IBUPROFEN- ibuprofen tablet
Contract Pharmacal Corp.

3852, 3846, 3909

Important: Read all product information before using.
DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Drug Facts

ACTIVE INGREDIENT (in each tablet)

Ibuprofen USP, 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

PURPOSE

Pain reliever/fever reducer

USES

Temporarily relieves minor aches and pains due to:
- headache
- muscular ache
- minor pain of arthritis
- toothache
- backache
- the common cold
- menstrual cramps
- temporarily reduces fever

WARNINGS

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:
- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or non-prescription NSAIDs (aspirin, ibuprofen, naproxen,

or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increases the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

DO NOT USE
- if you have ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer
- right before or after heart surgery

ASK DOCTOR before use if
- you have problems or serious side effects from taking pain relievers or fever reducers
- the stomach bleeding warning applies to you
- you have a history of stomach problems such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic

ASK A DOCTOR OR PHARMACIST before use if you are
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- under a doctor's care for any serious condition
- taking any other drug

WHEN USING this product
- take with food or milk if stomach upset occurs

STOP USE and ask a doctor if
- you experience and of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
  - You have symptoms of heart problems or stroke:
- chest pain
- trouble breathing
- weakness in one part or side of body
- slurred speech
- leg swelling

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

If PREGNANT OR BREAST FEEDING

ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in

the unborn child or complications during delivery.

KEEP OUT OF REACH OF CHILDREN

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

DIRECTIONS

- **do not take more than directed**
- **the smallest effective dose should be used**

Adults and children 12 years of age and over:

■ Take 1 tablet every 4 to 6 hours while symptoms persist ■ If pain or fever does not respond to 1 tablet, 2 tablets may be used ■ Do not exceed 6 tablets in 24 hours, unless directed by a doctor

Children under 12 years of age: ■ Ask a doctor

Other information

- store between 20˚ to 25˚C (68˚to 77˚F)
- avoid excessive heat above 40˚C (104˚F)

INACTIVE INGREDIENTS

(White) Carnauba Wax, Croscarmellose Sodium, Hypromellose, Microcrystalline Cellulose, Polyethylene Glycol, Polysorbate 80, Povidone, Pregelatinized Starch, Silicon Dioxide, Sodium Starch Glycolate, Stearic Acid, and Titanium Dioxide.

(Orange) Croscarmellose Sodium, FD&C Yellow #6 Lake, Microcrystalline Cellulose, Polyethylene Glycol, Povidone, Pregelatinized Starch, Silicon Dioxide, Sodium Starch Glycolate, Stearic Acid, Talc and Titanium Dioxide.

(Brown) Croscarmellose Sodium, Hydroxypropylcellulose, Hypromellose, Microcrystalline Cellulose, Polyethylene Glycol, Povidone, Pregelatinized Starch, Red Iron Oxide, Silicon Dioxide, Sodium Starch Glycolate, Stearic Acid, and Titanium Dioxide.

QUESTIONS or COMMENTS?

Call **1-800-231-4670**: weekdays 9:00 AM to 5:00 PM EST

**This product is not manufactured or distributed by McNeil, owner of the registered trademark Motrin®IB

Manufactured by:

Contract Pharmacal Corp.

135 Adams Avenue

Hauppauge, NY 11788 USA

www.cpc.com

XXXXX-10-18

Barcode

Peel here for more information

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

See New Warnings

CONTRACT PHARMACAL CORP NDC 10267-3909-2

**Compares to the active ingredient in Motrin ®IB

GLUTEN FREE

Ibuprofen Tablets, USP 200 mg

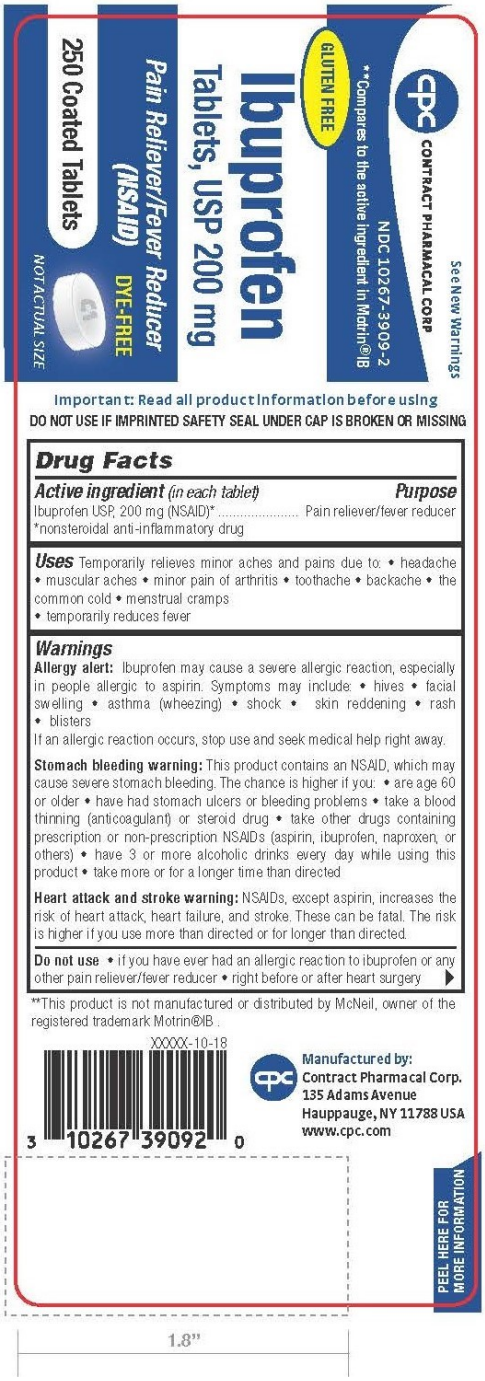
Pain Reliever/Fever Reducer

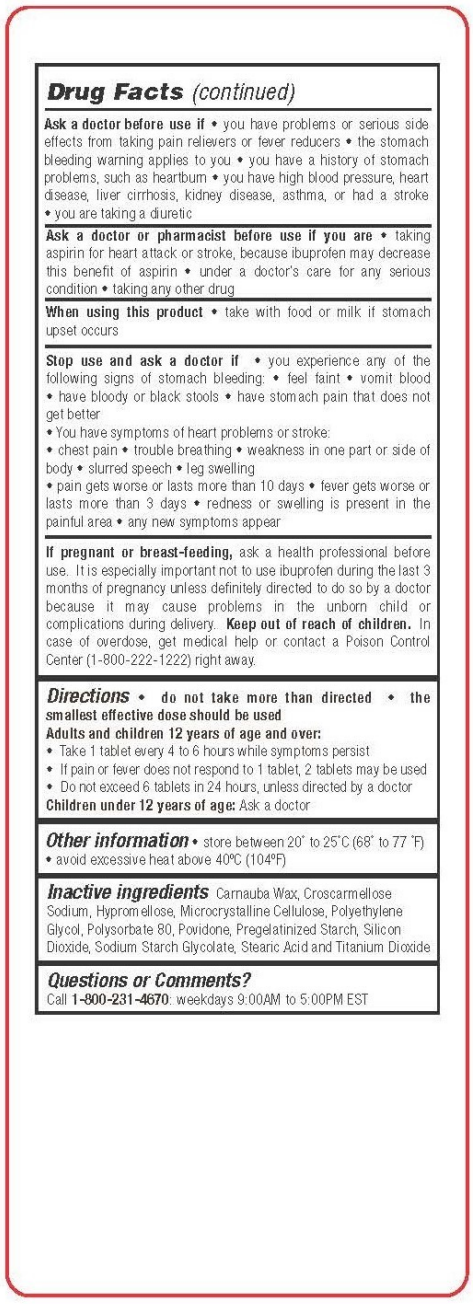
(NSAID)

250 Coated Tablets

DYE-FREE

NOT ACTUAL SIZE





See New Warnings

CONTRACT PHARMACAL CORP NDC 10267-3846-2

**Compares to the active ingredient in Motrin ® IB

GLUTEN FREE

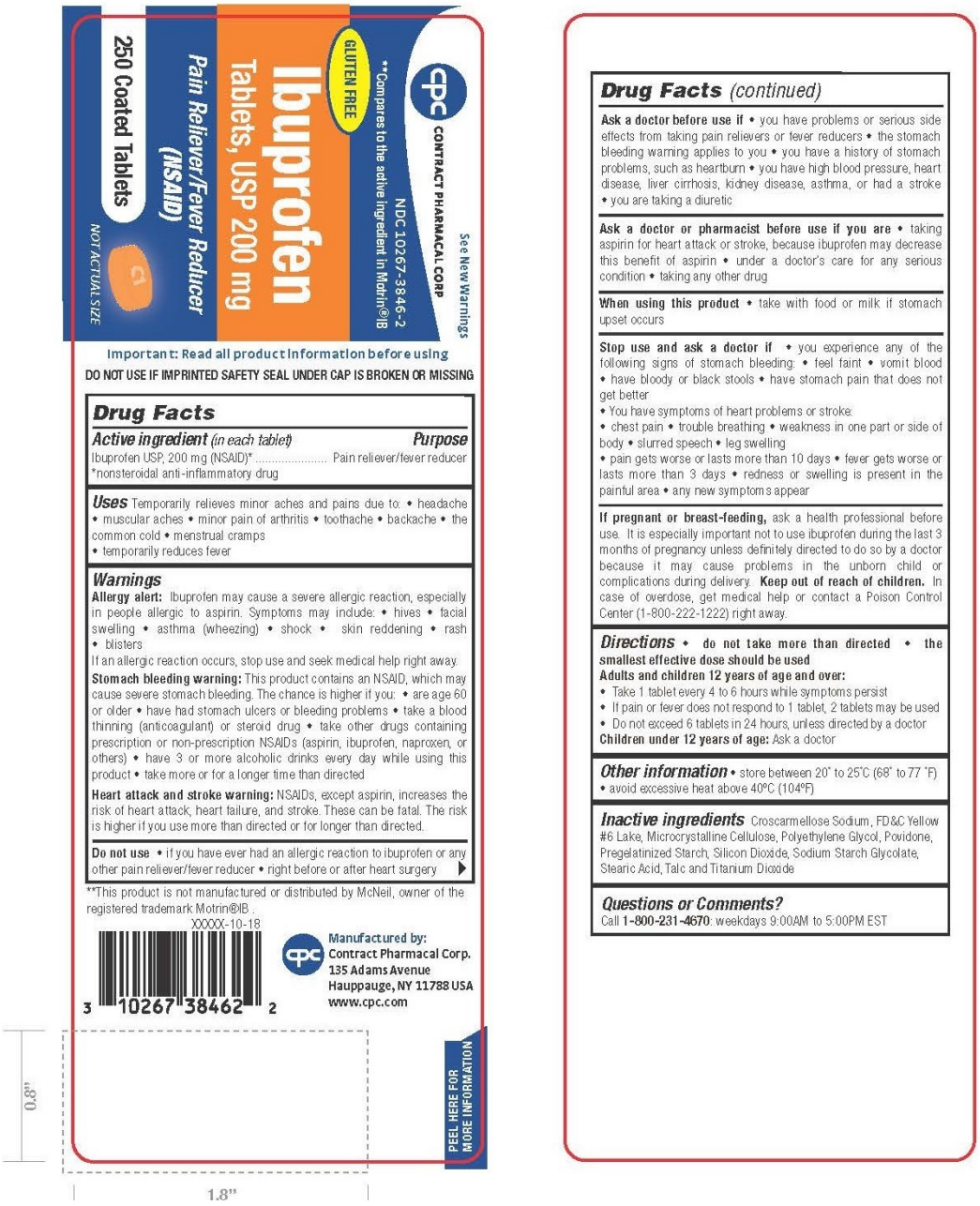
Ibuprofen Tablets, USP 200 mg

Pain Reliever/Fever Reducer

(NSAID)

250 Coated Tablets

NOT ACTUAL SIZE



See New Warnings

CONTRACT PHARMACAL CORP NDC 10267-3852-2

**Compares to the active ingredient in Motrin ® IB

GLUTEN FREE

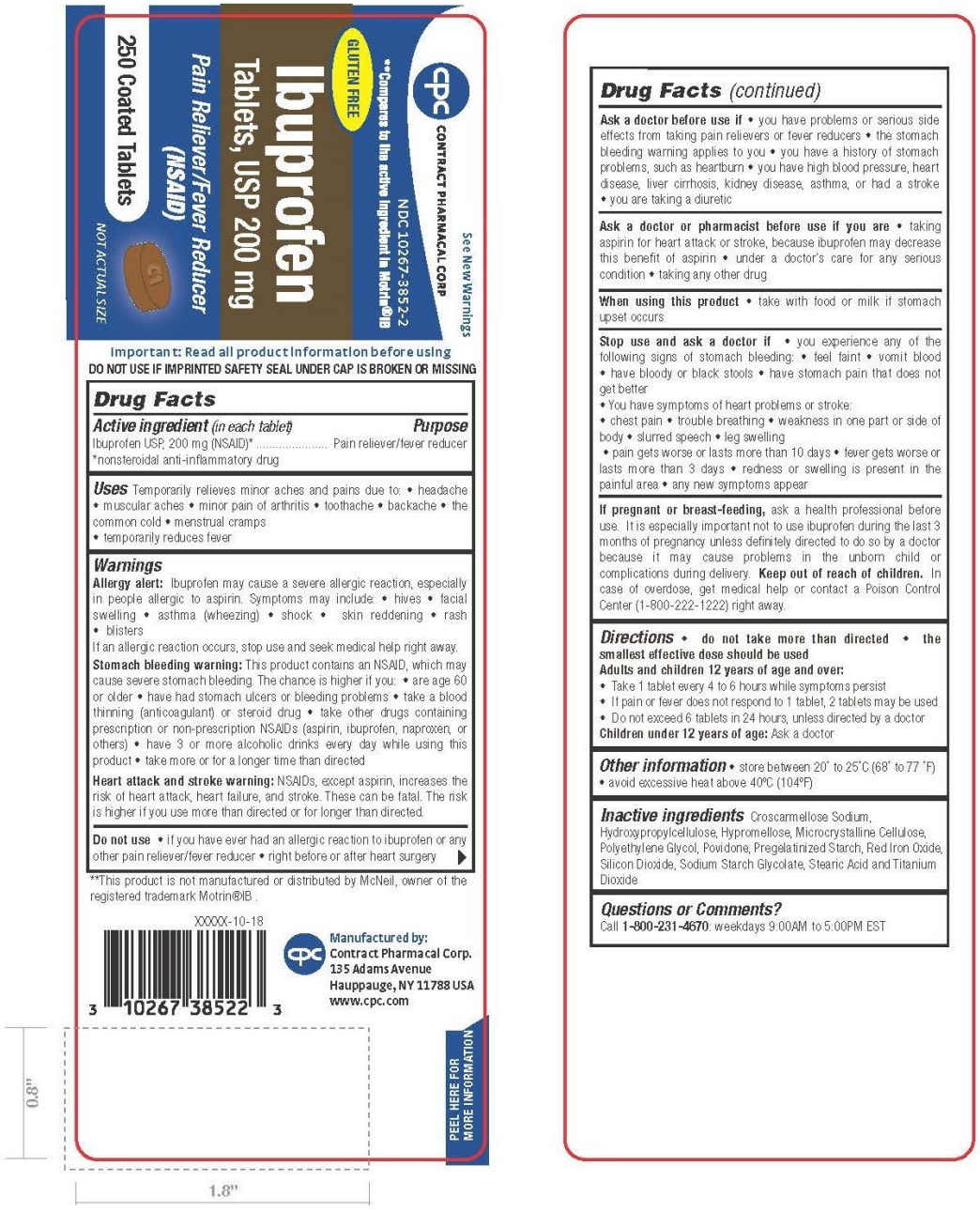
Ibuprofen Tablets, USP 200 mg

Pain Reliever/Fever Reducer

(NSAID)

250 Coated Tablets

NOT ACTUAL SIZE



IBUPROFEN

ibuprofen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10267-3852
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
STARCH, CORN (UNII: O8232NY3SJ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

Product Characteristics			
Color	brown	**Score**	no score
Shape	ROUND (convex)	**Size**	6mm
Flavor		**Imprint Code**	C1
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:10267-3852-2	250 in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA071265	01/15/2014	

IBUPROFEN

ibuprofen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10267-3846
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
STARCH, CORN (UNII: O8232NY3SJ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	orange	**Score**	no score
Shape	ROUND (convex)	**Size**	6mm
Flavor		**Imprint Code**	C1
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:10267-3846-2	250 in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA071265	01/15/2014	

IBUPROFEN

ibuprofen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10267-3909
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
STARCH, CORN (UNII: O8232NY3SJ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND (convex)	**Size**	6mm
Flavor		**Imprint Code**	C1
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:10267-3909-2	250 in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA071265	01/15/2014	

Labeler - Contract Pharmacal Corp. (057795122)

Registrant - Contract Pharmacal Corp. (057795122)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmacal Corp.		057795122	pack(10267-3852, 10267-3846, 10267-3909)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmacal Corp.		968334974	manufacture(10267-3852, 10267-3846, 10267-3909)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmacal Corp.		968335112	manufacture(10267-3852, 10267-3846, 10267-3909)

Revised: 11/2018