

**MODEL 2004FAA MODEL 3-EEMK MODEL 3-EEMK-1 MODEL AA-8565 MODEL
AA-8565-LATAM MODEL AWFAREMK MODEL CHAUTAUQUAEMK MODEL
EMK1000-10 MODEL FAREMK MODEL PMONTFAREMK MODEL SWEEMK MODEL
SWEEMK-1 MODEL QXEMK MODEL G4FAREMK MODEL AA-8565 (EXCLUDING
MIAMI AIR)- emergency response safety kit
Aerospace Accessory Service, Inc**

**Model 2004FAA
Model 3-EEMK
Model 3-EEMK-1
Model AA-8565
Model AA-8565-LATAM
Model AWFAREMK
Model CHAUTAUQUAEMK
Model emk1000-10
Model FAREMK
Model PMONTFAREMK
Model SWEEMK
Model SWEEMK-1
Model QXEMK
Model G4FAREMK
Model AA-8565 (excluding Miami Air)**

Aerospace Accessory Service

Aerospace Accessory Service

P/N:

S/N:

EXP:

Prep. By:

AEROSPACE **AA** ACCESSORY



F.A.A. No XM4R653M

SERVICE

E.A.S.A. No EASA 145.5194

P/N: _____ **EXP:** ____/____/____

S/N: _____ **PREP. BY:** _____

IF SEAL IS BROKEN OR EXPIRATION DATE ARRIVES,
REMOVE IMMEDIATELY FOR RE-CERTIFICATION

Aerospace Accessory Service, Inc.

Ph: 305-594-1955 Fax: 305-470-2026

www.aerospaceaccessory.com

**MODEL 2004FAA MODEL 3-EEMK MODEL 3-EEMK-1 MODEL AA-8565
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 MODEL G4FAREMK MODEL AA-8565 (EXCLUDING MIAMI AIR)**

emergency response safety kit kit

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:27860-001
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:27860-001-13	1 in 1 PACKAGE; Type 1: Convenience Kit of Co-Package		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1		1
Part 2		1
Part 3		1
Part 4		1
Part 5		1
Part 6		1
Part 7		1
Part 8		1
Part 9		1
Part 10		1
Part 11		1
Part 12		1
Part 13		1
Part 14		1
Part 15		1
Part 16		1
Part 17		1
Part 18		1
Part 19		1
Part 20		1
Part 21		1
Part 22		1
Part 23		1
Part 24		1
Part 25		1
Part 26		1
Part 27		1

Part 1 of 27

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information

Item Code (Source) NDC:0338-0049

Route of Administration INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	9 g in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA016677	12/09/1970	

Part 2 of 27

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information

Item Code (Source) NDC:0264-7800

Route of Administration INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	0.9 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019635	03/09/1988	

Part 3 of 27

ATROPINE SULFATE

atropine sulfate injection, solution

Product Information

Item Code (Source)	NDC:0409-4910
Route of Administration	INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS, ENDOTRACHEAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATROPINE SULFATE (UNII: 03J5ZE7KA5) (ATROPINE - UNII:7C0697DR9I)	ATROPINE SULFATE	0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SULFURIC ACID (UNII: O40UQP6WCF)	
WATER (UNII: 059QF0KO0R)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021146	01/19/2006	

Part 4 of 27

ATROPINE SULFATE

atropine sulfate injection

Product Information

Item Code (Source)	NDC:76329-3339
Route of Administration	PARENTERAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Atropine Sulfate (UNII: 03J5ZE7KA5) (ATROPINE - UNII:7C0697DR9I)	Atropine Sulfate	0.1 mg in 1 mL

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/01/2000	

Part 5 of 27

EPINEPHRINE

epinephrine injection

Product Information

Item Code (Source)	NDC:76329-3316
Route of Administration	INTRAVENOUS, INTRACARDIAC

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Epinephrine (UNII: YKH834O4BH) (EPINEPHRINE - UNII:YKH834O4BH)	Epinephrine	0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium Bisulfite (UNII: TZX5469Z6I)	
Sodium Chloride (UNII: 451W47IQ8X)	
Hydrochloric Acid (UNII: QTT17582CB)	
Sodium Citrate (UNII: 1Q73Q2JULR)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/01/1976	

Part 6 of 27

EPINEPHRINE

epinephrine injection, solution

Product Information

Item Code (Source)	NDC:0409-4933
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Epinephrine (UNII: YKH834O4BH) (EPINEPHRINE - UNII:YKH834O4BH)	Epinephrine	0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium Chloride (UNII: 451W47IQ8X)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA209359	03/10/2021	

Part 7 of 27

EPINEPHRINE

epinephrine injection, solution

Product Information

Item Code (Source)	NDC:0409-4921
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Route of Administration INTRAVENOUS, INTRACARDIAC, ENDOTRACHEAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EPINEPHRINE (UNII: YKH834O4BH) (EPINEPHRINE - UNII:YKH834O4BH)	EPINEPHRINE	0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/14/2005	01/01/2017

Part 8 of 27

LIDOCAINE HYDROCHLORIDE

lidocaine hydrochloride injection, solution

Product Information

Item Code (Source)	NDC:0409-1323
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040302	12/09/2005	

Part 9 of 27

LIDOCAINE

lidocaine hydrochloride injection, solution

Product Information

Item Code (Source)	NDC:63323-208
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA017584	09/05/2000	

Part 10 of 27

LIDOCAINE HYDROCHLORIDE

lidocaine hydrochloride injection

Product Information

Item Code (Source)	NDC:76329-3390
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA083173	06/01/2001	

Part 11 of 27**DEXTROSE MONOHYDRATE**

dextrose monohydrate injection

Product Information

Item Code (Source)	NDC:76329-3301
Route of Administration	PARENTERAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R00K)	DEXTROSE MONOHYDRATE	500 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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unapproved drug other		06/01/2000	
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Part 12 of 27

DEXTROSE

dextrose monohydrate injection, solution

Product Information

Item Code (Source)	NDC:0409-6648
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SLOG7R0OK)	DEXTROSE MONOHYDRATE	25 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019445	12/02/2005	

Part 13 of 27

NITROGLYCERIN

nitroglycerin tablet

Product Information

Item Code (Source)	NDC:68462-639
Route of Administration	SUBLINGUAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NITROGLYCERIN (UNII: G59M7S0WS3) (NITROGLYCERIN - UNII:G59M7S0WS3)	NITROGLYCERIN	0.4 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM STEARATE (UNII: 776XM7047L)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	

Product Characteristics

Color	white (white to off white)	Score	no score
Shape	ROUND (Flat faced)	Size	4mm
Flavor		Imprint Code	2;C
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206391	08/19/2017	

Part 14 of 27

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride injection

Product Information

Item Code (Source)	NDC:0641-0376
Route of Administration	INTRAMUSCULAR, INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZETHONIUM CHLORIDE (UNII: PH41D05744)	
WATER (UNII: 059QF0KO0R)	

SODIUM HYDROXIDE (UNII: 55X04QC32I)

HYDROCHLORIC ACID (UNII: QTT17582CB)

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA080817	11/27/1972	

Part 15 of 27

EPINEPHRINE

epinephrine injection, solution, concentrate

Product Information

Item Code (Source) NDC:54288-103

Route of Administration INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Epinephrine (UNII: YKH834O4BH) (EPINEPHRINE - UNII:YKH834O4BH)	Epinephrine	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium Chloride (UNII: 451W47IQ8X)	
Hydrochloric Acid (UNII: QTT17582CB)	
Water (UNII: 059QF0KO0R)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA205029	08/08/2014	

Part 16 of 27

EASY CARE FIRST AID DIPHENHYDRAMINE

diphenhydramine hydrochloride tablet, film coated

Product Information**Item Code (Source)** NDC:4422-0017**Route of Administration** ORAL**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	pink (pink)	Score	no score
Shape	OVAL (OVAL)	Size	11mm
Flavor		Imprint Code	048;D
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/2012	

Part 17 of 27**ALCOHOL PREP**

isopropyl alcohol swab

Product Information**Item Code (Source)** NDC:67777-121**Route of Administration** TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/01/2010	

Part 18 of 27

MOORE MEDICAL NON ASPIRIN

acetaminophen tablet, film coated

Product Information

Item Code (Source)	NDC:55670-467
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white (white)	Score	no score
Shape	ROUND (ROUND)	Size	10mm
Flavor		Imprint Code	AZ;234
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	12/30/2008	

Part 19 of 27

ASPIRIN

aspirin tablet, film coated

Product Information

Item Code (Source)	NDC:55670-131
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MINERAL OIL (UNII: T5L8T28FGP)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white (white)	Score	no score
Shape	ROUND (ROUND)	Size	10mm
Flavor		Imprint Code	TCL;011
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	12/30/2008	08/31/2022

Part 20 of 27

MOOREBRAND ASPIRIN

aspirin tablet, film coated

Product Information

Item Code (Source)	NDC:55670-616(NDC:50844-957)
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	Aspirin;44;157
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	10/05/2020	

Part 21 of 27

VENTOLIN HFA

albuterol sulfate aerosol, metered

Product Information

Item Code (Source)	NDC:0173-0682
Route of Administration	RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALBUTEROL SULFATE (UNII: 021SEF3731) (ALBUTEROL - UNII:QF8SVZ 843E)	ALBUTEROL	90 ug

Inactive Ingredients

Ingredient Name	Strength
NORFLURANE (UNII: DH9E53K1Y8)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020983	06/09/2006	

Part 22 of 27

ALBUTEROL SULFATE HFA

albuterol sulfate aerosol, metered

Product Information

Item Code (Source)	NDC:66993-019
Route of Administration	RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALBUTEROL SULFATE (UNII: 021SEF3731) (ALBUTEROL - UNII:QF8SVZ 843E)	ALBUTEROL	90 ug

Inactive Ingredients

Ingredient Name	Strength
NORFLURANE (UNII: DH9E53K1Y8)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA020983	01/15/2019	

Part 23 of 27

ALBUTEROL SULFATE

albuterol sulfate aerosol, metered

Product Information

Item Code (Source)	NDC:45802-088
Route of Administration	RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALBUTEROL SULFATE (UNII: 021SEF3731) (ALBUTEROL - UNII:QF8SVZ843E)	ALBUTEROL	90 ug

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
NORFLURANE (UNII: DH9E53K1Y8)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203760	02/26/2020	

Part 24 of 27

ALBUTEROL SULFATE HFA

albuterol sulfate aerosol, metered

Product Information

Item Code (Source)	NDC:0093-3174
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Route of Administration RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALBUTEROL SULFATE (UNII: 021SEF3731) (ALBUTEROL - UNII:QF8SVZ 843E)	ALBUTEROL	90 ug

Inactive Ingredients

Ingredient Name	Strength
NORFLURANE (UNII: DH9E53K1Y8)	
ALCOHOL (UNII: 3K9958V90M)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021457	01/16/2019	

Part 25 of 27

ALBUTEROL SULFATE

albuterol sulfate inhalant

Product Information

Item Code (Source)	NDC:69097-142
Route of Administration	RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALBUTEROL SULFATE (UNII: 021SEF3731) (ALBUTEROL - UNII:QF8SVZ 843E)	ALBUTEROL	108 ug

Inactive Ingredients

Ingredient Name	Strength
OLEIC ACID (UNII: 2UMI9U37CP)	
NORFLURANE (UNII: DH9E53K1Y8)	
ALCOHOL (UNII: 3K9958V90M)	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
ANDA	ANDA209959	04/08/2020	

Part 26 of 27

ALBUTEROL SULFATE

albuterol sulfate aerosol, metered

Product Information

Item Code (Source)	NDC:0254-1007
Route of Administration	RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALBUTEROL SULFATE (UNII: 021SEF3731) (ALBUTEROL - UNII:QF8SVZ843E)	ALBUTEROL	108 ug

Inactive Ingredients

Ingredient Name	Strength
OLEIC ACID (UNII: 2UMI9U37CP)	
NORFLURANE (UNII: DH9E53K1Y8)	
ALCOHOL (UNII: 3K9958V90M)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA020503	04/03/2019	

Part 27 of 27

PROAIR HFA

albuterol sulfate aerosol, metered

Product Information

Item Code (Source)	NDC:59310-579
Route of Administration	RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALBUTEROL SULFATE (UNII: 021SEF3731) (ALBUTEROL - UNII:QF8SVZ843E)	ALBUTEROL	90 ug

Inactive Ingredients

Ingredient Name	Strength
NORFLURANE (UNII: DH9E53K1Y8)	
ALCOHOL (UNII: 3K9958V90M)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021457	12/03/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
exempt device	ABC	01/01/2015	

Labeler - Aerospace Accessory Service, Inc (859100547)**Registrant** - Aerospace Accessory Service, Inc (859100547)**Establishment**

Name	Address	ID/FEI	Business Operations
Aerospace Accessory Service, Inc		859100547	manufacture, repack

Revised: 5/2021

Aerospace Accessory Service, Inc