and safe method although less sensitive than the intradermal test. Scratch testing can be used to determine the degree of sensitivity to a suspected allergen before using the intradermal test. This combination lessens the severity of response to an allergen which can occur in a very sensitive patient.

The most satisfactory testing site is the patient's back or volar surface of the arms from the axilla to 2.5 or 5cm above the wrist, skipping the anti-cubital space. If using the back as a testing site, the most

satisfactory area are from the posterior axillary fold to 2.5 cm from the spinal column, and from the top of the scapula to the lower rib margins.

Allergenic extracts for diagnostic use are to be administered in the following manner: To scratch surface of skin, use a circular scarifier. **Do not draw blood.** Tests sites should be 4 cm apart to allow for wheal and flare reaction. 1-30 scratch tests may be done at a time. A separate sterile scratch instrument is to be used on each patient to prevent transmission of homologous serum hepatitis or other infectious agents from one patient to another.

The recommended usual dosage for Scratch testing is one drop of allergen applied to each scratch site. **Do not let dropper touch skin.** Always apply a control scratch with each test set. Sterile Diluent (for a negative control) is used in exactly the same way as an active test extract. Histamine may be used as a positive control. Scratch or prick test sites should be examined at 15 and 30 minutes. To prevent excessive absorption, wipe off antigens producing large reactions as soon as the wheal appears. Record the size of the reaction.

Interpretation of Scratch Test

Skin tests are graded in terms of the wheal and erythema response noted at 10 to 20 minutes. Wheal and erythema size may be recorded by actual measurement as compared with positive and negative controls. A positive reaction consists of an area of erythema surrounding the scarification that is larger than the control site. For uniformity in reporting reactions, the following system is recommended. ⁽⁶⁾

REACTION	SYMBOL	CRITERIA
Negative	-	No wheal. Erythema absent or very slight (not more than 1 mm diameter).
One Plus	+	Wheal absent or very slight erythema present (not more than 3 mm diameter).
Two Plus	++	Wheal not more than 3mm or erythema not more than 5mm diameter.
Three Plus	+++	Wheal between 3mm and 5mm diameter, with erythema. Possible pseudopodia and itching.
Four Plus	++++	A larger reaction with itching and pain.

Diagnostic Use: Intradermal Skin Testing Method

Do not perform intradermal test with allergens which have evoked a 2+ or greater response to a Scratch test. Clean test area with alcohol, place sites 5 cm apart using separate sterile tuberculin syringe and a 25 gauge needle for each allergen. Insert needle tip, bevel up, into intracutaneous space. Avoid injecting into blood vessel, pull back gently on syringe plunger, if blood enters syringe change position of needle. The recommended dosage and range for intradermal testing is 0.05 ml of not more than 100 pnu/ml or 1:1000 w/v (only if puncture test is negative) of allergenic extract. Inject slowly until a small bleb is raised. It is important to make each bleb the same size.

Interpretation of Intradermal Test:

The patient's reaction is graded on the basis of size of wheal and flare as compared to control. Use 0.05 ml sterile diluent as a negative control to give accurate interpretation. The tests may be accurately interpreted only when the saline control site has shown a negative response. Observe patient for at least

30 minutes. Tests can be read in 15-20 minutes. Edema, erythema and presence of pseudopods, pain and itching may be observed in 4 plus reactions. For uniformity in reporting reactions the following system is recommended. ⁽⁶⁾

REACTION	SYMBOL	CRITERIA
Negative	-	No increase in size of bleb since injection. No erythema.
One Plus	+	An increase in size of bleb to a wheal not more than 5mm diameter, with associated erythema.
Two Plus	++	Wheal between 5mm and 8mm diameter with erythema.
Three Plus	+++	Wheal between 8mm and 12mm diameter with erythema and possible pseudopodia and itching or pain.
Four Plus	++++	Any larger reaction with itch and pain, and possible diffuse blush of the skin surrounding the reaction area.

Therapeutic Use: Recommended dosage & range

Check the listed ingredients to verify that it matches the prescription ordered. When using a prescription set, verify the patient's name and the ingredients listed with the prescription order. Assess the patient's physical and emotional status prior to giving as injection. Do not give injections to patients who are in acute distress. **Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.**

Dosage of allergenic extracts is a highly individualized matter and varies according to the degree of sensitivity of the patient, his clinical response and tolerance to the extract administered during the early phases of an injection regimen. The dosage must be reduced when transferring a patient from non-standardized or modified extract to standardized extract. Any evidence of a local or generalized reaction requires a reduction in dosage during the initial stages of immunotherapy as well as during maintenance therapy. After therapeutic injections patients should be observed for at least 20 minutes for reaction symptoms.

SUGGESTED DOSAGE SCHEDULE

The following schedule may act as a guide. **This schedule has not been proven to be safe or effective.** Sensitive patients may begin with smaller doses of weaker solutions and the dosage increments can be less.

STRENGTH	DOSE	VOLUME
Vial #1	1	0.05
1:100,000 w/v	2	0.10
10 pnu/ml	3	0.15
1 AU/ml	4	0.20
1 BAU/ml	5	0.30
	6	0.40
	7	0.50

Vial #2	8	0.05
1:10,000 w/v	9	0.10
100 pnu/ml	10	0.15
10 AU/ml	11	0.20
10 BAU/ml	12	0.30
	13	0.40
	14	0.50
Vial #3	15	0.05
1:1,000 w/v	16	0.10
1,000 pnu/ml	17	0.15
100 AU/ml	18	0.20
100 BAU/ml	19	0.30
	20	0.40
	21	0.50
Vial #4	22	0.05
1:100 w/v	23	0.07
10,000 pnu/ml	24	0.10
1,000 AU/ml	25	0.15
1,000 BAU/ml	26	0.20
	27	0.25
Maintenance Refill	28	0.25
1:100 w/v	29	0.25
10,000 pnu/ml	30	0.25
1,000 AU/ml	31	0.25
1,000 BAU/ml	32	0.25
subsequent doses	33	0.25

Preparation Instructions:

All dilutions may be made using sterile buffered diluent. The calculation may be based on the following ratio:

Volume desired x Concentration desired = Volume needed x Concentration available.

Example 1: If a 1:10 w/v extract is available and it is desired to use a 1:1,000 w/v extract substitute as follows:

Vd x Cd = Vn x Ca

 $10ml \ x \ 0.001 = Vn \ x \ 0.1$

0.1 ml = Vn

Using a sterile technique, remove 0.10 ml of extract from the 1:10 vial and place it into a vial containing 9.90 ml of sterile diluent. The resulting ratio will be a 10 ml vial of 1:1,000 w/v.

<u>Example 2</u>: If a 10,000 pnu/ml extract is available and it is desired to use a 100 pnu/ml extract substitute as follows:

10ml x 100 = Vn x 10,000

0.1 ml = Vn

Using a sterile technique, remove 0.10 ml of extract from the 10,000 pnu/ml vial and place it into a vial

containing 9.90 ml of sterile diluent. The resulting concentration will be a 10 ml vial of 100 pnu/ml.

<u>Example 3:</u> If a 10,000 AU/ml or BAU/ml extract is available and it is desired to use a 100 AU/ml or BAU/ml extract substitute as follows: Vd x Cd = Vn x Ca

 $10ml \times 100 = Vn \times 10,000$

0.1 ml = Vn

Using a sterile technique, remove 0.10 ml of extract from the 10,000 AU/ml or BAU/ml vial and place it into a vial containing 9.90 ml of sterile diluent. The resulting concentration will be 10ml vial of 100 AU/ml or BAU/ml.

Intervals between doses: The optimal interval between doses of allergenic extract has not been definitely established. The amount of allergenic extract is increased at each injection by not more than 50%-100% of the previous amount and the next increment is governed by the response to the last injection. There are three generally accepted methods of pollen hyposensitizing therapy.

1. PRESEASONAL

Treatment starts each year 6 to 8 weeks before onset of seasonal symptoms. Maximal dose reached just before symptoms are expected. Injections discontinued during and following season until next year.

2. CO-SEASONAL

Patient is first treated during season with symptoms. Low initial doses are employed to prevent worsening of condition. This is followed by an intensive schedule of therapy (i.e. injections given 2 to 3 times per week). Fewer Allergists are resorting to this Co-seasonal therapy because of the availability of more effective, symptomatic medications that allow the patient to go through a season relatively symptom free.

3. PERENNIAL

Initially this is the same as pre seasonal. The allergen is administered twice weekly or weekly for about 20 injections to achieve the maximum tolerated dose. Then, maintenance therapy may be administered once a week or less frequently.

Duration of Treatment: The usual duration of treatment has not been established. A period of two or three years of injection therapy constitutes an average minimum course of treatment.

HOW SUPPLIED

Allergenic extracts are supplied with units listed as: Weight/volume (W/V), Protein Nitrogen Units (PNU/ml), Allergy Units (AU/ml) or Bioequivalent Allergy Units (BAU/ml).

Sizes:

Diagnostic Scratch: 5 ml dropper application vials

Diagnostic Intradermal: 5 ml or 10 ml vials.

Therapeutic Allergens: 5 ml, 10 ml, 50 ml multiple dose vials.

STORAGE

The expiration date of allergen extracts is listed on the container label. Store extracts upon arrival at 2° to 8°C and keep them in this range during office use.

<u>WARRANTY</u>: We warrant that this product was prepared and tested according to the standards of the FDA and is true to label. Because of biological differences in individuals and because allergenic extracts are manufactured to be potent and because we have no control over the conditions of use, we cannot and do not warrant either a good effect or against an ill effect following use.

REFERENCES

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CONTAINER LABELING



NELCO LABS, INC. 154 BROOK AVE., DEER PARK, NY 11729





CATTLE EPITHELIUM

cattle epithelium injection, solution

Product Information					
Product T ype	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-1004		
Route of Administration	INTRADERMAL, SUBCUTANEOUS				
Active Ingredient/Active Moi	ety				
Ingre	Ingredient Name Basis of Strength Strength				
BOS TAURUS SKIN (UNII: 7J12CD6O9	L) (BOS TAURUS SKIN - UNII:7J12CD6O9)	L) BOS TAURUS SKIN	20000 [PNU] in 1 mL		
Inactive Ingredients					
	Ingredient Name		Strength		
SODIUM CHLORIDE (UNII: 451W47IQ	8 X)				

SODIUM BICARBONAT	E (UNII: 8MDF5V39QO)				
PHENOL (UNII: 339NCG	44TV)				
WATER (UNII: 059QF0K	OOR)				
GLYCERIN (UNII: PDC6	A3C0OX)				
Packaging					
# Item Code	Package Description	Marke	ting Start Date	Marl	eting End Date
1 NDC:36987-1004-1	5 mL in 1 VIAL, MULTI-DOSE				
2 NDC:36987-1004-2	10 mL in 1 VIAL, MULTI-DOSE				
3 NDC:36987-1004-3	30 mL in 1 VIAL, MULTI-DOSE				
4 NDC:36987-1004-4	50 mL in 1 VIAL, MULTI-DOSE				
Marketing Info	rmation				
0					
Marketing Category	Application Number or Monograph C	Citation	Marketing Start Da	te M	arketing End Date
BLA	BLA102192		08/29/1972		
DOG EPITHEL	IUM				
1					

dog epithelium injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-1012
Route of Administration	INTRADERMAL, SUBCUTANEOUS		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CANIS LUPUS FAMILIARIS SKIN (UNII: X2W7CLE97T) (CANIS LUPUS FAMILIARIS SKIN - UNII:X2W7CLE97T)	CANIS LUPUS FAMILIARIS SKIN	20000 [PNU] in 1 mL		

Inactive Ingredients	
Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
PHENOL (UNII: 339NCG44TV)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:36987-1012-1	5 mL in 1 VIAL, MULTI-DOSE		
2 NDC:36987-1012-2	10 mL in 1 VIAL, MULTI-DOSE		

3 NDC:36987-1012-3	30 mL in 1 VIAL, MULTI-DOSE		
4 NDC:36987-1012-4	50 mL in 1 VIAL, MULTI-DOSE		
Manulastin a Tarfa			
Marketing Info	rmation		
Marketing Info Marketing Category	rmation Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
U U		Marketing Start Date 08/29/1972	Marketing End Date

CHICKEN FEATHERS

chicken feathers injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-1020
Route of Administration	INTRADERMAL, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
GALLUS GALLUS FEATHER (UNII: 1FCM16V0FV) (GALLUS GALLUS FEATHER - UNII:1FCM16V0FV)	GALLUS GALLUS FEATHER	20000 [PNU] in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
PHENOL (UNII: 339 NCG44TV)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 I	NDC:36987-1020-1	5 mL in 1 VIAL, MULTI-DOSE		
2 I	NDC:36987-1020-2	10 mL in 1 VIAL, MULTI-DOSE		
3 I	NDC:36987-1020-3	30 mL in 1 VIAL, MULTI-DOSE		
4 I	NDC:36987-1020-4	50 mL in 1 VIAL, MULTI-DOSE		

Marketing Info	rmation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102192	08/29/1972	

DUCK FEATHERS

IUMAN PRESCRIPTION DRU NTRADERMAL, SUBCUTAN y lient Name NII: 83B65P4796) (ANAS PI Ingredient Name	IEOUS	em Code (Sourc Basis of S ANAS PLATYH FEATHER	trength RHYNCHOS	C:36987-1028 Strength 20000 [PNU] in 1 mL Strength
NTRADERMAL, SUBCUTAN y lient Name NII: 83B65P4796) (ANAS PI Ingredient Name	IEOUS	Basis of S ANAS PLATY	trength RHYNCHOS	Strength 20000 [PNU] in 1 mL
y lient Name NII: 83B65P4796) (ANAS PI Ingredient Name ()	IEOUS	Basis of S ANAS PLATY	trength RHYNCHOS	20000 [PNU] in 1 mL
lient Name NII: 83B65P4796) (ANAS PI Ingredient Name	LATYRHYNCHOS	ANAS PLATY	RHYNCHOS	20000 [PNU] in 1 mL
lient Name NII: 83B65P4796) (ANAS PI Ingredient Name	LATYRHYNCHO S	ANAS PLATY	RHYNCHOS	20000 [PNU] in 1 mL
NII: 83B65P4796) (ANAS PI Ingredient Name	LATYRHYNCHOS	ANAS PLATY	RHYNCHOS	20000 [PNU] in 1 mL
Ingredient Name	LATYRHYNCHOS			in 1 mL
()			5	Strength
()			5	Strength
739QO)				
•	Marketing	Start Date	Marketin	ng End Date
,				
Number or Monograph	Citation Ma	rketing Start Da	te Marke	eting End Da
	08/2	9/1972		
	age Description L, MULTI-DOSE AL, MULTI-DOSE AL, MULTI-DOSE AL, MULTI-DOSE AL, MULTI-DOSE	L, MULTI-DOSE AL, MULTI-DOSE AL, MULTI-DOSE AL, MULTI-DOSE AL, MULTI-DOSE Number or Monograph Citation Ma	L, MULTI-DOSE	L, MULTI-DOSE AL, MULTI-DOSE AL, MULTI-DOSE AL, MULTI-DOSE AL, MULTI-DOSE AL, MULTI-DOSE Number or Monograph Citation Marketing Start Date Market

GLYCERIN (UNII: PDC6A3C0OX)

Inactive Ingre	dients					
macuve mgre	ulents	Ingredient Name				Strength
SODIUM CHLORI	DE (UNII) 451					Strength
SODIUM BICARB						
PHENOL (UNII: 33						
WATER (UNII: 059						
GLYCERIN (UNII:	- ,	X)				
Packaging						
# Item Co	de	Package Description	Marketi	ng Start Date	Marketi	ng End Date
1 NDC:36987-103	6-1 5 m	L in 1 VIAL, MULTI-DOSE		0		0
2 NDC:36987-103		mL in 1 VIAL, MULTI-DOSE				
3 NDC:36987-103		mL in 1 VIAL, MULTI-DOSE				
4 NDC:36987-103		mL in 1 VIAL, MULTI-DOSE				
Marketing Cates	gory App	olication Number or Monograph	Citation	Marketing Start Da	nte Mark	eting End Dat
	DI A 10	2210.2				cung Litu Dut
	BLA10			8/29/1972		
GERBIL EP gerbil epithelium	ITHELI injection, so	UM				
GERBIL EP gerbil epithelium Product Inform	ITHELI injection, so	UM olution	C	8/29/1972		
BLA GERBIL EP gerbil epithelium Product Infor Product Type	ITHELI injection, so	UM	C			C:36987-1044
GERBIL EP gerbil epithelium Product Inform	ITHELI injection, so mation	UM olution	UG	8/29/1972		
GERBIL EP gerbil epithelium Product Infor Product Type Route of Adminis	ITHELI injection, so mation stration	UM olution HUMAN PRESCRIPTION DRI INTRADERMAL, SUBCUTAR	UG	8/29/1972		
GERBIL EP gerbil epithelium Product Infor Product Type	ITHELI injection, so mation stration	UM olution HUMAN PRESCRIPTION DRI INTRADERMAL, SUBCUTAR	UG	8/29/1972	re) ND	
GERBIL EP gerbil epithelium Product Infor Product Type Route of Adminis Active Ingredi MERIONES UNGU	ITHELI injection, so mation stration ient/Active	UM olution HUMAN PRESCRIPTION DRI INTRADERMAL, SUBCUTAN NTRADERMAL, SUBCUTAN MOIE ty Ingredient Name SKIN (UNII: 9 WN2H714TG) (MERION	UG NEOUS	8/29/1972 Item Code (Sourc	ce) ND	C:36987-1044
GERBIL EP gerbil epithelium Product Infor Product Type Route of Adminis Active Ingredi MERIONES UNGU	ITHELI injection, so mation stration ient/Active	UM olution HUMAN PRESCRIPTION DRI INTRADERMAL, SUBCUTAN NTRADERMAL, SUBCUTAN MOIE ty Ingredient Name SKIN (UNII: 9 WN2H714TG) (MERION	UG NEOUS	Basis of S MERIONES	ce) ND	C:36987-1044 Strength 20000 [PNU]
GERBIL EP gerbil epithelium Product Infor Product Type Route of Adminis Active Ingredi MERIONES UNGU	ITHELI injection, so mation stration ient/Active	UM olution HUMAN PRESCRIPTION DRI INTRADERMAL, SUBCUTAN NTRADERMAL, SUBCUTAN INTRADERMAL, SUBCUTAN SKIN (UNII: 9 WN2H714TG) (MERION WN2H714TG)	UG NEOUS	Basis of S MERIONES	ce) ND Strength TUS SKIN	C:36987-1044 Strength 20000 [PNU] in 1 mL
GERBIL EP gerbil epithelium Product Inform Product Type Route of Adminis Active Ingredi MERIONES UNGU UNGUICULATUS S	ITHELI injection, so mation stration ient/Active ICULATUS S IKIN - UNII:9 V dients	UM olution HUMAN PRESCRIPTION DR INTRADERMAL, SUBCUTAN INTRADERMAL, SUBCUTAN INTRADERMAL, SUBCUTAN SKIN (UNII: 9 WN2H714TG) (MERION WN2H714TG)	UG NEOUS	Basis of S MERIONES	ce) ND Strength TUS SKIN	C:36987-1044 Strength 20000 [PNU]
GERBIL EP gerbil epithelium Product Inform Product Type Route of Adminis Active Ingredi MERIONES UNGU UNGUICULATUS S Inactive Ingre SODIUM CHLORI	ITHELI injection, so mation stration ient/Active ficulatus s Skin - UNII:9V dients DE (UNII: 451	UM olution HUMAN PRESCRIPTION DR INTRADERMAL, SUBCUTAN INTRADERMAL, SUBCUTAN INTRADERMAL, SUBCUTAN SKIN (UNII: 9 WN2H714TG) (MERION WN2H714TG)	UG NEOUS	Basis of S MERIONES	ce) ND Strength TUS SKIN	C:36987-1044 Strength 20000 [PNU] in 1 mL
GERBIL EP gerbil epithelium Product Infor Product Type Route of Adminis Active Ingredi MERIONES UNGU UNGUICULATUS S Inactive Ingre SODIUM CHLORI	ITHELI injection, so mation stration ient/Active ICULATUS S SKIN - UNII:9 V dients DE (UNII: 451 ONATE (UNII	UM olution HUMAN PRESCRIPTION DR INTRADERMAL, SUBCUTAN INTRADERMAL, SUBCUTAN INTRADERMAL, SUBCUTAN SKIN (UNII: 9 WN2H714TG) (MERION WN2H714TG)	UG NEOUS	Basis of S MERIONES	ce) ND Strength TUS SKIN	C:36987-1044 Strength 20000 [PNU] in 1 mL
GERBIL EP gerbil epithelium Product Infor Product Type Route of Adminis Active Ingred	ITHELI injection, so mation stration ient/Active ficulatus s Skin - UNII:9 V dients DE (UNII: 451 ONATE (UNII 9 NCG44TV)	UM olution HUMAN PRESCRIPTION DR INTRADERMAL, SUBCUTAN INTRADERMAL, SUBCUTAN INTRADERMAL, SUBCUTAN SKIN (UNII: 9 WN2H714TG) (MERION WN2H714TG)	UG NEOUS	Basis of S MERIONES	ce) ND Strength TUS SKIN	C:36987-1044 Strength 20000 [PNU] in 1 mL

- '	ackaging					
#	Item Code	Pac	ckage Description	Marke	ting Start Date	Marketing End Date
L	NDC:36987-1044-1	5 mL in 1 V	IAL, MULTI-DOSE			
2	NDC:36987-1044-2	10 mL in 1	VIAL, MULTI-DOSE			
3	NDC:36987-1044-3	30 mL in 1	VIAL, MULTI-DOSE			
4	NDC:36987-1044-4	50 mL in 1	VIAL, MULTI-DOSE			
N	Iarketing Info	rmation				
	farketing Category		on Number or Monograp	h Citation	Marketing Start Dat	e Marketing End Dat
	LA	BLA102192	0 1		08/29/1972	
_						
~	OAT EPITHE	TIIM				
go	at epithelium injecti	on, solution				
р						
	raduct Informatio					
	roduct Informatio	on	LIUMAN DESCRIPTION D	PUC	them Code (Service	NDC-26097 1052
P	roduct Type		HUMAN PRESCRIPTION D		Item Code (Source) NDC:36987-1052
P:		on	INTRADERMAL, SUBCUT.		Item Code (Source) NDC:36987-1052
P R	roduct Type oute of Administrati	on Active Moi	INTRADERMAL, SUBCUT.			
P R A	roduct Type oute of Administration ctive Ingredient/A	on Active Moi Ingre	INTRADERMAL, SUBCUT. ety edient Name	ANEOUS	Basis of Stree	ngth Strength
P R A	roduct Type oute of Administration ctive Ingredient/A	on Active Moi Ingre	INTRADERMAL, SUBCUT.	ANEOUS	Basis of Stree	ngth Strength
P R A	roduct Type oute of Administration ctive Ingredient/A	on Active Moi Ingre	INTRADERMAL, SUBCUT. ety edient Name	ANEOUS	Basis of Stree	ngth Strength
P R A	roduct Type oute of Administration ctive Ingredient/A APRA HIRCUS SKIN (1	on Active Moie Ingre JNII: JLG98531	INTRADERMAL, SUBCUT. ety edient Name	ANEOUS	Basis of Stree	ngth Strength
P R A	roduct Type oute of Administration ctive Ingredient/A	on Active Moie Ingre JNII: JLG98531	INTRADERMAL, SUBCUT. ety edient Name	ANEOUS	Basis of Stree	ngth Strength SKIN 20000 [PNU] in 1
P R A C In	roduct Type oute of Administration ctive Ingredient/A APRA HIRCUS SKIN (1	on Active Moie Ingre JNII: JLG98531 ts	INTRADERMAL, SUBCUT. ety edient Name E2P) (CAPRA HIRCUS SKIN Ingredient Name	ANEOUS	Basis of Stree	ngth Strength
Pi Ra A C/ In	roduct Type oute of Administration ctive Ingredient/A APRA HIRCUS SKIN (19 nactive Ingredien	on Active Moi Ingr JNII: JLG9853 ts NII: 451W47IQ8	INTRADERMAL, SUBCUT ety edient Name E2P) (CAPRA HIRCUS SKIN Ingredient Name ^B X)	ANEOUS	Basis of Stree	ngth Strength SKIN 20000 [PNU] in 1
Pi Ra A C/ In SC	roduct Type oute of Administration ctive Ingredient/A APRA HIRCUS SKIN (1 Nactive Ingredien DDIUM CHLORIDE (U	on Active Moie Ingre JNII: JLG98531 ts NII: 451W47IQ8 E (UNII: 8MDF	INTRADERMAL, SUBCUT ety edient Name E2P) (CAPRA HIRCUS SKIN Ingredient Name ^B X)	ANEOUS	Basis of Stree	ngth Strength SKIN 20000 [PNU] in 1
Pi Ra A C/ In SC PH	roduct Type oute of Administration ctive Ingredient/A APRA HIRCUS SKIN (1 nactive Ingredien DDIUM CHLORIDE (U DDIUM BICARBONAT	on Active Moi Ingra JNII: JLG98531 ts NII: 451W47IQ8 E (UNII: 8 MDF 44TV)	INTRADERMAL, SUBCUT ety edient Name E2P) (CAPRA HIRCUS SKIN Ingredient Name ^B X)	ANEOUS	Basis of Stree	ngth Strength SKIN 20000 [PNU] in 1
Pi Ra A C/ In sc sc PH W.	roduct Type oute of Administration ctive Ingredient/A APRA HIRCUS SKIN (1 nactive Ingredien DDIUM CHLORIDE (U DDIUM BICARBONAT HENOL (UNII: 339NCG	on Active Moie Ingre JNII: JLG98531 ts NII: 451W471Q8 E (UNII: 8 MDF 44TV) O0R)	INTRADERMAL, SUBCUT ety edient Name E2P) (CAPRA HIRCUS SKIN Ingredient Name ^B X)	ANEOUS	Basis of Stree	ngth Strength SKIN 20000 [PNU] in 1
Pi Ra A C/ In sc sc PH W.	roduct Type oute of Administration ctive Ingredient/A APRA HIRCUS SKIN (19 hactive Ingredien DDIUM CHLORIDE (10 DDIUM BICARBONAT HENOL (UNII: 339NCG ATER (UNII: 059QF0K	on Active Moie Ingre JNII: JLG98531 ts NII: 451W471Q8 E (UNII: 8 MDF 44TV) O0R)	INTRADERMAL, SUBCUT ety edient Name E2P) (CAPRA HIRCUS SKIN Ingredient Name ^B X)	ANEOUS	Basis of Stree	ngth Strength SKIN 20000 [PNU] in 1
Pi Ra A C/ In sc sc PH W.	roduct Type oute of Administration ctive Ingredient/A APRA HIRCUS SKIN (19 hactive Ingredien DDIUM CHLORIDE (10 DDIUM BICARBONAT HENOL (UNII: 339NCG ATER (UNII: 059QF0K	on Active Moie Ingre JNII: JLG98531 ts NII: 451W471Q8 E (UNII: 8 MDF 44TV) O0R)	INTRADERMAL, SUBCUT ety edient Name E2P) (CAPRA HIRCUS SKIN Ingredient Name ^B X)	ANEOUS	Basis of Stree	ngth Strength SKIN 20000 [PNU] in 1
Pi Ra C C In S C S C PH W G	roduct Type oute of Administration ctive Ingredient/A APRA HIRCUS SKIN (1 hactive Ingredien DDIUM CHLORIDE (U DDIUM BICARBONAT HENOL (UNII: 339NCG ATER (UNII: 059QF0K LYCERIN (UNII: PDC6A	on Active Moie Ingre JNII: JLG98531 ts NII: 451W471Q8 E (UNII: 8 MDF 44TV) O0R)	INTRADERMAL, SUBCUT ety edient Name E2P) (CAPRA HIRCUS SKIN Ingredient Name ^B X)	ANEOUS	Basis of Stree	ngth Strength SKIN 20000 [PNU] in 1
Pi R A C A C A C A C A C A C A C A C A C A	roduct Type oute of Administration ctive Ingredient/A APRA HIRCUS SKIN (I hactive Ingredien DDIUM CHLORIDE (U DDIUM BICARBONAT HENOL (UNII: 339NCG ATER (UNII: 059QF0K LYCERIN (UNII: PDC6A	on Active Moie Ingre JNII: JLG9853J ts NII: 451W47IQ8 E (UNII: 8 MDF 44TV) O0R) A3C0OX)	INTRADERMAL, SUBCUT. ety edient Name E2P) (CAPRA HIRCUS SKIN Ingredient Name 8 X) 55V39QO)	ANEOUS	Basis of Strei 53E2P) CAPRA HIRCUS	ngth Strength SKIN 20000 [PNU] in 1 SKIN Strength
P1 R4 A C/ In SCC SCC SCC SCC SCC SCC SCC SCC SCC SC	roduct Type oute of Administration ctive Ingredient/A APRA HIRCUS SKIN (I hactive Ingredien DDIUM CHLORIDE (U DDIUM BICARBONAT HENOL (UNII: 339NCG ATER (UNII: 059QF0K LYCERIN (UNII: PDC6A ackaging Item Code	Active Moi Ingre JNII: JLG98531 ts NII: 451W47IQ4 E (UNII: 8 MDF 44TV) 00 R) A3C0OX) Pac	INTRADERMAL, SUBCUT. e ty edient Name E2P) (CAPRA HIRCUS SKIN Ingredient Name 8X) 75V39QO)	ANEOUS	Basis of Stree	ngth Strength SKIN 20000 [PNU] in 1
Pi RA A C C A In S S C G J W S S C A H T S S C A H T S S C A H T S S S C A H T S S S S S S S S S S S S S S S S S S	roduct Type oute of Administration ctive Ingredient/A APRA HIRCUS SKIN (I hactive Ingredien DDIUM CHLORIDE (U DDIUM BICARBONAT HENOL (UNII: 339NCG ATER (UNII: 059QF0K LYCERIN (UNII: PDC6A ackaging Item Code NDC:36987-1052-1	on Active Moia Ingra JNII: JLG98531 ts NII: 451W471Q4 E (UNII: 8 MDF 44TV) 00 R) A3C00X) Pac 5 mL in 1 V	INTRADERMAL, SUBCUT. e ty e dient Name E2P) (CAPRA HIRCUS SKIN Ingredient Name 8 X) 5 V39 QO) 5 V39 QO) 2 Ekage Description TAL, MULTI-DOSE	ANEOUS	Basis of Strei 53E2P) CAPRA HIRCUS	ngth Strength SKIN 20000 [PNU] in 11 SKIN 20000 [PNU] in 11
Pi Ra CA CA In SC SC SC SC SC SC SC SC SC SC SC SC SC	roduct Type oute of Administration ctive Ingredient/A APRA HIRCUS SKIN (14 hactive Ingredient DDIUM CHLO RIDE (14 DDIUM BICARBO NAT HENOL (UNII: 339NCG ATER (UNII: 059QF0K LYCERIN (UNII: PDC6A ackaging Item Code NDC:36987-1052-1 NDC:36987-1052-2	on Active Moia Ingra JNII: JLG98531 ts NII: 451W47IQ4 Te (UNII: 8MDF 44TV) O0R) A3C0OX) S 5 mL in 1 V 10 mL in 1	INTRADERMAL, SUBCUT. e ty edient Name E2P) (CAPRA HIRCUS SKIN Ingredient Name 8X) 5V39QO) 25V39QO) 25V39QO) 25V39QO)	ANEOUS	Basis of Strei 53E2P) CAPRA HIRCUS	ngth Strength SKIN 20000 [PNU] in 1 SKIN Strength
Pi Ra A C C A In S C C A S C S C	roduct Type oute of Administration ctive Ingredient/A APRA HIRCUS SKIN (19 hactive Ingredien DDIUM CHLORIDE (10 DDIUM BICARBONAT HENOL (UNII: 339NCG ATER (UNII: 059QF0K LYCERIN (UNII: PDC6A ackaging Item Code NDC:36987-1052-1 NDC:36987-1052-2 NDC:36987-1052-3	on Active Moie Ingre JNII: JLG98531 ts NII: 451W471Q8 E (UNII: 8 MDF 44⊤V) 00 R) 43⊤00X) A3⊂00X) Pac 5 mL in 1 V 10 mL in 1 30 mL in 1	INTRADERMAL, SUBCUT. e ty e dient Name E2P) (CAPRA HIRCUS SKIN Ingredient Name 8 X) 5 V39 QO) Capacity (Capacity (Capac	ANEOUS	Basis of Strei 53E2P) CAPRA HIRCUS	ngth Strength SKIN 20000 [PNU] in 1 SKIN Strength
P) Ra A CCA In SCCA SCCA SCCA SCCA SCCA SCCA SCCA RA RA RA RA RA RA RA RA RA RA RA RA RA	roduct Type oute of Administration ctive Ingredient/A APRA HIRCUS SKIN (14 hactive Ingredient DDIUM CHLO RIDE (14 DDIUM BICARBO NAT HENOL (UNII: 339NCG ATER (UNII: 059QF0K LYCERIN (UNII: PDC6A ackaging Item Code NDC:36987-1052-1 NDC:36987-1052-2	on Active Moie Ingre JNII: JLG98531 ts NII: 451W471Q8 E (UNII: 8 MDF 44⊤V) 00 R) 43⊤00X) A3⊂00X) Pac 5 mL in 1 V 10 mL in 1 30 mL in 1	INTRADERMAL, SUBCUT. e ty edient Name E2P) (CAPRA HIRCUS SKIN Ingredient Name 8X) 5V39QO) 25V39QO) 25V39QO) 25V39QO)	ANEOUS	Basis of Strei 53E2P) CAPRA HIRCUS	ngth Strength SKIN 20000 [PNU] in 1 SKIN Strength

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102192	08/29/1972	

uine	a pig epithelium	injection, sol	ution					
Pro	duct Informati	on						
Prod	luct T ype		HUMAN PRESCRIPTION DE	RUG	Ite m	Code (Sour	ce)	NDC:36987-1060
Rout	e of Administrati	ion	INTRADERMAL, SUBCUTA	NEOUS				
Acti	ve Ingredient/	Activa Mai	o tv					
Acu	ve ingreutent/		redient Name			Basis of S	tronath	Strength
	A PORCELLUS SI GM3H4U6QS8)	_	H4U6QS8) (CAVIA PORCEL	LUS SKIN -		CAVIA POR	_	20000 [PNU] in 1 mL
UINII.V	3/0511400(238)					SKIN		III I IIIL
Inco	tivo Inquadian	4 0						
mac	tive Ingredien	lts	Ingredient Name					Strength
וחס	IUM CHLORIDE (U	INII: 451W47IO						Strength
	IUM BICARBONAT							
	OL (UNII: 339NCC							
WAT	ER (UNII: 059QF0F	KOOR)						
GLY	C ERIN (UNII: PDC6	A3C0OX)						
Pacl	kaging							
ŧ	Item Code	Pa	ckage Description	Market	ing Sta	art Date	Marl	keting End Date
1 ND	C:36987-1060-1	5 mL in 1 V	/IAL, MULTI-DOSE					
2 ND	C:36987-1060-2	10 mL in 1	VIAL, MULTI-DOSE					
3 ND	C:36987-1060-3	30 mL in 1	VIAL, MULTI-DOSE					
	C:36987-1060-4	50 mL in 1	VIAL, MULTI-DOSE					
4 ND								
4 ND								
	rketing Info	rmation						
Ma	rketing Info keting Category		on Number or Monograph	1 Citation	Marke	eting Start D	ate M	arketing End Date

HAMSTER EPITHELIUM

hamster epithelium injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-1068

Active Ingredient/	Active Moi	ety				
	Ingr	edient Name		Basis of Stre	ngth	Strength
MESOCRICETUS AURA SKIN - UNII:3K873H631		NII: 3K873H631W) (MESOCRIO	CETUS AURATU		_	20000 [PNU] in 1 mL
Inactive Ingredier	ıts					
		Ingredient Name				Strength
SODIUM CHLORIDE (U	UNII: 451W47IQ	8 X)				
SODIUM BICARBONA	TE (UNII: 8 MDF	5V39QO)				
PHENOL (UNII: 339NCC	G44TV)					
WATER (UNII: 059QF01	KO0R)					
GLYCERIN (UNII: PDC6	A3C0OX)					
Packaging						
# Item Code	Pa	ckage Description	Marketing	Start Date N	larketi	ng End Date
1 NDC:36987-1068-1		/IAL, MULTI-DOSE	in the ting		un ne en	ng Liiu Dute
2 NDC:36987-1068-2		VIAL, MULTI-DOSE				
3 NDC:36987-1068-3		VIAL, MULTI-DOSE				
4 NDC:36987-1068-4		VIAL, MULTI-DOSE				
Marketing Info	rmation					
Marketing Category	Applicatio	on Number or Monograph	Citation Ma	rketing Start Date	Mark	eting End Da
BLA	BLA102192			.9/1972		-
UOC EDITUEI	TTINA					
HOG EPITHEI						
nog epithelium injecti	on, solution					
Product Informati	ion					
Product Type		HUMAN PRESCRIPTION DRU	JG It	em Code (Source)	ND	C:36987-1076
Route of Administrat	ion	INTRADERMAL, SUBCUTAN	NEOUS			
Active Ingredient/	Active Moi	ety				
	Ingr	edient Name		Basis of Streng	th	Strength

 SUS SCROFA SKIN (UNII: 3EM4VW6TQN) (SUS SCROFA SKIN - UNII:3EM4VW6TQN)
 SUS SCROFA SKIN
 20000 [PNU] in 1 mL

Inactive Ingredients

Ingredient Name

Strength

SO DIUM BICARBO NA'	FE (UNII: 8MDF5V39QO)		
PHENOL (UNII: 339NCC	G44TV)		
WATER (UNII: 059QF01	KOOR)		
GLYCERIN (UNII: PDC6	A3C0OX)		
Packaging			
Packaging			
00			
00	Package Description	Marketing Start Date	Marketing End Date
# Item Code	Package Description 5 mL in 1 VIAL, MULTI-DOSE	Marketing Start Date	Marketing End Date
# Item Code 1 NDC:36987-1076-1		Marketing Start Date	Marketing End Date
# Item Code 1 NDC:36987-1076-1 2 NDC:36987-1076-2	5 mL in 1 VIAL, MULTI-DOSE	Marketing Start Date	Marketing End Date
 # Item Code 1 NDC:36987-1076-1 2 NDC:36987-1076-2 3 NDC:36987-1076-3 	5 mL in 1 VIAL, MULTI-DOSE 10 mL in 1 VIAL, MULTI-DOSE	Marketing Start Date	Marketing End Date
00	5 mL in 1 VIAL, MULTI-DOSE 10 mL in 1 VIAL, MULTI-DOSE 30 mL in 1 VIAL, MULTI-DOSE	Marketing Start Date	Marketing End Date
 # Item Code 1 NDC:36987-1076-1 2 NDC:36987-1076-2 3 NDC:36987-1076-3 	5 mL in 1 VIAL, MULTI-DOSE 10 mL in 1 VIAL, MULTI-DOSE 30 mL in 1 VIAL, MULTI-DOSE	Marketing Start Date	Marketing End Date

Marketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End DateBLABLA10219208/29/1972

	_						
orse epithelium injecti	on, solution	l					
Product Informatio	n						
Product Type		HUMAN PRESCRIPTION DE	RUG	Ite m (Code (Source	e) N	NDC:36987-1084
Route of Administratio	n	INTRADERMAL, SUBCUTA	ANEOUS				
Active Ingredient/A	ctive Moi	ety					
	Ingr	edient Name			Basis of Str	ength	Strength
EQUUS CABALLUS SKIN (UNII: 88VZV9HGT4) (EQUUS CABALLUS SKIN - EQUUS CABALL UNII:88VZV9HGT4) SKIN					LLUS	20000 [PNU] in 1 mL	
In stine Inque dient	-						
Inactive Ingredient	5						
		Ingradiant Nama					Strongth
SODIUM CHI ORIDE (UN	JII: 451W47IO	Ingredient Name					Strength
		8X)					Strength
SO DIUM BICARBO NATI	E (UNII: 8 MDF	8X)					Strength
SODIUM BICARBONATI PHENOL (UNII: 339NCG4	E (UNII: 8 MDF 4TV)	8X)					Strength
SODIUM BICARBONATI PHENOL (UNII: 339NCG4 WATER (UNII: 059QF0K0	E (UNII: 8 MDF 4TV) D0R)	8X)					Strength
SODIUM CHLORIDE (UN SODIUM BICARBONATI PHENOL (UNII: 339NCG4 WATER (UNII: 059QF0K0 GLYCERIN (UNII: PDC6A	E (UNII: 8 MDF 4TV) D0R)	8X)					Strength
SODIUM BICARBONATI PHENOL (UNII: 339NCG4 WATER (UNII: 059QF0K0	E (UNII: 8 MDF 4TV) D0R)	8X)					Strength
SODIUM BICARBONATI PHENOL (UNII: 339NCG4 WATER (UNII: 059QF0K0 GLYCERIN (UNII: PDC6A	E (UNII: 8 MDF 4TV) D0R)	8X)					Strength
SODIUM BICARBONATI PHENOL (UNII: 339NCG4 WATER (UNII: 059QF0K0	E (UNII: 8 MDF 44TV) DOR) 3C0OX)	8X)	Marketing	g Stai	rt Date	Marke	Strength

3 ND	C:36987-1084-3	30 mL in 1	VIAL, MULTI-DOSE					
4 ND	C:36987-1084-4	50 mL in 1	VIAL, MULTI-DOSE					
Ma	rketing Info	rmation						
Mar	keting Category	Applicatio	on Number or Monograph	Citation	Marke	ting Start D	Date M	larketing End Dat
BLA		BLA102192			08/29/19	972		
MO	USE EPITH	ELIUM						
nous	e epithelium injeo	ction, solutio	n					
Pro	duct Informatio	on						
Prod	luct T ype		HUMAN PRESCRIPTION DR	UG	Ite m	Code (Sour	ce)	NDC:36987-1092
Rout	e of Administrati	on	INTRADERMAL, SUBCUTA	NEOUS				
	ve Ingredient/	Active Moi	ety					
Actr	ve ingreatent/	Ingr	adiant Nama			Dania of St	tuonath	Strongth
	-	•	edient Name	ZIN		Basis of St	-	-
MUS	-	•	edient Name IGB09) (MUS MUSCULUS SF	KIN -		Basis of St MUS MUSCU SKIN	-	Strength 20000 [PNU] in 1 mL
MUS UNII:3	- MUSCULUS SKIN	(UNII: 390 AN9	GB09) (MUS MUSCULUS SF	XIN -		MUS MUSCU	-	20000 [PNU] in 1 mL
MUS UNII:3 Inac	MUSCULUS SKIN 390 AN9GB09)	(UNII: 390 AN9	GB09) (MUS MUSCULUS SF Ingredient Name	KIN -		MUS MUSCU	-	20000 [PNU]
MUS UNII:3 Inac SODI	MUSCULUS SKIN 390 AN9GB09) tive Ingredien	(UNII: 390 AN9 ts NII: 451W47IQ	GB09) (MUS MUSCULUS SF Ingredient Name 8X)	XIN -		MUS MUSCU	-	20000 [PNU] in 1 mL
MUS UNII:3 Inac SODI SODI	MUSCULUS SKIN 390 AN9GB09)	(UNII: 390 AN9 ts NII: 451W47IQ `E (UNII: 8 MDF	GB09) (MUS MUSCULUS SF Ingredient Name 8X)	KIN -		MUS MUSCU	-	20000 [PNU] in 1 mL
MUS UNII:3 Inac SODI SODI PHEN	MUSCULUS SKIN 390 AN9GB09) stive Ingredien IUM CHLORIDE (U	(UNII: 390 AN9 ts NII: 451W47IQ3 'E (UNII: 8 MDF 44TV)	GB09) (MUS MUSCULUS SF Ingredient Name 8X)	XIN -		MUS MUSCU	-	20000 [PNU] in 1 mL
MUS UNII:3 Inac SODI SODI PHEN WAT	MUSCULUS SKIN 390 AN9GB09) Trive Ingredien IUM CHLORIDE (U IUM BICARBONAT	(UNII: 390 AN9 ts NII: 451W47IQ E (UNII: 8 MDF 44TV) :00R)	GB09) (MUS MUSCULUS SF Ingredient Name 8X)	KIN -		MUS MUSCU	-	20000 [PNU] in 1 mL
MUS UNII:3 Inac SODI SODI PHEN WAT	MUSCULUS SKIN 390 AN9GB09) Etive Ingredien IUM CHLORIDE (U IUM BICARBONAT ROL (UNII: 339NCG ER (UNII: 059QF0K	(UNII: 390 AN9 ts NII: 451W47IQ E (UNII: 8 MDF 44TV) :00R)	GB09) (MUS MUSCULUS SF Ingredient Name 8X)	KIN -		MUS MUSCU	-	20000 [PNU] in 1 mL
MUS UNII:3 Inac SODI SODI PHEN WAT GLY(MUSCULUS SKIN 390 AN9GB09) Etive Ingredien IUM CHLORIDE (U IUM BICARBONAT IOL (UNII: 339NCG ER (UNII: 059QF0K CERIN (UNII: PDC6.	(UNII: 390 AN9 ts NII: 451W47IQ E (UNII: 8 MDF 44TV) :00R)	GB09) (MUS MUSCULUS SF Ingredient Name 8X)	KIN -		MUS MUSCU	-	20000 [PNU] in 1 mL
MUS UNIE: SO DI SO DI PHEN WAT: GL YC	MUSCULUS SKIN 390 AN9GB09) Etive Ingredien RUM CHLORIDE (U RUM BICARBONAT ROL (UNII: 339NCG ER (UNII: 059QF0K CERIN (UNII: PDC6.	(UNII: 390 AN9 ts NII: 451W47IQ3 E (UNII: 8 MDF 44TV) C00 R) A3C0 O X)	Ingredient Name 8X) 5V39QO)		ting Sta	MUS MUSCU SKIN	JLUS	20000 [PNU] in 1 mL Strength
MUS UNII:3 Inac SODI SODI PHEN WAT GLYC Pacl #	MUSCULUS SKIN 390 AN9GB09) Etive Ingredien IUM CHLORIDE (U IUM BICARBONAT IOL (UNII: 339NCG ER (UNII: 059QF0K CERIN (UNII: PDC6.	(UNII: 390 AN9 ts NII: 451W47IQ 'E (UNII: 8 MDF 44TV) (O0R) A3C0OX) Pae	GB09) (MUS MUSCULUS SF Ingredient Name 8X)		ting Sta	MUS MUSCU	JLUS	20000 [PNU] in 1 mL
MUS UNII:3 Inac SODI SODI PHEN WAT GLY(Pacl # 1 ND	MUSCULUS SKIN 390 AN9GB09) etive Ingredien IUM CHLORIDE (U IUM BICARBONAT ROL (UNII: 339NCG ER (UNII: 059QF0K CERIN (UNII: PDC6. kaging Item Code	(UNII: 390 AN9 ts NII: 451W47IQ3 E (UNII: 8 MDF 44TV) COR) A3C0OX) Pao 5 mL in 1 V	Ingredient Name BX) 5V39QO)		ting Sta	MUS MUSCU SKIN	JLUS	20000 [PNU] in 1 mL Strength
MUS UNII:3 SODI SODI PHEN GLY(Pacl # 1 ND 2 ND	MUSCULUS SKIN 390 AN9GB09) tive Ingredien UM CHLORIDE (U UM BICARBONAT OL (UNII: 339NCG ER (UNII: 059QF0K CERIN (UNII: PDC6. kaging Item Code	(UNII: 390 ANS ts NII: 451W47IQ E (UNII: 8 MDF 44TV) :00 R) A3C0 OX) A3C0 OX) 5 mL in 1 V 10 mL in 1	Ingredient Name Type Style="background-color: gray; color: blue;">Ingredient Name Style="background-color: blue;">Ingredient Name Style="background-color: blue;">Style="background-color: blue;">Style="background-color: blue;">Style="background-color: blue;">Style="background-color: blue;">Style="background-color: blue;">Style="background-color: blue;">Style="background-color: blue;">Style="background-color: blue;">Style="background-color: blue;">Ingredient Name Style="background-color: blue;">Style="background-color: blue;"/Style="background-color: blue;"/>Style="background-color: blue;"/>Style="		ting Sta	MUS MUSCU SKIN	JLUS	20000 [PNU] in 1 mL Strength
MUS UNII:3 SODI SODI SODI SODI SODI SODI SODI SODI	MUSCULUS SKIN 390 AN9GB09) tive Ingredien UM CHLORIDE (U UM BICARBONAT ROL (UNII: 339NCG ER (UNII: 059QF0K CERIN (UNII: PDC6. Kaging Item Code 0C:36987-1092-1	(UNII: 390 ANS ts NII: 451W47IQ E (UNII: 8 MDF 44TV) COR) A3C0OX) A3C0OX) 5 mL in 1 V 10 mL in 1 30 mL in 1	Ingredient Name Ingredient Name X) SV39QO) Kage Description VIAL, MULTI-DOSE		ting Sta	MUS MUSCU SKIN	JLUS	20000 [PNU] in 1 mL Strength
MUS UNII:3 SODI SODI SODI SODI SODI SODI SODI SODI	MUSCULUS SKIN 390 AN9GB09) Etive Ingredien RUM CHLORIDE (U RUM CHLORIDE (U RUM CHLORIDE (U RUM BICARBONAT ROL (UNII: 339NCG ER (UNII: 059QF0K CERIN (UNII: PDC6.) Kaging Item Code 0C:36987-1092-1 0C:36987-1092-3	(UNII: 390 ANS ts NII: 451W47IQ E (UNII: 8 MDF 44TV) COR) A3C0OX) A3C0OX) 5 mL in 1 V 10 mL in 1 30 mL in 1	Ingredient Name BX) 5V39QO) Ckage Description TIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE		ting Sta	MUS MUSCU SKIN	JLUS	20000 [PNU] in 1 mL Strength
MUS UNII:3 SODI SODI PHEN WAT GLYC PEC # 1 ND 2 ND 3 ND 4 ND	MUSCULUS SKIN 390 AN9GB09) Etive Ingredien UM CHLORIDE (U UM BICARBONAT NOL (UNII: 339NCG ER (UNII: 059QF0K CERIN (UNII: PDC6.) Kaging Item Code 0C:36987-1092-1 0C:36987-1092-2 0C:36987-1092-3 0C:36987-1092-4	(UNII: 390 ANS ts NII: 451W47IQ 'E (UNII: 8 MDF 44TV) :00 R) A3C0 OX) A3C0 OX)	Ingredient Name BX) 5V39QO) Ckage Description TIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE		ting Sta	MUS MUSCU SKIN	JLUS	20000 [PNU] in 1 mL Strength
MUS UNIE: SODI SODI PHEN WAT GLYC Pacl 4 ND 3 ND 4 ND	MUSCULUS SKIN 390 AN9GB09) Etive Ingredien RUM CHLORIDE (U RUM CHLORIDE (U RUM CHLORIDE (U RUM BICARBONAT ROL (UNII: 339NCG ER (UNII: 059QF0K CERIN (UNII: PDC6.) Kaging Item Code 0C:36987-1092-1 0C:36987-1092-3	(UNII: 390 ANS ts NII: 451W47IQ E (UNII: 8 MDF 44TV) COOR) A3C0OX) A3C0OX) 5 mL in 1 10 mL in 1 30 mL in 1 50 mL in 1 50 mL in 1	Ingredient Name BX) 5V39QO) Ckage Description TIAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marke		MUS MUSCU SKIN	JLUS	20000 [PNU] in 1 mL Strength

RABBIT EPITHELIUM

rabbit epithelium injection, solution

Product Information	on							
Product Type		HUMAN PRESCRIPTION DI	RUG	Ite m	Code (Sour	ce)	NDC	2:36987-1100
Route of Administrati	on	INTRADERMAL, SUBCUTA	ANEOUS					
Active Ingredient//	Active Moi	ety						
	Ingr	edient Name			Basis of	Streng	gth	Strength
ORYCTOLAGUS CUNIC CUNICULUS SKIN - UNII		(UNII: Z91WAU43WC) (ORYC C)	CTOLAGUS		ORYCTOLA CUNICULUS			20000 [PNU] in 1 mL
Inactive Ingredien	ts							
		Ingredient Name					5	Strength
SODIUM CHLORIDE (U	NII: 451W47IQ8	3X)						
SODIUM BICARBONAT	TE (UNII: 8 MDF	5V39QO)						
PHENOL (UNII: 339NCG								
FIEROL (UNII. 555NCG	441V)							
,								
WATER (UNII: 059QF0K	(OOR)							
WATER (UNII: 059QF0K	(OOR)							
WATER (UNII: 059QF0K GLYCERIN (UNII: PDC6	(OOR)							
WATER (UNII: 059QF0K GLYCERIN (UNII: PDC6 Packaging	COOR) A3COOX) Pac	ckage Description	Marketi	ng Sta	rt Date	Mar	rketin	ng End Date
WATER (UNII: 059QF0K GLYCERIN (UNII: PDC6 Packaging # Item Code	COOR) A3COOX) Pac	: kage Description IAL, MULTI-DOSE	Marketi	ng Sta	ırt Date	Mar	rketin	ng End Date
WATER (UNII: 059QF0K GLYCERIN (UNII: PDC6 Packaging # Item Code 1 NDC:36987-1100-1	COOR) A3COOX) Pac 5 mL in 1 V	· ·	Marketi	ng Sta	rt Date	Mar	rketin	ng End Date
WATER (UNII: 059QF0K) GLYCERIN (UNII: PDC6) Packaging # Item Code 1 NDC:36987-1100-1 2 NDC:36987-1100-2	COOR) A3COOX) A3COOX 5 mL in 1 V 10 mL in 1	IAL, MULTI-DOSE	Marketi	ng Sta	rt Date	Mar	rketin	ng End Date
 WATER (UNII: 059QF0K GLYCERIN (UNII: PDC6) Packaging # Item Code 1 NDC:36987-1100-1 2 NDC:36987-1100-2 3 NDC:36987-1100-3 	COOR) A3COOX) A3COOX 5 mL in 1 V 10 mL in 1 30 mL in 1	IAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Sta	rt Date	Mar	rketin	ng End Date
WATER (UNII: 059QF0K GLYCERIN (UNII: PDC6 Packaging	COOR) A3COOX) A3COOX 5 mL in 1 V 10 mL in 1 30 mL in 1	IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Sta	rt Date	Mar	rketin	ng End Date
 WATER (UNII: 059QF0K GLYCERIN (UNII: PDC6) Packaging # Item Code 1 NDC:36987-1100-1 2 NDC:36987-1100-2 3 NDC:36987-1100-3 	COOR) A3COOX) A3COOX 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1	IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE	Marketi	ng Sta	Irt Date	Mar	rketin	ng End Date
 WATER (UNII: 059QF0K GLYCERIN (UNII: PDC6A Packaging Item Code NDC:36987-1100-1 NDC:36987-1100-2 NDC:36987-1100-3 NDC:36987-1100-3 	COOR) A3COOX) A3COOX) 5 mL in 1 V 10 mL in 1 30 mL in 1 50 mL in 1	IAL, MULTI-DOSE VIAL, MULTI-DOSE VIAL, MULTI-DOSE			rt Date			ng End Date eting End Dat

RAT EPITHELIUM								
rat epithelium injection, solution								
Product Information								
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:36987-1108					
Route of Administration	INTRADERMAL, SUBCUTANEOUS							
Active Ingredient/Active Moi	ety							

Ingredient Name					Strength	Strength
	F TUS NORVEGICUS I:Y69HPD48AI)	SKIN (UNII: Y69HPD48AI) (RATTUS NORV	I - RATTUS NO SKIN	RATTUS NORVEGICUS SKIN		
Ina	ctive Ingredien	ts				
		Ingredient Name				Strength
SOE	DIUM CHLORIDE (U	NII: 451W47IQ8X)				
SOE	DIUM BICARBONAT	Έ (UNII: 8MDF5V39QO)				
PHE	E NOL (UNII: 339NCG	44TV)				
WAT	TER (UNII: 059QF0K	O0R)				
	YCERIN (UNII: PDC6.	A2COOX)				
GLI		AJCUUX)				
GLI		AJCUUX)				
GLI						
	ckaging Item Code	Package Description	Marketii	1g Start Date	Marke	ting End Date
Pac #	ckaging		Marketin	ng Start Date	Marke	ting End Date
Pac # 1 N	ckaging Item Code	Package Description	Marketin	ng Start Date	Marke	ting End Date
Pac # 1 N 2 N	ckaging Item Code DC:36987-1108-1	Package Description 5 mL in 1 VIAL, MULTI-DOSE	Marketin	ıg Start Date	Marke	ting End Date
Pac # 1 2 N 3 N	ckaging Item Code DC:36987-1108-1 DC:36987-1108-2	Package Description 5 mL in 1 VIAL, MULTI-DOSE 10 mL in 1 VIAL, MULTI-DOSE	Marketin	ng Start Date	Marke	ting End Date
Pac # 1 2 N 3 N	Ckaging Item Code DC:36987-1108-1 DC:36987-1108-2 DC:36987-1108-3	Package Description 5 mL in 1 VIAL, MULTI-DOSE 10 mL in 1 VIAL, MULTI-DOSE 30 mL in 1 VIAL, MULTI-DOSE	Marketii	ıg Start Date	Marke	ting End Date
Pac # 1 2 N 3 N	Ckaging Item Code DC:36987-1108-1 DC:36987-1108-2 DC:36987-1108-3	Package Description 5 mL in 1 VIAL, MULTI-DOSE 10 mL in 1 VIAL, MULTI-DOSE 30 mL in 1 VIAL, MULTI-DOSE	Marketin	ng Start Date	Marke	ting End Date
Pac # 1 N1 2 N1 3 N1 4 N1	ckaging Item Code DC:36987-1108-1 DC:36987-1108-2 DC:36987-1108-3 DC:36987-1108-3	Package Description5 mL in 1 VIAL, MULTI-DOSE10 mL in 1 VIAL, MULTI-DOSE30 mL in 1 VIAL, MULTI-DOSE50 mL in 1 VIAL, MULTI-DOSE	Marketin	ıg Start Date	Marke	ting End Date
Pac # 1 2 N 3 N 4 N	ckaging Item Code DC:36987-1108-1 DC:36987-1108-2 DC:36987-1108-3 DC:36987-1108-4	Package Description 5 mL in 1 VIAL, MULTI-DOSE 10 mL in 1 VIAL, MULTI-DOSE 30 mL in 1 VIAL, MULTI-DOSE 50 mL in 1 VIAL, MULTI-DOSE 50 mL in 1 VIAL, MULTI-DOSE state mathematical 50 mL in 1 VIAL, MULTI-DOSE 50 mL in 1 VIAL, MULTI-DOSE				
Pac # 1 2 N 3 N 4 N	ckaging Item Code DC:36987-1108-1 DC:36987-1108-2 DC:36987-1108-3 DC:36987-1108-3 DC:36987-1108-4	Package Description5 mL in 1 VIAL, MULTI-DOSE10 mL in 1 VIAL, MULTI-DOSE30 mL in 1 VIAL, MULTI-DOSE50 mL in 1 VIAL, MULTI-DOSE	Citation 1	ng Start Date Marketing Start		ting End Date rketing End Dat

Labeler - Nelco Laboratories, Inc. (054980867)

Registrant - Nelco Laboratories, Inc. (054980867)

Establishment

Name	Address	ID/FEI	Business Operations
Nelco Laboratories, Inc.		054980867	manufacture

Revised: 12/2009

Nelco Laboratories, Inc.