INTEGRA F - ferrous fumarate and polysacchride iron complex and folic acid capsule
U.S. Pharmaceutical Corporation

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.

---

see all prescribing information for Integra F

DESCRIPTION: Each capsule contains: Ferrous Fumarate (anhydrous) .....191.1 mg Polysaccharide Iron Complex..... 135.9 mg (Equivalent to about 125 mg of elemental iron) Folic Acid .....1 mg Ascorbic Acid (from ProAscorb C‡) ..... 40 mg Vitamin B3 (from ProAscorb C‡) .....3 mg

CLINICAL PHARMACOLOGY: Integra FTM is unique in that it utilizes two (2) different forms of iron, i.e., Ferrous Fumarate and Polysaccharide Iron Complex (as cell-contracted akaganèite), making available a total of 125 mg of elemental iron per capsule as follows:
Ferrous Fumarate (anhydrous) 191.1 mg Polysaccharide iron complex (PIC) 135.9 mg
Ferrous Fumarate: Provides about 62.5 mg of elemental iron per dose. Ferrous Fumarate is an anhydrous salt of a combination of ferrous iron and fumaric acid, containing 33% of iron per weight. The acute toxicity in experimental animals is low and Ferrous Fumarate is well tolerated clinically. As a ferrous salt, it is more efficiently absorbed in the duodenum. Ferrous Fumarate contrasts very favorably with the availability of the 20% of elemental iron of ferrous sulfate, and the 13% of elemental iron of ferrous gluconate.
Polysaccharide Iron Complex: Provides about 62.5 mg elemental iron, as a cell-contracted akaganèite. It is a product of ferric iron complexed to a low molecular weight polysaccharide. This polysaccharide is produced by the extensive hydrolysis of starch and is a dark brown powder that dissolves in water to form a very dark brown solution, which is virtually odorless and tasteless.
Folic Acid: Folic Acid is one of the important hematopoetic agents necessary for proper regeneration of the blood-forming elements and their function. Folic acid is a precursor of a large family of compounds which serve as coenzymes in carbon transfer reactions. These reactions are required for the synthesis of purine and pyrimidine bases, inter-conversion of glycine and serine, biosynthesis of methionine methyl groups and degradation of histidine. Additionally, folic acid increases jejunal glycolytic enzymes and is involved in the desaturation and hydroxylation of long-chain fatty acids in the brain. A deficiency in folic acid results in megaloblastic anemia.
All IntegraTM products include a unique patented source of iron, e.g. Ferrous Fumarate and Polysaccharide Iron Complex (U.S. Patent No: 11/243,043 Pending). "An increase in tolerability is observed with the (patented formulation) and is believed to occur as the result of distributing the total iron content in the composition among compounds that provide iron to the patient's blood stream via two different mechanisms. The ferrous salts are readily absorbed in the upper gut, by direct dissolution and absorption of the ferrous iron by the bloodstream. However, the iron available from PIC is absorbed in the

lower gut, via an active protein transport mechanism".

Clinical Studies: Because Ferrous Fumarate is an organic complex, it contains no free ions, either ferric or ferrous. Polysaccharide Iron Complex is clinically non-toxic. Prior studies in rats demonstrated that Polysaccharide Iron Complex (PIC), administered as a single oral dose to Sprague Dawley rats did not produce evidence of toxicity at a dosage level of 5000 mg Iron/kg: (An Acute Oral Toxicity Study in Rats with Polysaccharide-Iron Complex. T.N.Merriman, M. Aikman and R.E. Rush, Springborn Laboratories. Inc. Spencerville, Ohio Study No. 3340.1 March - April 1994). Other clinical studies had demonstrated that Polysaccharide Iron gives a good hematopoietic response with an almost complete absence of the side effects usually associated with oral iron therapy. Picinni and Ricciotti suggested in 1982, that "the therapeutic effectiveness of Polysaccharide Iron Complex when compared with iron fumarate in the treatment of iron deficiency anemia, appears to be as active as the iron fumarate and as well tolerated, however, it exerted a greater influence on the level of hemoglobin and on the number of red cells..." and that, "it has been exceptionally well tolerated by all patients" (Picinni, L.-Ricciotti, M. 1982. Therapeutic effectiveness of an iron-polysaccharide complex in comparison with iron fumarate in the treatment of iron deficiency anemias): PANMINERVA MEDICA-EUROPA MEDICA, Vol. 24, No. 3, pp. 213-220 (July-September 1982).
As mentioned above, the patented source of iron used in Integra FTM (Ferrous Fumarate and Polysaccharide Iron Complex) provides a high level of elemental iron with a low incidence of gastric distress.
CONCLUSION: Based on the results of this study, the oral combination of Ferrous Fumarate and Polysaccharide Iron Complex was better tolerated and safer than the oral administration of Ferrous Fumarate alone. The conclusion of this research stated, that the addition of PIC to Ferrous Fumarate surprisingly allows the same concentration of Ferrous Fumarate to be better tolerated than the Ferrous Fumarate alone.

INDICATIONS: Integra FTM is indicated for the treatment of iron deficiency anemia, and folate deficiency anemia. Integra FTM is indicated in pregnancy for the prevention and treatment of iron deficiency and to supply a maintenance dosage of folic acid.

CONTRAINDICATIONS: Integra FTM is contraindicated in patients with known hypersensitivity to any of its ingredients; also, all iron compounds are contraindicated in patients with hemosiderosis, hemochromatosis, or hemolytic anemias. Pernicious anemia is a contraindication, as folic acid may obscure its signs and symptoms.

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately. WARNING: Folic acid alone is improper therapy in the treatment for pernicious anemia and other megaloblastic anemias where Vitamin B12 is deficient. PRECAUTIONS: General: Anemia is a manifestation that requires appropriate investigation to determine its cause or causes. No single regimen fits all cases and the status of the patient observed in follow-up is the final criterion for adequacy of therapy. Periodic clinical and laboratory studies are considered essential. Blood examinations including hemoglobin and hematacrit should be done at the usual intervals to make certain that therapy is adequate. Use with care in the presence of peptic ulcer, regional enteritis, and ulcerative colitis. Folic acid, especially in doses above 0.1 mg -0.4 mg daily may obscure pernicious anemia, in that hematological remission can occur while neurological manifestations remain progressive.

USAGE IN PREGNANCY: Before Integra FTM is prescribed for megaloblastic anemia in pregnancy, appropriate diagnostic exclusion of Addisonian pernicious anemia, (due to faulty or blocked absorption of vitamin B12, or extrinsic factor or either a genetic, immunological or surgical basis) should be carried out.

Pediatric Use: Safety and effectiveness of this product have not been established in pediatric patients.

Geriatric Use: No clinical studies have been performed in patients age 65 and over to determine whether older persons respond differently from younger persons. Dosage should always begin at the low end of the dosage scale and should consider that elderly persons may have decreased hepatic, renal, or cardiac function and or concomitant diseases.

Adverse Reactions: Folic Acid: Allergic sensitizations have been reported following both oral and parenteral administration of folic acid. Ferrous Fumarate: Gastrointestinal disturbances (anorexia, nausea, diarrhea, constipation, heartburn and vomiting) occur occasionally, but are usually mild and may subside with continuation of therapy. Reducing the dose and administering it with meals will minimize these effects in the sensitive patient. Increasing fiber in the diet can relieve constipation. Iron may turn stools black. This is a harmless effect that is a result of unabsorbed iron. Although the absorption of iron is best when taken between meals, giving Integra FTM after meals may control occasional G.I. disturbances. Integra FTM is best absorbed when taken at bedtime.

OVERDOSE: Iron: Signs and Symptoms: Iron is toxic. Acute overdosage of iron may cause nausea and vomiting and, in severe cases, cardiovascular collapse and death. Other symptoms include pallor and cyanosis, melena, shock, drowsiness and coma. The estimated overdose of orally ingested iron is 300-mg/kg body weight. When overdoses are ingested by children, severe reactions, including fatalities, have resulted. Integra FTM should be stored beyond the reach of children to prevent against accidental iron poisoning. Keep this and all other drugs out of the reach of children. Treatment: For specific therapy, exchange transfusion and chelating agents should be used. For general management, perform gastric lavage with sodium bicarbonate solution or milk. Administer intravenous fluids and electrolytes and use oxygen.

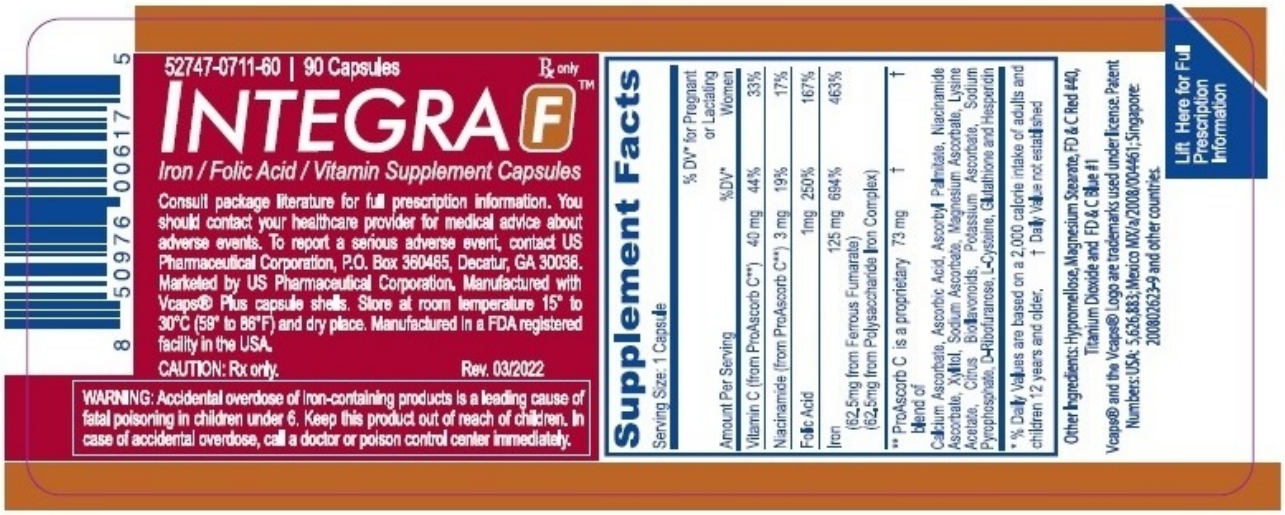
DOSAGE AND ADMINISTRATION: Adults (persons over 12 years of age), One (1) capsule daily, between meals, or as prescribed by a physician. Do not exceed recommended dosage. Do not administer to children under the age of 12.

HOW SUPPLIED: Integra F™ are maroon Vcaps® capsules printed in white with "Integra F" on the cap and "US" logo on the body. Packed in child resistant caps and light resistant bottles of 90 capsules (52747-0711-60) and 30 capsules (52747-0711-30). The listed product numbers are not National Drug Codes. Instead, US Pharmaceutical Corporation has assigned these product codes formatted according to standard industry practice to meet the formatting requirements of pharmacy and healthcare insurance computer systems.

CAUTION: Rx only.

Packaging

PACKAGE 90 CAPSULES



Supplement Facts

Serving Size: 1 Capsule

Amount Per Serving		%DV*	% DV* for Pregnant or Lactating Women
Vitamin C (from ProAscorb C**)	40 mg	44%	33%
Niacinamide (from ProAscorb C**)	3 mg	19%	17%
Folic Acid	1mg	250%	167%
Iron (62.5mg from Ferrous Fumarate) (62.5mg from Polysaccharide Iron Complex)	125 mg	694%	463%
** ProAscorb C is a proprietary blend of	73 mg	†	†

Calcium Ascorbate, Ascorbic Acid, Ascorbyl Palmitate, Niacinamide Ascorbate, Xylitol, Sodium Ascorbate, Magnesium Ascorbate, Lysine Acetate, Citrus Bioflavonoids, Potassium Ascorbate, Sodium Pyrophosphate, D-Ribofuranose, L-Cysteine, Glutathione and Hesperidin

* % Daily Values are based on a 2,000 calorie intake of adults and children 12 years and older. † Daily Value not established

Other Ingredients: Hypromellose, Magnesium Stearate, FD & C Red #40, Titanium Dioxide and FD & C Blue #1

52747-0711-60

Integra F ™

℞ only

IRON / FOLIC ACID / VITAMIN SUPPLEMENT CAPSULES

INDICATIONS: Integra F™ is indicated for the treatment of iron deficiency anemia and folate deficiency as in extended convalescence, menorrhagia, pregnancy, puberty, excessive blood loss and advanced age. Also for treatment of condition in which iron deficiency and vitamin C deficiency occur together, as well as cases of metabolic stress, and in convalescence.

CONTRAINDICATIONS: Integra F™ is contraindicated in patients with a known hypersensitivity to any of its ingredients; also, all iron compounds are contraindicated in patients with hemosiderosis, hemochromatosis, or hemolytic anemias. It is also contraindicated in patients suffering from pernicious anemia as folic acid may obscure its signs and symptoms.

Ferrous Fumarate and Polysaccharide Iron Complex: All Integra™ products include a unique patented source of iron, e.g. Ferrous Fumarate and Polysaccharide Iron Complex (U.S. Patent No: 11/243,043 Pending). "An increase in tolerability is observed with the (patented formulation) and is believed to occur as the result of distributing the total iron content in the composition among compounds that provide iron to the patient's blood stream via two different mechanisms. The ferrous salts are readily absorbed in the upper gut, by direct dissolution and absorption of the ferrous iron by the bloodstream. However, the iron available from PIC is absorbed in the lower gut, via an active protein transport mechanism".

Clinical Studies: Picinni, L.-Ricciotti, M. 1982. Therapeutic effectiveness of an iron-polysaccharide complex in comparison with iron fumarate in the treatment of iron deficiency anemias: PANMINERVA MEDICA-EUROPA MEDICA, Vol. 24, No. 3, pp. 213-220 (July-September 1982).

Folic Acid: Folic Acid is one of the important hematopoietic agents necessary for proper regeneration of the blood-forming elements and their function. Additionally, folic acid increases jejunal glycolytic enzymes and is involved in the desaturation and hydroxylation of long-chain fatty acids in the brain. A deficiency in folic acid results in megaloblastic anemia.

WARNING: Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B_{12} is deficient.

PRECAUTIONS: Folic acid in doses above 0.1 mg - 0.4 mg daily may obscure pernicious anemia, in that hematological remission can occur while neurological manifestations remain progressive.

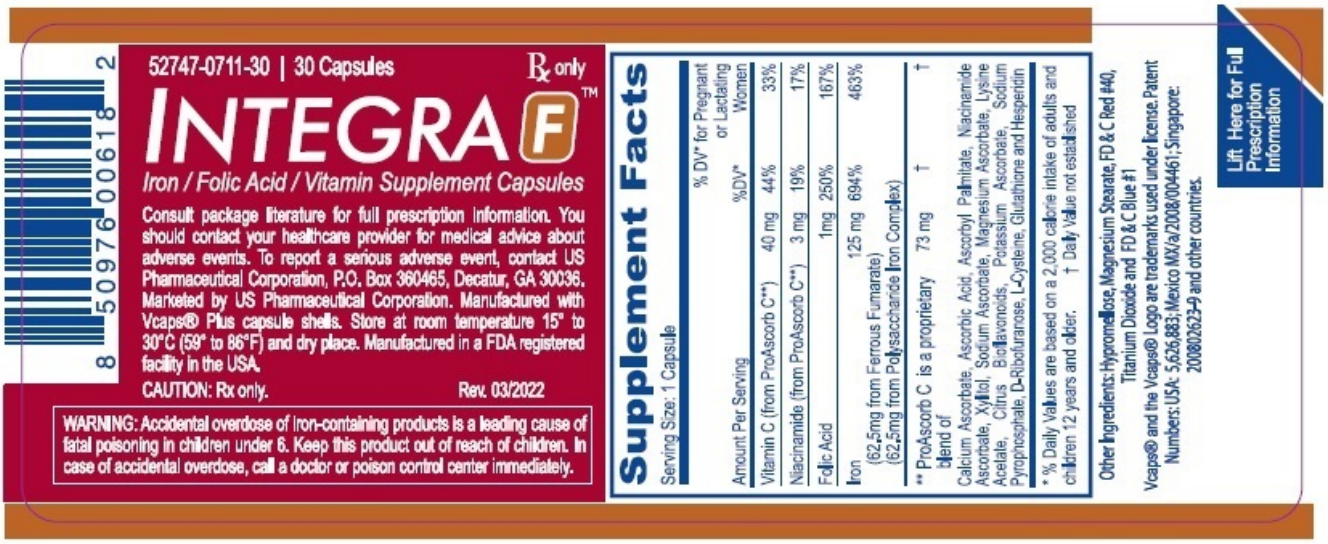
OVERDOSE: Iron: Signs and Symptoms: Iron is toxic. Acute overdosage of iron may cause nausea and vomiting and, in severe cases, cardiovascular collapse and death. Other symptoms include pallor and cyanosis, melena, shock, drowsiness and coma. The estimated overdose of orally ingested iron is 300-mg/kg body weight. When overdoses are ingested by children, severe reactions, including fatalities, have resulted.

DOSAGE AND ADMINISTRATION: Adults (persons over 12 years of age), one (1) capsule daily, between meals, or as prescribed by a physician. Do not exceed recommended dosage. Do not administer to children under the age of 12.

HOW SUPPLIED: Integra F™ are maroon Vcaps® capsules printed in white with "Integra F" on the cap and "US" logo on the body. Packed in child resistant caps and light resistant bottles of 90 capsules (52747-0711-60) and 30 capsules (52747-0711-30). The listed product numbers are not National Drug Codes. Instead, US Pharmaceutical Corporation has assigned these product codes formatted according to

standard industry practice to meet the formatting requirements of pharmacy and healthcare insurance computer systems.
CAUTION: Rx only.

PACKAGE 30 CAPSULES



Supplement Facts

Serving Size: 1 Capsule

Amount Per Serving		%DV*	% DV* for Pregnant or Lactating Women
Vitamin C (from ProAscorb C**)	40 mg	44%	33%
Niacinamide (from ProAscorb C**)	3 mg	19%	17%
Folic Acid	1mg	250%	167%
Iron (62.5mg from Ferrous Fumarate) (62.5mg from Polysaccharide Iron Complex)	125 mg	694%	463%
** ProAscorb C is a proprietary blend of Calcium Ascorbate, Ascorbic Acid, Ascorbyl Palmitate, Niacinamide Ascorbate, Xylitol, Sodium Ascorbate, Magnesium Ascorbate, Lysine Acetate, Citrus Bioflavonoids, Potassium Ascorbate, Sodium Pyrophosphate, D-Ribofuranose, L-Cysteine, Glutathione and Hesperidin	73 mg	†	†

* % Daily Values are based on a 2,000 calorie intake of adults and children 12 years and older. † Daily Value not established

Other Ingredients: Hypromellose, Magnesium Stearate, FD & C Red #40, Titanium Dioxide and FD & C Blue #1

52747-0711-30

Integra F ™

℞ only

IRON / FOLIC ACID / VITAMIN SUPPLEMENT CAPSULES

INDICATIONS: Integra F™ is indicated for the treatment of iron deficiency anemia and folate deficiency as in extended convalescence, menorrhagia, pregnancy, puberty, excessive blood loss and advanced age. Also for treatment of condition in which iron deficiency and vitamin C deficiency occur together, as well as cases of metabolic stress, and in convalescence.

CONTRAINDICATIONS: Integra F™ is contraindicated in patients with a known hypersensitivity to any of its ingredients; also, all iron compounds are contraindicated in patients with hemosiderosis, hemochromatosis, or hemolytic anemias. It is also contraindicated in patients suffering from pernicious anemia as folic acid may obscure its signs and symptoms.

Ferrous Fumarate and Polysaccharide Iron Complex: All Integra™ products include a unique patented source of iron, e.g. Ferrous Fumarate and Polysaccharide Iron Complex (U.S. Patent No: 11/243,043 Pending). "An increase in tolerability is observed with the (patented formulation) and is believed to occur as the result of distributing the total iron content in the composition among compounds that provide iron to the patient's blood stream via two different mechanisms. The ferrous salts are readily absorbed in the upper gut, by direct dissolution and absorption of the ferrous iron by the bloodstream. However, the iron available from PIC is absorbed in the lower gut, via an active protein transport mechanism".
Clinical Studies: Picinni, L.-Ricciotti, M. 1982. Therapeutic effectiveness of an iron-polysaccharide complex in comparison with iron fumarate in the treatment of iron deficiency anemias: PANMINERVA MEDICA-EUROPA MEDICA, Vol. 24, No. 3, pp. 213-220 (July-September 1982).

Folic Acid: Folic Acid is one of the important hematopoietic agents necessary for proper regeneration of the blood-forming elements and their function. Additionally, folic acid increases jejunal glycolytic enzymes and is involved in the desaturation and hydroxylation of long-chain fatty acids in the brain. A deficiency in folic acid results in megaloblastic anemia.

WARNING: Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B_{12} is deficient.

PRECAUTIONS: Folic acid in doses above 0.1 mg - 0.4 mg daily may obscure pernicious anemia, in that hematological remission can occur while neurological manifestations remain progressive.

OVERDOSE: Iron: Signs and Symptoms: Iron is toxic. Acute overdosage of iron may cause nausea and vomiting and, in severe cases, cardiovascular collapse and death. Other symptoms include pallor and cyanosis, melena, shock, drowsiness and coma. The estimated overdose of orally ingested iron is 300-mg/kg body weight. When overdoses are ingested by children, severe reactions, including fatalities, have resulted.

DOSAGE AND ADMINISTRATION: Adults (persons over 12 years of age), one (1) capsule daily, between meals, or as prescribed by a physician. Do not exceed recommended dosage. Do not administer to children under the age of 12.

HOW SUPPLIED: Integra F™ are maroon Vcaps® capsules printed in white with "Integra F" on the cap and "US" logo on the body. Packed in child resistant caps and light resistant bottles of 90 capsules (52747-0711-60) and 30 capsules (52747-0711-30). The listed product numbers are not National Drug Codes. Instead, US Pharmaceutical Corporation has assigned these product codes formatted according to standard industry practice to meet the formatting requirements of pharmacy and healthcare insurance computer systems.

CAUTION: Rx only.

INTEGRA F

ferrous fumarate and polysacchride iron complex and folic acid capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:52747-711
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	62.5 mg
FERROUS ASPARTO GLYCINATE (UNII: H7426RGB3L) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	62.5 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	40 mg
NIACIN (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A)	NIACIN	3 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	red (Maroon body and cap)	**Score**	no score
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	Integra;F;US
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:52747-711-60	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2009	
2	NDC:52747-711-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/27/2009	

Labeler - U.S. Pharmaceutical Corporation (079467662)

Registrant - U.S. Pharmaceutical Corporation (079467662)

Revised: 11/2022 U.S. Pharmaceutical Corporation