

NATIONAL RECALL ALERT CENTER - IMMEDIATE WARNING ALERT NOTIFICATION
THE FOLLOWING HAVE BEEN RECALLED OR ARE SUBJECT TO FIELD CORRECTION
THIS LISTING IS ISSUED BY - NATIONAL RECALL ALERT CENTER, WASHINGTON, D.C.

SUMMARY PAGE

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Route to _____ Status _____

THE FOLLOWING IS A CLASS I RECALL. THERE IS A REASONABLE PROBABILITY THAT THE USE OF THE AFFECTED PRODUCT MAY CAUSE SERIOUS INJURY OR DEATH IF THE PROBLEM IS NOT CORRECTED.

PRODUCT Concentrated Acetaminophen Drops, Bulk Pharmacy Container, Institutional Use Only, 80 mg/0.8 mL, 16 oz (473 mL) bottle, NDC 42192-504-16
RECALL NUMBER # D-1970-2009
CODE All lot codes
MANUFACTURED & RECALLED BY Brookstone Pharmaceuticals, LLC, Alpharetta, GA
QUANTITY 6,633 bottles
DISTRIBUTION Nationwide
REASON Possible overdosing may result from product packaging and the absence of an integrated dosage delivery device.

Route to _____ Status _____

THE FOLLOWING IS A CLASS I RECALL. THERE IS A REASONABLE PROBABILITY THAT THE USE OF THE AFFECTED PRODUCT MAY CAUSE SERIOUS INJURY OR DEATH IF THE PROBLEM IS NOT CORRECTED.

THIS IS AN UPDATE TO NRAC ISSUE #1743 DATED 7/21/09

PRODUCT 1) Propofol Injectable Emulsion 1%, 1000 mg/100 mL (10 mg/mL) in 100 mL vials, Rx only, NDC 0703-2859-01
RECALL NUMBER # D-1966-2009
PRODUCT 2) Propofol Injectable Emulsion 1%, 200 mg/20 mL (10 mg/mL) in 20 mL vials, Rx only, NDC 0703-2856-01
RECALL NUMBER # D-1967-2009
PRODUCT 3) Propofol Injectable Emulsion 1%, 500 mg/50 mL (10 mg/mL) in 50 ml vials, Rx only, NDC 0703-2858-01
RECALL NUMBER # D-1968-2009
PRODUCT 4) Propofol Injectable Emulsion 1%, 1000 mg/100 mL (10 mg/mL) in 100 mL vials, Rx only, NDC 0703-2859-01
RECALL NUMBER # D-1969-2009
CODE 1) Lot # 31305429B, Exp 01/11; Lot # 31305430B, Exp 01/11
2) Lot # 31305323B, Exp 01/11
3) Lot # 31305431B, Exp 01/11
4) Lot # 31305324B, Exp 01/11
MANUFACTURER Teva Parenteral Medicines, Inc., Irvine, CA
RECALLED BY Teva Pharmaceuticals USA, Inc., Sellersville, PA
QUANTITY 268,765 vials
DISTRIBUTION Nationwide
REASON Non-Sterility: contamination with endotoxins

Route to _____ Status _____

PRODUCT Neocate® specialized infant formula product
RECALL NUMBER Not available at the time of this publication
CODE Lot Number #P91877 (No other Neocate® products or lot numbers are involved)
The affected cans were distributed in commerce between September 1, 2009 and September 11, 2009
MANUFACTURED & RECALLED BY Nutricia North America, Inc.
QUANTITY Approximately 3,700 cans
DISTRIBUTION Nationwide to pharmacies, health care professionals and consumers
REASON A blending error caused the product to contain protein levels lower than that declared on the label
CONTACT 800-365-7354, option 8-6061

Route to _____ Status _____

PRODUCT ACIST Automated Manifold Kit, REF Model BT2000, SKU # 014613, Sterile R. The automated manifold kit is comprised of an injection manifold, a pressure transducer cartridge, a check valve, tubing (low, high and peristaltic pump), and a saline spike. This kit is designed for exclusive use with the ACIST CMS2000, E2000 Voyager and CVi models of Angiographic Contrast Delivery Systems. This kit is for single use.
RECALL NUMBER # Z-1872-2009
CODE Lot numbers: 2968J 3088N 3168H 3178H 2968K 3088P 3168J 3308U 2968L 3088T 3168K 3468W
MANUFACTURER NPA de Mexico S.A. de C.V., Tijuana, Mexico
RECALLED BY ACIST Medical Systems, Eden Prairie, MN
QUANTITY 62,280
DISTRIBUTION Nationwide, Canada and Hong Kong

REASON ACIST Medical Systems initiated a recall due to an increase in the incidence of field reports related to a bulge on the side and/or leaks in the bond of the 2.5 high-pressure tubing of BT2000 kits during a procedure which can result in unsatisfactory performance of the ACIST BT2000 Automated Manifold Kit.

Route to _____ Status _____

PRODUCT 1) Clinitron CII Air Fluidized Therapy Units. Intended to prevent and/or treat pressure ulcer development and wound deterioration in patients who have a significant risk of developing these problems and who generally also have one or more of the following conditions: immobility, poor nutrition, diminished level of consciousness, reduced subcutaneous tissue or multi-system failure.
2) Clinitron Up-Lift" Air Fluidized Therapy Units.

RECALL NUMBER # Z-1902-2009
PRODUCT
RECALL NUMBER # Z-1903-2009
CODE All serial numbers.
MANUFACTURED & RECALLED BY Hill-Rom Manufacturing, Inc., Charleston, SC
QUANTITY 625 units
DISTRIBUTION Nationwide and Internationally
REASON Incorrectly repaired power cord wires can potentially overheat resulting in smoldering sound foam in the base of the therapy bed.

Route to _____ Status _____

PRODUCT BHM Combi Sling, 100% Polyester Shell/100% Polyester Strap; soft polyester net fabric sling for ceiling and floor patient lifts, Part 626002: Combi Deluxe - Medium, capacity 68-113 kg, 150-250 lbs; Part 626002M: Combi Mesh Deluxe - Medium, capacity 68-113 kg, 150-250 lbs; Part 626002C Combi Sling Deluxe Small, capacity 20-68 kg, 45-150 lbs; Part 626002C-M Combi Sling Mesh Deluxe Small, capacity 20-68 kg, 45-150 lbs; Part 626003: Combi Deluxe - Large, capacity 113-272 kg, 250-600 lbs; Part 626003M: Combi Mesh Deluxe - Large, capacity 113-272 kg, 250-600 lbs; and Part 626003X: Combi Oversize Heavy Duty, capacity 113-272 kg, 250-600 lbs. Between 2004 and 2006, the Combi Slings were labeled as BHM Medical Inc. (800) 868-0441, 100% Polyester Shell/100% Nylon Strap. Prior to 2004, the slings were labeled Medi-Man, 100% Polyester Shell. The accessory is intended to be used with patient lift for the transfer of patient in hospitals, nursing homes, or other health care facilities by trained caregivers.

RECALL NUMBER # Z-1990-2009
CODE All lots released prior to 2/1/09.
MANUFACTURED & RECALLED BY B.H.M. Medical, Inc., Magog, Canada
QUANTITY 1,396 slings
DISTRIBUTION Nationwide
REASON Premature failure of the stitching at the junction of the shoulder strap and sling body of the BHM/Medi-Man Combi Sling used with patient lifts.

Route to _____ Status _____

PRODUCT 1) Empty M9 aluminum oxygen cylinders packaged in shipping containers (1 per container) labeled as: Product #0022-57P, Desc: CYL 02 ALUM 240 LITER, Catalog #31-10-2012
RECALL NUMBER # Z-2031-2009

PRODUCT 2) Empty D aluminum oxygen cylinders packaged in shipping containers labeled as: Product #0022-44P, CYL 02 ALUM 400 LITER, Catalog #31-10-0014

RECALL NUMBER # Z-2032-2009

PRODUCT 3) Empty D aluminum oxygen cylinders packaged in shipping containers labeled as: Product #0022-58 P, Desc CYL 02 ALUM 400 LITER, Catalog #31-10-2014

RECALL NUMBER # Z-2033-2009

PRODUCT 4) Empty Jumbo D aluminum oxygen cylinders, 72 cylinders per skid labeled as: Product #0022-96D, Desc: CYL 02, JUMBO D, A VLV, 72/SKID, Catalog #31-10-0117

RECALL NUMBER # Z-2034-2009

PRODUCT 5) Empty Jumbo D aluminum oxygen cylinders packaged in shipping containers labeled as: Product #0022-96P, Desc CYL 02, JUMBO D, W/TYPE B POST, Catalog #31-10-2017

RECALL NUMBER # Z-2035-2009

PRODUCT 6) Empty Jumbo D aluminum oxygen cylinders packaged in shipping containers labeled as: Product 0022-96, Desc CYL 02 ASSY., 637.2 LITER, Catalog #31-10-0017

RECALL NUMBER # Z-2036-2009

PRODUCT 7) Empty D aluminum oxygen cylinders packaged in shipping containers labeled as: Product #65261-E, Desc D PORTABLE W STRAIGHT POS, Catalog #65261-E

RECALL NUMBER # Z-2037-2009

PRODUCT 8) First Responder Kit containing a 240-liter aluminum oxygen cylinder with individually packaged regulator, cannula, and bag mask resuscitator, all packaged in a shipping container labeled as: Product #L903, Desc FIRST RESPONDER KIT, Catalog #L903

RECALL NUMBER # Z-2038-2009

CODE InterMed 08-05-3B and InterMed 09-01-1B located on the post valve

MANUFACTURED & RECALLED BY Allied Healthcare Products, Inc., St. Louis, MO

QUANTITY 359 cylinders

DISTRIBUTION Nationwide

REASON Medical valves do not meet quality specifications that may cause the valve to fail and result in uncontrolled release of oxygen when the valve is in the open position.

Route to _____ Status _____

PRODUCT 1) GE Healthcare Signa Ovation 0.35T, Model Numbers: a) Ovation 1-3 (2276937), b) Ovation 4 (2377062-2, 2377062-5, 2377062-8, or 5118172), and c) Ovation 5 (5148725). The 0.35T Signa Ovation with Excite Magnetic Resonance system is an open, whole body scanner designed to support improved higher resolution imaging and shorter scan times. The 0.35T Signa Ovation with Excite Magnetic Resonance system is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures and organs of the body including, but not limited to, the musculoskeletal, vascular, cardiac, and neuron systems.

RECALL NUMBER # Z-1722-2009

PRODUCT 2) Signa Openspeed 0.7T MR Systems, Model Numbers: Openspeed 3 (2138300-30), Openspeed 4 (2377062-5), Openspeed 5 (2377062-5, 2377062-30)

RECALL NUMBER # Z-1723-2009

CODE 1) Model number: 2276937; Serial Numbers: 00000869965YM4, 00000801207YM2, 00000813952YM9, 00000952559YM3, 00000236062MR6, 00000869966YM2, 00000801206YM4, 00000813945YM3, 00000813950YM3, 00000869958YM9, 00000952561YM9, 00000813958YM6, 00000919518YM1, 00000813944YM6, 00000837353YM2, 00000813960YM2, 00000837350YM8, 00000264247MR1, 00000897708YM4, 00000897716YM7, 00000919512YM4, 00000919526YM4, 00000026540VE5, 00000919509YM0, 00000813959YM4, 00000801204YM9, 00000813947YM9, 00000952560YM1, 00000952565YM0, 00000897711YM8, 00000897717YM5, 00000919515YM7, 00000952552YM8, 00000813951YM1, 00000897701YM9, 00000869949YM8, 00000837359YM9, 00000919519YM9, 00000813946YM1, 00000869956YM3, 00000897706YM8, 00000952563YM5,

00000869947YM2, 00000801199YM1, 00000801193YM4, 00000837362YM3,
00000952548YM6, 00000952549YM4, 00000837360YM7, 00000952547YM8,
00000837346YM6, 00000869952YM2, 00000869954YM8, 00000919514YMO,
00000919524YM9, 00000837358YM1, 00000919521YM5, 00000869962YM1,
00000919513YM2, 00000897705YM0, 00000952555YM1, 00000813943YM8,
00000869961YM3, 00000813956YM0, 00000801203YM1, 00000801208YM0,
00000801209YM8, 00000813948YM7, 00000813953YM7, 00000813954YM5,
00000837347YM4, 00000837351YM6, 00000837352YM4, 00000837354YM0,
00000837357YM3, 00000837361YM5, 00000837363YM1, 00000837364YM9,
00000837365YM6, 00000869950YM6, 00000869951YM4, 00000869953YM0,
00000869955YM5, 00000869957YM1, 00000869960YM5, 00000869963YM9,
00000897698YM7, 00000897699YM5, 00000897700YM1, 00000897702YM7,
00000897703YM5, 00000897704YM3, 00000897707YM6, 00000897715YM9,
00000919507YM4, 00000919510YM8, 00000919516YM5, 00000919517YM3,
00000919520YM7, 00000919523YM1, 00000952550YM2, 00000952553YM6,
00000952557YM7, 00000952558YM5, 00000952562YM7, 00000952566YM8,
00000952554YM4, 00000919511YM6, 00000869948YM0, 00000897714YM2,
00000813957YM8, 00000813955YM2, 00000897712YM6, 00000813949YM5; Model
number: 5118172; Serial Numbers; 00000000564YR5, 00000000565YR2,
00000000563YR7, 00000000561YR1; Model number: 2377062-2; Serial Number:
00000963007YM0; Model number: 2377062-5; Serial Numbers: 00000000120YR6,
00000000123YR0, 00000000132YR1, 00000000124YR8, 00000000137YR0,
00000000130YR5, 00000000134YR7, 00000000138YR8, 00000962592YM2,
00000000146YR1, 00000000117YR2, 00000000116YR4, 00000000118YR0,
00000943610YM6, 00000000152YR9, 00000000140YR4, 00000000110YR7,
00000000135YR4, 00000000106YR5, 00000000129YR7, 00000000141YR2,
00000000125YR5, 00000000142YR0, 00000000113YR1, 00000000150YR3,
00000000105YR7, 00000000131YR3, 00000000139YR6, 00000000155YR2,
00000000108YR1, 00000000143YR8, 00000000101YR6, 00000000109YR9,
00000000153YR7, 00000951021YM5, 00000000119YR8, 00000000136YR2,
00000000128YR9, 00000000100YR8, 00000000112YR3, 00000000121YR4,
00000000154YR5; Model Number: 2377062-8; Serial Numbers: 00000000776YR5,
00000000792YR2, 00000000793YR0, 00000000801YR1, 00000000803YR7,
00000000829YR2, 00000000836YR7, 00000000758YR3, 00000000765YR8,
00000000755YR9, 00000000756YR7, 00000000774YR0, 00000000784YR9,
00000000785YR6, 00000000798YR9, 00000000827YR6, 00000000816YR9,
00000000779YR9, 00000000828YR4, 00000000789YR8, 00000000838YR3,
00000000773YR2, 00000000788YR0, 00000000796YR3, 00000000763YR3,
00000000766YR6, 00000000767YR4, 00000000787YR2, 00000000790YR6,
00000000800YR3, 00000000834YR2, 00000000840YR9, 00000000830YR0,
00000000832YR6, 00000000786YR4, 00000000764YR1, 00000000775YR7,
00000000818YR5, 00000000768YR2, 00000000757YR5, 00000000760YR9,
00000000762YR5, 00000000783YR1, 00000000809YR4, 00000000782YR3,
00000000812YR8, 00000000826YR8, 00000000835YR9, 00000000770YR8,
00000000771YR6, 00000000825YR0, 00000000759YR1, 00000000821YR9,
00000000841YR7, 00000000831YR8, 00000000808YR6, 00000000823YR5,
00000000824YR3, 00000000772YR4, 00000000810YR2, 00000000837YR5,
00000000769YR0, 00000000815YR1, 00000000833YR4, 00000000804YR5,
00000000778YR1, 00000000780YR7, 00000000795YR5, 00000000799YR7,
00000000805YR2, 00000000807YR8, 00000000819YR3, 00000000839YR1,
00000000811YR0, 00000000761YR7, 00000000777YR3, 00000000781YR5,
00000000791YR4, 00000000797YR1, 00000000794YR8; and Model Number: 5148725;
Serial Numbers: 00000154413HM9, 00000176551HM0, 00000139846HM0,
00000192389HM5, 00000177143HM5, 00000193109HM6, 00000148905HM3,
00000147526HM8, 00000138166HM4, 00000000SPI275, 00000188489HM9,
00000167482HM9, 00000169104HM7, 00000171692HM7, 00000157419HM3,

00000266430MR8, 00000155516HM8, 00000155515HM0, 00000160809HM0,
00000175023HM1, 00000150718HM5, 00000162563HM1, 00000164072HM1,
00000165772HM5, 00000172421HM0, 00000172816HM1, 00000172869HM0,
00000173908HM5, 00000177792HM9, 00000178519HM5, 00000179361HM1,
00000180127HM3, 00000180746HM0, 00000182071HM1, 00000182249HM3,
00000182597HM5, 00000183130HM4, 00000187365HM2, 00000188810HM6,
00000189105HM0, 00000191017HM3, 00000191154HM4, 00000196647HM2,
00000200577HM5, 00000265078MR6, 00000157418HM5, 00000174348HM3,
00000189943HM4, 00000181736HM0, 00000146891HM7, 00000158641HM1,
00000147906HM2, 00000169833HM1, 00000170940HM1, 00000190359HM0,
00000191544HM6, 00000193220HM1, 00000193936HM2, 00000195772HM9,
00000144797HM8, 00000150152HM7, 00000170109HM3, 00000181735HM2,
00000197645HM5, 00000168323HM4 and 00000181517HM4

2) Model Number: 2138300-30; Serial Numbers: 00000203387MR6, 00000208208MR9,
00000216409MR3, 00000229302MR5, 00000229306MR6, 00000230309MR7,
00000231588MR5, 00000237930MR3, 00000239847MR7, 00000241694MR9,
00000247255MR3, 00000253103MR6, 00000189633MR1, 00000192104MR8,
00000193652MR5, 00000194218MR4, 00000194219MR2, 00000194950MR2,
00000196364MR4, 00000197334MR6, 00000198709MR8, 00000199443MR3,
00000201708MR5, 00000201709MR3, 00000201710MR1, 00000201901MR6,
00000202223MR4, 00000203386MR8, 00000204837MR9, 00000204838MR7,
00000204839MR5, 00000206438MR4, 00000206439MR2, 00000207493MR8,
00000207494MR6, 00000208209MR7, 00000208210MR5, 00000209712MR9,
00000209713MR7, 00000212511MR0, 00000212513MR6, 00000212514MR4,
00000212515MR1, 00000215366MR6, 00000216405MR1, 00000216406MR9,
00000216407MR7, 00000216409MR3, 00000217198MR1, 00000217201MR3,
00000221250MR4, 00000221251MR2, 00000221253MR8, 00000221254MR6,
00000222950MR8, 00000225273MR2, 00000225274MR0, 00000225942MR2,
00000226318MR4, 00000228022MR0, 00000228023MR8, 00000228024MR6,
00000228773MR8, 00000229303MR3, 00000229304MR1, 00000229305MR8,
00000230308MR9, 00000230312MR1, 00000231591MR9, 00000231592MR7,
00000232328MR5, 00000233644MR4, 00000233646MR9, 00000234832MR4,
00000234833MR2, 00000234834MR0, 00000237051MR8, 00000237052MR6,
00000237053MR4, 00000237926MR1, 00000237927MR9, 00000237928MR7,
00000237929MR5, 00000239480MR7, 00000239482MR3, 00000239483MR1,
00000239484MR9, 00000239845MR1, 00000239846MR9, 00000241126MR2,
00000241127MR0, 00000241693MR1, 00000241695MR6, 00000243405MR8,
00000244231MR7, 00000244232MR5, 00000247252MR0, 00000247253MR8,
00000247254MR6, 00000247256MR1, 00000250184MR9, 00000250185MR6,
00000250186MR4, 00000250187MR2, 00000253039MR2, 00000253102MR8, Unknown;
Model Number: 2377062-5; Serial Numbers: 00000000100YR8, 00000000119YR8,
00000000129YR7, 00000000102YR4, 00000000103YR2, 00000000105YR7,
00000000106YR5, 00000000108YR1, 00000000109YR9, 00000000111YR5,
00000000113YR1, 00000000118YR0, 00000000120YR6, 00000000122YR2,
00000000124YR8, 00000000127YR1, 00000000128YR9, 00000000131YR3,
00000000132YR1, 00000000133YR9, 00000000134YR7, 00000000135YR4,
00000000136YR2, 00000000137YR0, 00000000142YR0, 00000000144YR6,
00000000146YR1, 00000000149YR5, 00000000150YR3, 00000000151YR1,
00000000152YR9, 00000000155YR2, 00000943610YM6, 00000951021YM5,
00000962592YM2; Model Number: 2377062-30 Serial Numbers: 00000003047YR8,
00000003011YR4, 00000003022YR1, 00000003023YR9, 00000003024YR7,
00000003025YR4, 00000003026YR2, 00000003027YR0, 00000003028YR8,
00000003029YR6, 00000003030YR4, 00000003031YR2, 00000003033YR8,
00000003034YR6, 00000003035YR3, 00000003036YR1, 00000003039YR5,
00000003041YR1, 00000003042YR9, 00000003043YR7 and 00000003044YR5

MANUFACTURER Yokogawa Medical Systems, Ltd., Tokyo, Japan
RECALLED BY GE Medical Systems, LLC, Waukesha, WI
QUANTITY 308 units
DISTRIBUTION Nationwide and Internationally
REASON GE Healthcare has identified a potential pinch point hazard on Ovation MR Scanner when using CTL Array XL Body Flex and Opened Body coil. A patient's hand may be pinched between the magnet bore ceiling cover and the CTL Array, XL Body Flex, or Open Body coil if the patient puts his/her hand on the top of the coil. Two injuries and four complaints filed. 2/20/09: Recall being expanded to include the OpenSpeed Systems.

Route to _____ Status _____

PRODUCT [Leckey 4-Point Pelvic Harness Belts, catalog 081326990. Sold as a component of the following chairs: a\) Leckey Contour Advance Seat, Size 1, catalog 081117209; b\) Leckey Contour Advance Seat, Size 2, catalog 081117217; c\) Leckey Squiggles Saddle Seat, catalog 081326941; d\) Leckey Early Sitting System, catalog 081395193](#)

RECALL NUMBER # Z-2040-2009
CODE All belts supplied on the affected seating systems between September 2007 and December 2008

MANUFACTURER James Leckey Design, Ltd., Northern Ireland, Belfast, United Kingdom
RECALLED BY Patterson Medical Holdings, Inc., Bolingbrook, IL
QUANTITY 226 units
DISTRIBUTION Nationwide and Canada
REASON The plastic buckles on the hip belts of the 4-Point Pelvic Harness may break.

Route to _____ Status _____

PRODUCT [a\) Specimen Gate Laboratory, Product Code: 5002-0180, Software Version: 1.2 and 1.3. The intended use of the product is data management in prenatal and neonatal screening laboratories designed to allow viewing and management of assay results.](#)

RECALL NUMBER # Z-1905-2009
PRODUCT [b\) Specimen Gate Laboratory - MSMS Data Suite, Product Code: 5002-0310](#)
RECALL NUMBER # Z-1906-2009
CODE Software Versions: 1.2 and 1.3

MANUFACTURER PerkinElmer Life and Analytical Sciences, Wallac, OY, Turku, Finland
RECALLED BY Perkin Elmer, Waltham MA
QUANTITY 39 units
DISTRIBUTION Nationwide and Canada
REASON If Result Codes are used and if they are manually edited, they are correct unless the laboratory specifically uses the View Assay button in the Specimen History screen to open another assay, and then returns back to the original assay.

Route to _____ Status _____

PRODUCT [ArthroWand Saber 30 with Integrated Cable wand, Catalog number AC4330-01](#)

RECALL NUMBER # Z-1900-2009
CODE Lot numbers 4T011660-A, 4T01670-A, 4T01670-B, 4T02460-A, 4T02670-A, 4T02980-A, 4T02980-B, 4T03160-A, 4T04480-A, 4T04480B, 4T04860-A, 4T04980-A, 4T04980-B, 4T06680-A, 4T06680-B, 4T06770-A, 4T07360-A, 4T07460-A, 4T07880-A, 4T08580-A, 4T09270-A, 4T09370-A, 4T09370-B, 4T09370-C, 4T09380-A, 4T09460-A, 4T09580-A,

4T09880-A, 4T10980-A, 4T12260-A, 4T12680-A, 4T12970-A, 4T13380-A, 4T13960-A, 4T13960-B, 4T14980-A, 4T14980-B, 4T15680-A, 4T16360-A, 4T17670-A, 4T17770-A, 4T18760-A, 4T18760-B, 4T18860-A, 4T19770-A, 4T20260-A, 4T20570-A, 4T20660-A, 4T21050-A, 4T22960-A, 4T22960-B, 4T22970-A, 4T24270-A, 4T24270-B, 4T24960-A, 4T25650-A, 4T26970-A, 4T27160-A, 4T27750-A, 4T28260-A, 4T28260-B, 4T29350-A, 4T30270-A, 4T30370-A, 4T32050-A, 4T32060-A, 4T32770-A, 4T33260-A, 4T34150-A, and 4T34960-A

MANUFACTURED & RECALLED BY ArthroCare Corp., Sunnyvale, CA
QUANTITY 23,443 units
DISTRIBUTION Nationwide and Internationally
REASON Potential Sterility Loss-- Due to wearing or puncture in the Tyvek lid, the product may lose sterility.

Route to _____ Status _____

PRODUCT DePuy P.F.C. Sigma Knee System, Non-Porous Cruciate Retaining Femoral Component, 73 mm M/L 69 mm A/P, 5 left, sterile; REF 96-0005. The device is used for total or unicompartmental knee arthroplasty and is intended to provide increased patient mobility and reduced pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. The device is used as a Orthopedic knee implant.

RECALL NUMBER # Z-1686-2009
CODE Lot Numbers: 2833275, 2833276, 2833277, 2833278, 2833279, 2835157, 2835908, 2835909, 2837020, 2838165, 2839666, 2839667, 2839668, 2839670, 2839671, 2839672, 2839675, 2840479, 2840480, 2841253, 2842526, 2842527, 2842528, 2842930, 2843263, 2843265, 2843267, 2843268, 2843270, 2844381, 2844383, 2844386, 2844796, 2844799, 2844800, 2845530, 2845534, 2846326, 2846330, 2846332, 2852392, 2852394, 2855015, 2855016, 2857271, 2857272, 2857881, 2857882, 2857884, 2857885, 2858572, 2858573, 2858574, 2858576, 2858577, 2859195, 2859197, 2859198, 2859199, 2859915, 2859916, 2859917, 2859920, 2860448, 2860449, 2860452, 2860455, 2860456, 2861519, 2861520, 2861699, 2862589, 2862591, 2863841, 2863843, 2864833, 2864834, 2864835, 2864837, 2864839, 2866038, 2868313, 2868314, 2869119, 2869120, 2869121, 2869122, 2869123, 2871182, 2871183, 2871835, 2871836, 2874434, 2874435, 2874436, 2876307, 2876309, 2876311, 2876314, 2881638, 2885685, 2885689, 2886278, 2886968 and 2886974

MANUFACTURER DePuy (Ireland) Ltd., Co. Cork, Ireland
RECALLED BY Depuy Orthopedics, Inc., Warsaw, IN
QUANTITY 260 units
DISTRIBUTION Nationwide
REASON There may be a crack on the lateral side of the condyle in the posterior chamber region.

Route to _____ Status _____

PRODUCT 1) Children's Tylenol Plus, Multi-Symptom Cold, (each 5 mL contains: Acetaminophen 160 mg, Chlorpheniramine maleate 1 mg, Dextromethorphan HBr 5 mg, and Phenylephrine HCl 2.5 mg), 4 fl oz (120 mL) bottles, Grape Flavor, Oral Suspension, Product code 3910400, UPC 300450391049

RECALL NUMBER # D-1952-2009
PRODUCT 2) Children's Tylenol, (acetaminophen 160 mg/5 mL), 4 fl oz (120 mL) bottle, Grape Flavor Oral Suspension. Product code 2960400, UPC 300450296047

RECALL NUMBER # D-1953-2009

PRODUCT 3) Children's Tylenol, (acetaminophen 160 mg/5 mL), 4 fl oz (120 mL) bottle, bubblegum Yum Flavor, Oral Suspension. Product code 4070400, UPC 300450407047

RECALL NUMBER # D-1954-2009

PRODUCT 4) Children's Tylenol, (acetaminophen 160 mg/5 mL), 4 fl oz (120 mL) bottle, very berry Strawberry Flavor, Oral Suspension. Product code 4930400, UPC 300450493040

RECALL NUMBER # D-1955-2009

PRODUCT 5) Concentrated Tylenol, Infants' Drops, (acetaminophen 80 mg/0.8 mL), Grape Flavor. Packaged in the following configurations: 1/4 fl oz (7.5 mL) bottle with dropper, a) Product code 1224000, UPC 300450122407; 1/2 fl oz (15 mL) bottle with dropper, b) Product code 1221500, UPC 300450122155; 1 fl oz (30 mL) bottle with dropper, c) Product code 1220100, UPC 300450122018; 1 fl oz (30 mL) bottle with dropper, d) Product code 1221000, UPC 300450122100; (For Hospital/Government Use Only), 1/2 fl oz (15 mL) bottle, e) Product code 1221800, UPC 350580144183

RECALL NUMBER # D-1956-2009

PRODUCT 6) Concentrated Tylenol, Infants' Drops, (acetaminophen 80 mg/0.8 mL), Cherry Flavor. Packaged in the following configurations: 1/2 fl oz (15 mL) bottle with dropper, a) Product code 1861500, UPC 300450186157; 1 fl oz (30 mL) bottle with dropper, b) Product code 1863000, UPC 300450186300; (For hospital/government use only), 4 fl oz (120 mL) bottle, c) Product code 1230300, UPC 350580123034

RECALL NUMBER # D-1957-2009

PRODUCT 7) Children's Tylenol, (acetaminophen 160 mg/5 mL), 4 fl oz (120 mL) bottle, Dye Free Cherry Flavor, Oral Suspension. Product code 1660400, UPC 300450166043

RECALL NUMBER # D-1958-2009

PRODUCT 8) Children's Tylenol, (acetaminophen 160 mg/5 mL), Cherry Blast Flavor, Oral Suspension. Packaged in the following configurations: 4 fl oz (120 mL) bottle, Product code 1230400, UPC 300450123046; 1 fl oz (30 mL) bottle, Product code 1230100, UPC 300450123015

RECALL NUMBER # D-1959-2009

PRODUCT 9) Children's Tylenol Plus, Cough & Runny Nose, (each 5 mL contains: Acetaminophen 160 mg, Chlorpheniramine maleate 1 mg, and Dextromethorphan HBr 5 mg), 4 fl oz (120 mL) bottle, Cherry Flavor, Oral Suspension. Product code 2490400, UPC 300450249043

RECALL NUMBER # D-1960-2009

PRODUCT 10) Children's Tylenol Plus Flu, (each 5 mL contains: Acetaminophen 160 mg, Chlorpheniramine maleate 1 mg, Dextromethorphan HBr 5 mg, and Phenylephrine HCl 2.5 mg), 4 fl oz (120 mL) bottle, Bubble Gum Flavor, Oral Suspension. Product code 3860400, UPC 300450386045

RECALL NUMBER # D-1961-2009

PRODUCT 11) Children's Tylenol Plus Cold, (each 5 mL contains: Acetaminophen 160 mg, Chlorpheniramine maleate 1 mg, and Phenylephrine HCl 2.5 mg), 4 fl oz (120 mL) bottle, Grape Flavor, Oral Suspension. Product code 3870400, UPC 300450387042

RECALL NUMBER # D-1962-2009

PRODUCT 12) Children's Tylenol Plus Cough & Sore Throat, (each 5 mL contains: Acetaminophen 160 mg and Dextromethorphan HBr 5 mg), 4 fl oz (120 mL) bottle, Cherry Flavor, Oral Suspension. Product code 2470400, UPC 300450247049

RECALL NUMBER # D-1963-2009

PRODUCT 13) Concentrated Tylenol Infants' Drops, (acetaminophen 80 mg/0.8 mL), 1 fl oz (30 mL) bottle with dropper, Dye-Free Cherry Flavor. Product code 1670100, UPC 300450167019

RECALL NUMBER # D-1964-2009

PRODUCT 14) Children's Tylenol Plus Cold & Allergy, (each 5 mL contains: Acetaminophen 160 mg, Diphenhydramine HCl 12.5 mg, and Phenylephrine 2.5 mg), 4 fl oz (120 mL) bottle, Bubble Gum Flavor, Oral Suspension. Product code 3900400, UPC 300450390042

RECALL NUMBER # D-1965-2009

CODE 1) Lot numbers: SBM041 exp 1/10, SBM067 exp 2/10, SCM037 exp 2/10, SDM027 exp 3/10, and SEM109 exp 5/10
2) Lot numbers: SBM042 exp 2/10, SCM015 exp 2/10, SCM036 exp 2/10, and SDM034 exp 3/10
3) Lot numbers: SBM043 exp 2/10, SBM044 exp 2/10, and SCM029 exp 2/10

- 4) Lot numbers: SBM045 exp 2/10, SCM011 exp 2/10, SCM030 exp 2/10, and SDM035 exp 3/10
- 5) a) Lot numbers: SBM064 exp 2/10, SCM033 exp 3/10, and SDM020 exp 3/10; b) Lot numbers: SCM012 exp 2/10, SCM067 exp 3/10, SDM007 exp 3/10, and SDM068 exp 3/10; c) Lot numbers: SCM082 exp 3/10, SDM039 exp 3/10, and SDM040 exp 3/10; d) Lot number: SDM078 exp 3/10; e) Lot number: SCM034 exp 2/10
- 6) a) Lot numbers: SBM065 exp 2/10, SCM005 exp 2/10, SCM006 exp 2/10, and SDM032 exp 3/10; b) Lot numbers: SDM038 exp 3/10 and SDM009 exp 3/10; c) Lot number: SDM028 exp 3/10
- 7) Lot numbers: SBM066 exp 2/10 and SCM068 exp 2/10
- 8) Lot numbers: SBM068 exp 2/10, SCM035 exp 2/10, SCM070 exp 3/10, SCM080 exp 3/10, and SDM005 exp 3/10; Product code 1230100, Lot number: SDM064 exp 3/10
- 9) Lot numbers: SBM069 exp 2/10, SBM070 exp 2/10, SCM081 exp 3/10, and SDM006 exp 3/10
- 10) Lot numbers: SCM013 exp 2/10, SCM014 exp 2/10, and SCM069 exp 3/10
- 11) Lot numbers: SCM016 exp 2/10 and SFM024 exp 5/10;
- 12) Lot number: SCM017 exp 2/10
- 13) Lot numbers: SCM083 exp 3/10, SCM084 exp 3/10, SDM008 exp 3/10
- 14) Lot number: SDM033 exp 3/10

MANUFACTURED & RECALLED BY McNeil Consumer Healthcare, Div of McNeil-PPC, Inc., Fort Washington, PA
 QUANTITY 7,983,648 bottles
 DISTRIBUTION Nationwide
 REASON The raw material used to manufacture the finished product may have been contaminated with B cepacia.

Route to _____ Status _____

PRODUCT Pevnar Pneumococcal 7-valent Conjugate Vaccine (Diphtheria CRM 197 Protein), for pediatric use only, Disposable Syringe, One Dose (0.5mL) IM NDC 0005-1970-49 (single dose 0.5mL pre-filled syringe), RX only, contains no preservative, and carton labeled NDC 0005-1970-50 Wyeth, for pediatric use only, Pneumococcal 7-valent Conjugate Vaccine (Diphtheria CRM 197 Protein), Pevnar, for intramuscular use only, RX only, 10 One Dose (0.5mL) Disposable Syringes and One carton contains 10 single dose (0.5mL) pre-filled syringes. This is shipped 45 cartons of 10 x 1(0.5mL) single dose pre-filled syringes per shipper.

RECALL NUMBER # B-1571-09
 CODE Lot D50002
 MANUFACTURER Wyeth Pharmaceuticals, Inc., Pearl River, NY.
 RECALLED BY Wyeth Pharmaceuticals, Inc., Philadelphia, PA
 QUANTITY 96,280 doses
 DISTRIBUTION Nationwide
 REASON Pevnar Pneumococcal 7-valent Conjugate Vaccine, single dose pre-filled syringes not intended for commercial use, was distributed.

Route to _____ Status _____

THE FOLLOWING IS AN UPDATE TO NRAC ISSUE #1746 ADDENDUM DATED 8/15/09

PRODUCT Advair Diskus 100/50mcg (fluticasone propionate/salmeterol inhalation powder, 100/50mcg), Rx only, NDC 0173-0695-00. Product Order Number: 01730695009
 RECALL NUMBER # D-1972-2009

CODE Lot number: 9ZP7632, Expiration Date: April 2010
MANUFACTURED & RECALLED BY GlaxoSmithKline, Inc., Zebulon, NC
QUANTITY 23,932 units
DISTRIBUTION Nationwide
REASON Defective delivery system; There is a potential for the foil strip of the inhaler to tear rather than to peel back, which can result in medication not being available to the user as they advance doses through the Diskus unit.

Route to _____ Status _____

PRODUCT Acetaminophen 500 mg Pain Reliever-Fever Reducer, packaged under the following labels: CareOne Pain Relief Extra Strength Acetaminophen Cooling Sensation Caplets, 500 mg, 100 caplets, OTC; Equaline Extra Strength Pain Relief, acetaminophen, 500 mg, 100 caplets, OTC, NDC 41163-010-78; Good Neighbor Pharmacy Extra Strength Pain Reliever Cool Ice Caplets, acetaminophen, 500 mg, 100 caplets, OTC, NDC 24385-618-78; TopCare Extra Strength Pain Relief, acetaminophen, 500 mg, 100 caplets, OTC, NDC 36800-010-78; TopCare Extra Strength Pain Relief, acetaminophen, 500 mg, 50 caplets, OTC, NDC 36800-010-71

RECALL NUMBER # D-1974-2009
CODE Lot numbers: 9FE2629 and 9FE2453
MANUFACTURED & RECALLED BY L. Perrigo, Co., Allegan, MI
QUANTITY 56,520 bottles
DISTRIBUTION IL, MN, NY, PA
REASON Presence of foreign substance; incorrect coating on tablets

Route to _____ Status _____

PRODUCT Balneol for Her, Hydrocortisone 0.25%, Anti-Itch Lotion, a) 20 count/2 gm packets (UPC #3 68220-078-10 1) and b) 3fl.oz (89 mL) bottles (UPC #368220-078-03 3)

RECALL NUMBER # D-1971-2009
CODE a) Lot number 6911, b) Lot number 6889
MANUFACTURER Span Packaging Services LLC, Greenville, SC
RECALLED BY Alaven Pharmaceutical LLC, Marietta, GA
QUANTITY 13,128 units

DISTRIBUTION Nationwide
REASON Stability testing does not support the potency of the product throughout the product's shelf life.
