

# Enforcement Report - Week of February 21, 2018

## Class I Drugs Event

<b>Event ID:</b> 78952	<b>Product Type:</b> Drugs
<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 01/17/2018	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated
<b>Center Classification Date:</b> 02/09/2018	<b>Initial Firm Notification of Consignee or Public:</b> Letter
<b>Recalling Firm:</b> Magno Humphries Laboratories, Inc 8800 SW Commercial St Tigard OR United States	
<b>Distribution Pattern:</b> Nationwide in the USA	

## Associated Products

<b>Product Description:</b> Senna Laxative (sennosides) tablets, 8.6 mg, 100-count bottles, Manufactured for: Basic Drugs, Inc., Vandalia, Ohio 45377, UPC Code 3 07610 22020 1.
<b>Product Quantity:</b> 2,400 bottles
<b>Reason for Recall:</b> Labeling: Label Mix-Up: Customer complaint received that a bottle labeled as Senna Laxative contained only tablets of Naproxen Sodium 220 mg.
<b>Recall Number:</b> D-0342-2018
<b>Code Information:</b> Lot # 352300, Exp 01/19

## Class I Drugs Event

<b>Event ID:</b> 79055	<b>Product Type:</b> Drugs
<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 01/26/2018	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated
<b>Center Classification Date:</b> 02/09/2018	<b>Initial Firm Notification of Consignee or Public:</b> Press Release
<b>Recalling Firm:</b> Primus Pharmaceuticals, Inc. 7373 N. Scottsdale Rd., Suite B-200 Scottsdale AZ United States	
<b>Distribution Pattern:</b> Nationwide in the USA.	

## Associated Products

<b>Product Description:</b> Limbrel (flavocoxid 250 mg) capsules, 60-count bottle, Rx only, Manufactured for: Primus Pharmaceuticals, Inc., Scottsdale, AZ 85253; Manufactured by: Cornerstone Research and Development, Ogden, UT 84404, NDC 68040-601-16.
<b>Product Quantity:</b> 7,826 bottles
<b>Reason for Recall:</b> Marketed Without An Approved NDA/ANDA: Based on the labeling claims, these products are unapproved drugs for which the safety and efficacy have not been established and, therefore, subject to recall.
<b>Recall Number:</b> D-0344-2018
<b>Code Information:</b> All lots within expiry.

<b>Product Description:</b> Limbrel (flavocoxid 500 mg) capsules, 60-count bottle, Rx only, Manufactured for: Primus Pharmaceuticals, Inc., Scottsdale, AZ 85253; Manufactured by: Cornerstone Research and Development, Ogden, UT 84404, NDC 68040-602-16.
<b>Product Quantity:</b> 135,277 bottles
<b>Reason for Recall:</b> Marketed Without An Approved NDA/ANDA: Based on the labeling claims, these products are unapproved drugs for which the safety and efficacy have not been established and, therefore, subject to recall.

<b>Recall Number:</b> D-0345-2018
<b>Code Information:</b> All lots within expiry.
<b>Product Description:</b> Limbrel250 (flavocoxid and citrated zinc bisglycinate) 250 mg/50 mg capsules, 60-count bottle, Rx only, Manufactured for: Primus Pharmaceuticals, Inc., Scottsdale, AZ 85253; Manufactured by: Cornerstone Research and Development, Ogden, UT 84404, NDC 68040-605-16.
<b>Product Quantity:</b> 4,006 bottles
<b>Reason for Recall:</b> Marketed Without An Approved NDA/ANDA: Based on the labeling claims, these products are unapproved drugs for which the safety and efficacy have not been established and, therefore, subject to recall.
<b>Recall Number:</b> D-0346-2018
<b>Code Information:</b> All lots within expiry.
<b>Product Description:</b> Limbrel500 (flavocoxid and citrated zinc bisglycinate) 500 mg/50 mg capsules, 60-count bottle, Rx only, Manufactured for: Primus Pharmaceuticals, Inc., Scottsdale, AZ 85253; Manufactured by: Cornerstone Research and Development, Ogden, UT 84404, NDC 68040-606-16.
<b>Product Quantity:</b> 160,489 bottles
<b>Reason for Recall:</b> Marketed Without An Approved NDA/ANDA: Based on the labeling claims, these products are unapproved drugs for which the safety and efficacy have not been established and, therefore, subject to recall.
<b>Recall Number:</b> D-0347-2018
<b>Code Information:</b> All lots within expiry.

<b>Class II Drugs Event</b>	
<b>Event ID:</b> 77992	<b>Product Type:</b> Drugs
<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 08/22/2017	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated
<b>Center Classification Date:</b> 02/09/2018	<b>Initial Firm Notification of Consignee or Public:</b> Letter
<b>Recalling Firm:</b> Sage Products Inc 3909 3 Oaks Rd Cary IL United States	
<b>Distribution Pattern:</b> Distributed Nationwide in the USA and Puerto Rico, Canada, United Kingdom, Ireland, Netherlands, New Zealand	
<b>Associated Products</b>	
<b>Product Description:</b> Q.Care, Oral Cleansing & Suctioning System q4. Contains: 1 Covered Yankauer and Y-Connector, 2 Suction Toothbrush packages and Antiplaque solution, 4 Suction Oral Swab packages with Perox-A-Mint solution. Manufactured by: Sage Products, LLC., 3909 Three Oaks Road, Cary, IL 60013 Product Code: 6434; UPC 6 18029 83035 7	
<b>Product Quantity:</b> 1182 kits	
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products	
<b>Recall Number:</b> D-0348-2018	
<b>Code Information:</b> Product Code: 6434; Lots: 58519, 58536, EXP 10/02/2017; 59366, EXP 11/13/2017; 60250, 60266, EXP 01/02/2018; 60974, EXP 02/23/2018; 61427, EXP 03/30/2018.	
<b>Product Description:</b> Q Care, Oral Cleansing & Suctioning System Corinz. Contains: 1 Covered Yankauer and Y-Connector, 2 Suction Toothbrush packages with Corinz Antiseptic Cleansing & Moisturizing Oral Rinse, 4 Suction Oral Swab packages with Corinz Antiseptic Cleansing & Moisturizing Oral Rinse, 2 Oropharyngeal Suction Catheter packages. Manufactured by: Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013	
<b>Product Quantity:</b>	
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products	
<b>Recall Number:</b> D-0349-2018	

<b>Code Information:</b> Product Code: 6462; Lots: 55152, EXP 08/28/2017; 57055, EXP 09/26/2017; 57078, EXP 11/13/2017; 58213, EXP 12/22/2017; 58255, EXP 04/02/2018, 59031, EXP 04/03/2018; 59036, 59087, EXP 06/15/2018; 59781, EXP 07/30/2018; 59803, EXP 07/16/2018.
<b>Product Description:</b> Toothette Oral Care Perox-A-Mint Solution, Oral Debriding Agent, 1.5 fl. oz./44 mL. packet. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6065. UPC 6 18029 80018 3  <b>Product Quantity:</b> 7490 PACKETS  <b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products  <b>Recall Number:</b> D-0350-2018  <b>Code Information:</b> Product Code: 6065; Lots: 51450; EXP 9/19/2017; 52551, EXP 11/30/2017; 53180, EXP 1/16/2018; 54074, EXP3/11/2018; 54855, EXP 4/28/2018; 010437, EXP1/12/2019; 020637, EXP 2/14/2019; 51256, EXP 5/27/2018; 081066, EXP 8/25/2018; 090246, EXP 9/8/2018; 110026, 11/8/2018; 110625, EXP 11/19/2017.
<b>Product Description:</b> QCare Oral Cleansing and Suctioning System with Corinz. Includes: Two (2) Suction Toothbrush packages with 0.25fl.oz/7mL Corinz Antiseptic Cleansing and Moisturizing Oral Rinse and Four (4) Suction Oral Swab packages with 0.25 fl.oz/7mL Corinze Antiseptic Cleansing and Moisturizing Oral Rinse. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6464 UPC 6 18029 83077 7  <b>Product Quantity:</b> 1680 KITS  <b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products  <b>Recall Number:</b> D-0351-2018  <b>Code Information:</b> Product Code: 6464; Lots: 55175 EXP 8/28/2017; 57086, 58011, EXP 11/13/2017; 58604, EXP 4/3/2018; 60373, EXP 8/2/2018; 60590, EXP 9/4/2018; 61540, EXP 10/16/2018.
<b>Product Description:</b> QCare Rx Oral Cleansing and Suctioning System with 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse q2. Contains: 1 Covered Yankauer and Y-Connector, 2 Untreated Suction Toothbrush packages, 2 Single dose bottles of 0.12% CHG Oral Rinse, 4 Suction Oral Swab packages with Perox-A-Mint Solution, 6 Suction Oral Swab packages with Alcohol-Free Mouthwash, 4 Oropharyngeal Suction Catheter packages. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013 Product Code 6912 UPC 6 18029 83016 6  <b>Product Quantity:</b> 48,003 cases  <b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products  <b>Recall Number:</b> D-0352-2018  <b>Code Information:</b> Product Code: 6912; Lots: 52736, 52807, 52878, 52994, 53067, 53084, 53137, 53192, EXP 08/31/2017; 53363, 53459, 53695, 53748, 53868, EXP 9/30/2017; 53916, 54003, 54011, 54012, 54015, 54024, 54049, 54057, 54265, 54279, 54293, EXP 10/31/2017; 54487, 54562, 54613, EXP 12/31/2017; 54686, 54703, 54736, 54745, 54748, 54751, 54817, 54979, 55047, EXP 11/30/2017; 55546, 55561, 55580, 55589, 55602, 55615, 55680, 55709, 55718, 55726, 55735, 55740, 55843, 55857, 55868, 55880, 55900, 55960, EXP 12/31/2017; 56348, 56418, 56604, 56670, 56820, 56944, 56975, 57140, 57201, EXP 02/28/2018; 57506, 57579, 57733, 57900, EXP 03/31/2018; 57925, 58229, 58281, EXP 04/30/2018; 58696, 58762, 59044, EXP 6/30/2018; 59456, 59546, EXP 7/31/2018; 59766, 59830, 60293, 60358, EXP 8/31/2018; 60416, 60563, 60623, 60983, EXP 9/30/2018; 61780, 62118, EXP 12/13/2018
<b>Product Description:</b> Toothette Suction Toothbrush with Perox-A-Mint solution and Mouth Moisturizer. Includes 0.25 fl.oz./7mL Perox-A-Mint solution, 0.07oz/2g Mouth Moisturizer. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. NDC: 53462-922-16  <b>Product Quantity:</b> 38,792 cases  <b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products  <b>Recall Number:</b> D-0353-2018  <b>Code Information:</b> Product Code: 6512; Lots: 51381, EXP 8/8/2017; 51433, 51453, EXP 8/15/2017; 51931, EXP 9/12/17; 52754 EXP 10/31/2017; 53326, EXP 11/28/2017; 53826, EXP 1/9/2018; 54266, EXP /15/2018; 54606, EXP 3/6/2018; 54872, EXP 3/21/2018; 55310, 55319, EXP 4/17/2018; 55823, EXP 5/22/2018; 56030, EXP 6/5/2018; 56039, EXP 5/30/2018; 56054, EXP 6/5/2018; 56385, 56408, 56417, EXP 6/26/2018; 56424, 56432, 56440, 56450, EXP 7/5/2018; 56828, EXP 7/27/2018; 57436, EXP 8/29/2018; 57860, EXP 9/25/2018; 58010, EXP 10/2/2018; 58126, EXP 10/9/2018; 58753 EXP 11/6/2018; 59089, 59129, 59143, EXP 11/13/2018; 59762, EXP 1/2/2019; 60261, 60308, EXP 1/22/2019; 60957, EXP 3/12/2019; 61411 EXP 4/9/2019; 61715, EXP 4/23/2019.
<b>Product Description:</b> QCare RX Q2 Oral Cleansing & Suctioning System with 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse Corinz. Contains 1 Covered Yankauer and Y-Connector, 2 Untreated Suction Toothbrush packages, 2 Single dose bottles of 0.12% CHG Oral Rinse, 10 Suction Oral Swab packages with Corinz Antiseptic Cleansing and Moisturizing Oral Rinse and 2 Oropharyngeal Suction Catheter packages. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6962, UPC 6 18029 83076 0  <b>Product Quantity:</b> 9,006 cases  <b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical

products
<b>Recall Number:</b> D-0354-2018
<b>Code Information:</b> Product Code: 6962; Lots: 55604, 55619, 56000, 56052 EXP 08/28/2017; 56211, 56282, 56783, EXP 09/26/2017; 57204, 57614, 58027, EXP 11/13/2017; 58549, 58587, EXP 04/03/2018; 59493, EXP 07/16/2018; 60043, 60079, EXP 07/30/2018; 60476, EXPO 08/02/2018; 60490 EXP 09/04/2018; 60790, EXP 09/06/2018; 61405, EXP 09/11/2018; 61456, 61799, EXP 10/16/2018
<b>Product Description:</b> Toothette Short Term Oral Swab System with Perox-A-Mint Solution. Contains: 20 Individually wrapped Toothette Plus Oral Swabs with sodium bicarbonate, 1.5 fl.oz/44mL bottle of Perox-A-Mint solution and One (1) 0.5 oz/14g tube of Mouth Moisturizer, Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6002 UPC (01)00618029820921
<b>Product Quantity:</b> 966 cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0355-2018
<b>Code Information:</b> Product Code: 6002; Lots: Product Code: 6002; Lots: 52149, EXP 08/04/2017; 52982, EXP 09/21/2017; 53942, 54042, EXP 01/19/2018; 54925, 54952, 54958, 54959, 54962, EXP 03/08/2018; 55872, EXP 04/25/2018; 57449, EXP 08/25/2018; 58381, EXP 09/14/2018; 59302, EXP 09/22/2018; 59765, EXP 11/22/2018; 61788, 61831 EXP 02/14/2019.
<b>Product Description:</b> Oral Cleansing & Suctioning System q4. Contains 1 Covered Yankauer, 2 Untreated Suctino Toothbrush packages with Antiplaque solution, 4)Suction Oral Swab packages with Perox-A-Mint solution, 2 Oropharyngeal Suction Catheter packages, Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6504. UPC 6 18029 83045 6
<b>Product Quantity:</b> 2,199 cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0356-2018
<b>Code Information:</b> Product Code: 6504; Lots: 58174, EXP 09/11/2017; 59297, EXP 11/13/2017; 60127, EXP 01/02/2018; 60673, EXP 02/05/2018; 61002, EXP 02/23/2018; 61817, EXP 03/21/2018; 61825, EXP 04/27/2018
<b>Product Description:</b> Toothette Oral Care Antiseptic Oral Rinse 1.5 fl.oz/44 ml. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6122 UPC 6 18029 80079 4
<b>Product Quantity:</b> 4,061 cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0357-2018
<b>Code Information:</b> Product Code: 6122; Lots: 020387, EXP 02/13/2019; 041657, EXP 05/03/2019; 010507, EXP 01/16/2019; 050926, EXP 05/24/2018; 081026, EXP 08/24/2018; 090636, EXP 09/26/2018; 100176, 10/11/2018; 110575, EXP 11/24/2017; 10786, EXP 11/23/2018; 120936, EXP 12/21/2018. 110575
<b>Product Description:</b> Toothette Oral Care Short Term Oral Swab System with Perox-A- Mint solution. Contains 20 Toothette Plus Oral Swabs with sodium bicarbonate, 1.5 fl.oz/44ml bottle Perox-A-Mint solution, .5 oz/14g tube of Mouth Moisturizer, .3 oz./9g tube of Sodium Bicarbonate Mouthpaste, I Ultra-Soft Toothbrush, Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6001, UPC (01)00618029800039
<b>Product Quantity:</b> 2,429 cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0358-2018
<b>Code Information:</b> Product Code: 6001; Lots: 52267, EXP 08/04/2017; 52278, 52974, 09/21/2017; 53633, 53661, 53663, 53667, EXP 12/06/2017; 54107, EXP 01/19/2018; 55208, EXP 04/25/2018; 56290, EXP 11/19/2017; 56815, EXP 05/27/2018; 57889, EXP 09/08/2018; 58819 EXP 09/14/2018; 59332, EXP 09/22/2018; 60214, EXP 11/22/2018; 61607, EXP 01/23/2019; 62124, EXP 02/14/2019.
<b>Product Description:</b> Toothette Oral Care Short Term Oral Swab System with Perox-A- Mint solution. Contains 20 Toothette Plus Oral Swabs with sodium bicarbonate, 1.5 fl.oz/44ml bottle Perox-A-Mint solution, .5 oz/14g tube of Mouth Moisturizer, .3 oz./9g tube of Sodium Bicarbonate Mouthpaste, I Ultra-Soft Toothbrush, Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6001-D NDC: 53462-024-30
<b>Product Quantity:</b> 835 cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products

<b>Recall Number:</b> D-0359-2018
<b>Code Information:</b> Product Code: 6001-D; Lots: 52414, 53322, EXP 09/21/2017; 53336, EXP 12/02/2017; 53673, EXP 12/06/2017; 54438, EXP 01/19/2018; 54932, EXP 03/08/2018; 55506, EXP 04/25/2018; 2015323-01, EXP 09/21/2017
<b>Product Description:</b> Toothette Oral Care Short-Term Oral Swab System with Perox-A-Mint solution, Contains 20 Toothette Plus Oral Swabs with sodium bicarbonate, 1.5 fl.oz/44ml bottle Perox-A-Mint solution , .5 oz/14g tube of Mouth Moisturizer, Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product code 6000, UPC 6 18029 8001 5
<b>Product Quantity:</b> 25,409 cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0360-2018
<b>Code Information:</b> Lots:52115, EXP 08/04/2017; 52284, 52631, 53005, EXP 09/21/2017; 53012, 53343, EXP 12/02/2017; 53475, 53754, EXP 12/06/2017; 53765, 54130, 54146, 54158, 54166, 54179, 54502, EXP 01/19/2018; 54518, 54658, 54984, EXP 03/08/2018; 55063, 55540, 56029, EXP 04/25/2018; 56308, 56427, EXP 11/19/2017; 56442, 56620, EXP 05/27/2018; 56713, EXP 04/25/2018; 56737, 57067, 57325, EXP 05/27/2018; 57531, EXP 08/25/2018; 57932, 58115, EXP 09/08/2018; 58712, EXP 04/25/2018; 58757, 59015, EXP 09/14/2018; 59086, 59518, EXP 09/22/2018; 59565, 59764, EXP 11/22/2018; 60101, 60582, EXP 12/19/2018; 60637, EXP 01/23/2019; 61184, EXP 05/27/2018; 61195, 61654, EXP 01/23/2019;
<b>Product Description:</b> Toothette Oral Care Short Term Oral Care System with Perox-A-Mint solution, Contains 1.5 fl oz/44 ml bottle of Perox-A-Mint solution, 0.5 oz/14g tube of Mouth Moisturizer, 0.3 oz/9g tube of Sodium Bicarbonate Mouthpaste, 1 Ultra-Soft Toothbrush, Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6002-D UPC (01)00618029821461
<b>Product Quantity:</b> 849 cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0361-2018
<b>Code Information:</b> Product Code: 6002-D; Lots: 57942, EXP 09/08/2018; 58186, 58673, EXP 09/14/2018; 60297, EXP 12/19/2018; 61893, EXP 02/14/2019.
<b>Product Description:</b> Independent Care System Corinz, Contains: 1.5 fl oz bottle Corinz Mouthwash, 0.5 oz/14g tube of Mouth Moisturizer, 0.3 oz/9g tube of Sodium Bicarbonate Mouthpast, 1 Ultra-Soft toothbrush. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6004 UPC 6 18029 82148 5
<b>Product Quantity:</b> 94 cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0362-2018
<b>Code Information:</b> Product Code: 6004; Lots: 61610, EXP 11/17/2018
<b>Product Description:</b> Toothette Oral Care Daily Oral Cleansing Kit Petite Size with Antiseptic Oral Rinse. Contains: 10 Petite Size Oral Swabs, individually wrapped, 1.5 fl oz/44ml bottle of Antiseptic Oral Rinse, .5 oz/14g tube of Mouth Moisturizer, Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6006 UPC (01)00618029800053
<b>Product Quantity:</b> 637 cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0363-2018
<b>Code Information:</b> Product Code: 6006; Lots: 54523,54629, 55528, EXP 02/06/2018; 56864, 57915, EXP 04/12/2018; 58884, 60137, 61047, EXP 05/23/2018; 61123, EXP 02/10/2019
<b>Product Description:</b> Toothette Oral Care Single Use System With Perox-A-Mint solution. Contains: 2 Toothette Plus swabs with sodium bicarbonate, .25 fl oz/7ml tube of Perox-A-Mint solution. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6012 UPC (01)00618029800077
<b>Product Quantity:</b> 14,753 cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0364-2018
<b>Code Information:</b> Product Code: 6012; Lots: 51502, EXP 08/15/2017; 51883, 09/06/2017; 53585, EXP12/19/2018; 54222, 54226, EXP 02/06/2018; 54811, EXP 03/21/2018; 55

574, EXP 05/08/2018; 56190, EXP 06/12/2018; 56346, EXP 06/26/2018; 56616, EXP 07/12/2018; 57066, EXP 08/07/2018; 57873, EXP 09/25/2018; 58634, EXP 08/28/2018; 58664, EXP 11/06/2018; 59719, EXP 01/02/2019; 61340, EXP 04/02/2019; 62326, EXP 06/11/2019

<b>Product Description:</b> Toothette Oral Care Single Use System with Perox-A-Mint solution and Mouth Moisturizer. Contains 2 Toothette Plus Swabs with sodium bicarbonate, .25 fl oz/7ml Perox-A-Mint solution and .07 oz/2g Mouth Moisturizer, Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6013 UPC 6 18029 80008 4
<b>Product Quantity:</b> 15,644 cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0365-2018
<b>Code Information:</b> Product Code: 6013; Lots: 51361, EXP 8/8/2017; 51834, EXP 9/6/2017; 52473, EXP 10/17/2017; 53225, EXP 11/28/2017; 54102, EXP 1/30/2018; 54754, EXP 3/13/2018; 55222, 55264, EXP 4/10/2018, 56683, EXP 7/17/2018; 57262, EXP 8/21/2018; 57803, EXP 9/18/2018; 58492, EXP 10/30/2018; 59311, EXP 12/4/2018; 60069, EXP 11/27/2018; 61063, EXP 3/19/2019; 61629, EXP 4/17/2019.

<b>Product Description:</b> Toothette Oral Care Perox-A- Mint solution, Oral Debriding Agent 8 fl oz/237 ml. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6060 UPC (01)00618029800152
<b>Product Quantity:</b> 945 cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0366-2018
<b>Code Information:</b> Product Code: 6060; Lots: 53057, EXP 12/7/2017; 57537, 59140, 60722, EXP 5/23/2017.

<b>Product Description:</b> Toothette Oral Care Short Term Oral Swab System with Antiseptic Oral Rinse, Contains 20 Toothette Plus Oral Swabs with sodium bicarbonate, 1.5 fl oz/44ml bottle of Antiseptic Oral Rinse, .5 oz. 14g tube of Mouth Moisturizer. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6100 UPC (01)00618029820969
<b>Product Quantity:</b> 2,548 cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0367-2018
<b>Code Information:</b> Product Code: 6100; Lots: 57856, 58296, 58814, EXP 11/24/2017; 54496, 55225, 56214, EXP 02/06/2018; 56280, 57109, 58288, EXP 04/12/2018; 59175, 59487, 60187, EXP 05/23/2018; 58815, 59157, EXP 05/24/2018; 61262, 61740, EXP 02/10/2019.

<b>Product Description:</b> Toothette Oral Care Suction Swab System With Antiseptic Oral Rinse and Mouth Moisturizer. Contains 2 Suction Swabs with sodium bicarbonate 0.25 fl oz/7ml Antiseptic Oral Rinse 0.7 oz/2g Mouth Moisturizer, Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6115
<b>Product Quantity:</b> 640 cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0368-2018
<b>Code Information:</b> Product Code: 6115; Lots: 58483, EXP 10/09/2017; 59783, EXP 01/08/2018; 61117, EXP 03/05/2018.

<b>Product Description:</b> Toothette Oral Care Single Use System with Antiseptic Oral Rinse and Mouth Moisturizer. Contains 2 Toothette Plus swabs with sodium bicarbonate, .25 fl oz/7ml Antiseptic Oral Rinse, 0.7 fl oz/2g Mouth Moisturizer, Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6113 UPC (01)00618029820990
<b>Product Quantity:</b> 879 cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0369-2018
<b>Code Information:</b> Product Code: 6113; Lots: 57874, EXP 09/19/2017; 58903, EXP 11/15/2017; 60045, EXP 01/08/2018; 61109, EXP 01/22/2018.

<b>Product Description:</b> Toothette Oral Care Suction Toothbrushes with Antiseptic Oral Rinse and Mouth Moisturizer, Contains 2 Suction Toothbrushes with sodium bicarbonate. 0.25 fl oz/7ml Antiseptic Oral Rinse, 0.07 oz/2g Mouth Moisturizer, Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6173
<b>Product Quantity:</b> 887 cases

**Reason for Recall:**

Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products

**Recall Number:**

D-0370-2018

**Code Information:**

Product Code: 6173; Lots: 57899, EXP 09/19/2017; 58919, EXP 11/15/2017; 60058, EXP 01/08/2018; 61135, EXP 03/05/2018.

**Product Description:**

Q Care Continue Care for the non-ventilated patient. Contains, 1 Covered Yankauer, 2 Suction Toothbrush packages with Corinz Antiseptic Cleansing and Moisturizing Oral Rinse, 2 Suction Oral Swab packages with Corinz Antiseptic Cleansing and Moisturizing Oral Rinse. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6306 UPC 6 18029 83041 8

**Product Quantity:**

5,217 cases

**Reason for Recall:**

Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products

**Recall Number:**

D-0371-2018

**Code Information:**

Product Code: 6306; Lots: 55203, 55207, 55505, EXP 08/28/2017; 56466, 56502, 56508, 56515, EXP 09/26/2017; 57265, EXP 11/13/2017; 58129, EXP 12/11/2017; 59085, EXP 6/15/2018; 59742, EXP 7/16/2018 60163, EXP 08/02/2018; 60834, 61371, 61402, EXP 09/11/2018; 61913, EXP 11/12/2018.

**Product Description:**

Q Care Continue Care for the non-ventilated patient. Contains, 1 Covered Yankauer, 3 Suction Toothbrush packages with Corinz Antiseptic Cleansing and Moisturizing Oral Rinse. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6308 UPC 6 18029 83040 1

**Product Quantity:**

2,938 cases

**Reason for Recall:**

Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products

**Recall Number:**

D-0372-2018

**Code Information:**

Product Code: 6308; Lots: 55134, EXP 08/28/2017, 56144, 56521, EXP 09/26/2017; 57495, EXP 11/13/2017; 58716, EXP 04/03/2018; 59486, EXP 06/15/2018; 59504, EXP 07/16/2018; 60426, EXP 08/02/2018; 61665,EXP 10/16/2018; 62033, 62058, EXP 11/12/2018.

**Product Description:**

Q CARE q4 Oral Cleaning & Suctioning System Contains 1 Covered Yankauer and Y-Connector, 2 Suction Toothbrush packages with Antiplaque solution, 4 Suction Oral Swab packages with Antiseptic Oral Rinse. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6404 UPC 6 18029 84133 9

**Product Quantity:**

2,194 cases

**Reason for Recall:**

Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products

**Recall Number:**

D-0373-2018

**Code Information:**

Product Code: 6404; Lots: 58394, EXP 10/02/2017; 59185, EXP 11/03/2017; 59782, EXP 11/27/2017; 59799, EXP 01/02/2018; 60776, EXP 01/22/2018; 61185, EXP 02/23/2018.

**Product Description:**

Q CARE q2 Oral Cleansing & Suctioning System, Contains 1 Covered Yankauer and Y-Connector, 2 Suction Toothbrush packages with Antiplaque solution, 4 Suction Oral Swab packages with Antiseptic Oral Rinse, 6 Suction Oral Swab packages with Alcohol-Free mouthwash, 4 Oropharyngeal Suction Catheter packages, Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6412 UPC 6 18029 84137 7

**Product Quantity:**

6,200 cases

**Reason for Recall:**

Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products

**Recall Number:**

D-0374-2018

**Code Information:**

Product Code: 6412; Lots: 58432, EXP 10/02/2017; 59402, EXP 11/13/2017; 59864, EXP 01/02/2018; 60799, EXP 01/22/2018; 61115 EXP 02/23/2018; 61557, EXP 03/30/2018.

**Product Description:**

Q CARE q4 Oral Cleansing & Suctioning System, Contains 1 Covered Yankauer and Y-Connector, 2 Suction Toothbrush packages with Antiplaque solution, 4 Suction Oral Swab packages with Antiseptic Oral Rinse, 2 Oropharyngeal Suction Catheter packages, Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6414 UPC 6 18029 84138 4

**Product Quantity:**

13,041 cases

**Reason for Recall:**

Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products

<b>Recall Number:</b> D-0375-2018
<b>Code Information:</b> Product Code: 6414; Lots: 57847, EXP 09/18/2017; 57852, 57875, EXP 08/14/2017; 58246, EXP 09/20/2017; 58802, 58851, EXP 10/09/2017; 58924, 59091, 59116, EXP 11/03/2017; 59494, EXP 11/27/2017; 60123, EXP 01/02/2018; 60466, 60880, 60925, 01/22/2018; 61364, 03/05/2018; 61705, EXP03/30/2018; 62061, EXP 04/17/2018; 62076, EXP 04/27/2018
<b>Product Description:</b> Q CARE q2 Oral Cleansing & Suctioning System, Contains 1 Covered Yankauer and Y-Connector, 2 Suction Toothbrush packages with Antiplaque solution, 4 Suction Oral Swab packages with Perox-A-Mint solution, 6 Suction Oral Swab packages with Alcohol-Free mouthwash, 4 Oropharyngeal Suction Catheter packages, Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6422 UPC 6 18029 83031 9
<b>Product Quantity:</b> 5,579 cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0376-2018
<b>Code Information:</b> Product Code: 6422; Lots: 57496, 57555, EXP 08/14/2017; 58045, EXP 09/11/2017; 58972, EXP 11/03/2017; 59162EXP 11/13/2017; 59835, EXP 01/02/2018; 60309, EXP 02/05/2018; 61188, EXP 02/23/2018
<b>Product Description:</b> Q CARE q4 Oral Cleansing & Suctioning System, Contains 1 Covered Yankauer and Y-Connector, 2 Suction Toothbrush packages with Antiplaque solution, 4 Suction Oral Swab packages with Perox-A-Mint solution, 2 Oropharyngeal Suction Catheter packages, Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6424 UPC 6 18029 83027 2
<b>Product Quantity:</b> 9,110 cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0377-2018
<b>Code Information:</b> Product Code: 6424; Lots: 57386, EXP 08/14/2017; 58035, EXP 09/11/2017; 58363, 58566, 58582, EXP 10/02/2017; 58760, 58889, EXP 11/03/2017; 59288, EXP 11/13/2017; 59467, EXP 11/27/2017; 59983, 60094, EXP 01/02/2018; 60324, EXP 02/05/2018; 61001, EXP 02/23/2018.
<b>Product Description:</b> Oral Cleaning and Suctioning System q2. Contains 1 Covered Yankauer, 2 Untreated Suction Toothbrush packages with Antiplaque solution, 4 Suction Oral Swab packages with Perox-A-Mint- solution, 6 Suction Oral Swab packages with Alcohol-Free Mouthwash solution, 2 Oropharyngeal Suction Catheter packages. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6502 UPC 6 18029 80060 2
<b>Product Quantity:</b> 852 cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0378-2018
<b>Code Information:</b> Product Code: 6502; Lots: 57627, EXP 08/14/2017; 58677, EXP 10/02/2017; 60110, EXP 01/02/2018; 61463, EXP 03/30/2018.
<b>Product Description:</b> Toothette Oral Care Suction Swabs with Perox-A-Mint solution and Mouth Moisturizer, Contains 2 Suctino Swabs with sodium bicarbonate, 0.25 fl oz/7ml Perox-A-Mint solution, 0.07 oz/2g Mouth Moisturizer. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6513
<b>Product Quantity:</b> 42,628 cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0379-2018
<b>Code Information:</b> Product Code: 6513; Lots: 51175, 51220, EXP 08/01/2017; 51570, EXP 08/15/2017; 51786, EXP 08/29/2017; 52104, EXP 09/19/2017; 52550, 52570,EXP 10/17/2017; 53460, EXP 12/12/2017, 53922, EXP 1/16/2018; 54161,EXP 02/06/2018; 54294, EXP 02/15/2018; 54395, EXP 02/20/2018; 54459,EXP 02/27/2018; 54963, EXP 03/28/2018; 54992, 55040, 55049, 55060, 55070, EXP 4/3/2018; 55486, 55617, EXP 05/08/2018; 56210, EXP 06/19/2018; 56772, 56777, EXP 07/24/2018; 57105, EXP 08/14/2018; 57329, EXP 08/21/2018; 57507, EXP09/05/2018; 58173, EXP 10/09/2018; 58429, EXP 10/24/2018; 59037, EXP 11/13/2018; 59549, EXP 12/11/2018; 59920, EXP 01/15/2019; 60566, EXP 02/19/2019; 60863, EXP 03/05/2019; 61292, EXP 04/02/2019; 61980, EXP 05/07/2019.
<b>Product Description:</b> Toothette Oral Care Suction Swab System with Perox-A-Mint Solution, Contains 6 Packages of 2 Suction Swabs with sodium, bicarbonate and a .25 fl oz/7ml pouch of Perox-A-Mint solution, 10 Applicator Swabs, .5 oz/14g tube of Mouth Moisturizer. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6550 6 18029 80065 7
<b>Product Quantity:</b> 11194 CASES
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products



<b>Recall Number:</b> D-0380-2018
<b>Code Information:</b> Product Code: 6550; Lots: 51590, EXP 08/15/2017; 52134, EXP 09/19/2017; 52179, EXP 09/26/2017; 52589, EXP 10/24/2017; 52966, EXP 11/07/2017; 53692, EXP 01/03/2018; 53883, EXP 01/16/2018; 54371, 54422, EXP 02/20/2018; 54622, 54677, EXP 03/06/2018; 54920, 54934, 54941, 54942, 54944, EXP 03/28/2018; 55296, EXP 04/17/2018; 55896, EXP 05/22/2018; 55925, 55934, 55951, EXP 05/30/2018; 56464, EXP 07/05/2018; 56936, EXP 08/07/2018; 57683, EXP 09/12/2018; 58244, EXP 10/16/2018; 58850, EXP 11/06/2018; 59283, EXP 11/20/2018; 59339, EXP 12/04/2018; 59636, EXP 12/18/2018; 59930, EXP 01/15/2019; 60592, 60648, EXP 02/26/2019; 60977, EXP 03/12/2019; 61022, EXP 03/19/2019; 61991, EXP 05/07/2019.
<b>Product Description:</b> Toothette Oral Care Suction Swab System with Perox-A-Mint Solution, Contains 6 Packages of 2 Suction Swabs with sodium, bicarbonate and a .25 fl oz/7ml pouch of Perox-A-Mint solution, 2 Packages of 1 Suction Toothbrush with sodium bicarbonate and a .25 fl oz/7ml pouch of Perox-A-Mint solution, 10 Applicator Swabs, .5 oz/14g tube of Mouth Moisturizer. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6552 UPC 6 18029 82115 7
<b>Product Quantity:</b> 5303 Cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0381-2018
<b>Code Information:</b> Product Code: 6552; Lots: 52573, 52926, 53596, EXP 10/03/2017; 53610, 54288, EXP 12/19/2017; 54723, EXP 02/27/2018; 55878, 55890, 56617, 56637, EXP 04/24/2018; 56644, 56647, 56652, 57299, 57317, EXP 06/12/2018; 57305, EXP 05/08/2018; 57321, 60919, 61943, 58386, EXP 08/07/2018; 58398, EXP 10/02/2018; 59723, EXP 10/16/2018; 59739, EXP 12/11/2018;
<b>Product Description:</b> Toothette Oral Care Suction Toothbrushes with Perox-A-Mint solution. Contains 2 Suction Toothbrushes with sodium bicarbonate, 0.25 fl oz/7ml Perox-A-Mint solution. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6570
<b>Product Quantity:</b> 6472 Cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0382-2018
<b>Code Information:</b> Product Code: 6570; Lots: 51571, EXP 08/15/2017; 52105, EXP 09/19/2017; 53077, EXP 11/14/2017; 54259, EXP 02/06/2018; 55243, 04/10/2018; 56167, EXP 06/12/2018; 56874, EXP 07/31/2018; 57748, EXP 09/18/2018; 59258, EXP 11/20/2018; 60144, EXP 11/27/2018; 61149, EXP 03/26/2019; 62084, EXP 05/14/2019.
<b>Product Description:</b> Toothette Oral Care Suction Toothbrushes with Perox-A-Mint solution. Contains 1 Suction toothbrush with sodium bicarbonate, 0.25 fl oz /7ml Perox-A-Mint solution. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6571
<b>Product Quantity:</b> 8466 Cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0383-2018
<b>Code Information:</b> Product Code: 6571; Lots: 52384, EXP 10/03/2018; 53134, EXP 11/28/2017; 53387, EXP 12/05/2017; 54215, EXP 02/06/2018; 54967, EXP 03/28/2018; 55997, EXP 05/30/2018; 56180, EXP 06/12/2018; 56854, EXP 07/31/2018; 57334, EXP 08/21/2018; 58305, EXP 10/16/2018; 59844, EXP 01/08/2019; 60753, 60761, 60772, 60780, 60788,EXP 03/05/2019; 61664, EXP 04/23/2019; 62156, EXP 05/14/2019.
<b>Product Description:</b> Toothette Oral Care Suction Toothbrush with Perox-A-Mint solution and Mouth Moisturizer. Contains 1 Suction Toothbrush with sodium Bicarbonate, 0.25 fl oz /7ml Perox-A-Mint solution, 0.07 oz/2g Mouth Moisturizer, 1 Applicator Swab, Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6572
<b>Product Quantity:</b> 10505 Cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0384-2018
<b>Code Information:</b> Product Code: 6572; Lots: 52349, 52367, 52370, 52438, EXP 10/03/2017; 52457, 52471, EXP 10/17/2017; 53106, EXP 11/14/2017; 53569, EXP 12/19/2017; 53945, EXP 01/30/2018; 54354, EXP 02/20/2018; 54950, EXP 03/28/2018; 55452, EXP 04/24/2018; 56131, EXP 06/12/2018; 56901, EXP 07/31/2018; 57791, EXP 09/18/2018; 58455, EXP 10/24/2018; 59447, EXP 12/11/2018; 59869, EXP 01/08/2019; 60887, EXP 03/12/2019; 61883, EXP 04/30/2019.
<b>Product Description:</b> Oral Cleansing & Suctioning System q2 with 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse. Contains 1 Covered Yankauer and Y-Connector, 2 Untreated Suction Toothbrush packages, 2 Single dose bottles of 0.12% CHG Oral Rinse, packages SYS W/CHG 10, Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6592
<b>Product Quantity:</b> 2424 Cases

<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0385-2018
<b>Code Information:</b> Product Code: 6592; Lots: 54071, EXP 10/31/2017; 54664, EXP 12/31/2017; 55007, EXP 11/30/2017; 55866, EXP 12/31/2017; 56487, 56516, 57057, EXP 02/28/2018; 58756, 58766, EXP 06/30/2018; 59618, EXP 07/31/2018; 60036, 60346, EXP 08/31/2019.
<b>Product Description:</b> Oral Cleansing & Suctioning System with 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse q2, Contains 1 Covered Yankauer and Y-Connector, 2 Untreated Suction Toothbrush packages, 2 Single dose bottles of 0.12% CHG Oral Rinse, 4 Packages Suction Oral Swab with sodium bicarbonate, Perox-A-Mint solution and Mouth Moisturizer, 6 Packages Suction Oral Swab with sodium bicarbonate, Alcohol Free Mouthwash and Mouth Moisturizer, 2 Oropharyngeal Suction Catheter packages. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6592-S UPC 6 18029 82133 1
<b>Product Quantity:</b> 25 Cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0386-2018
<b>Code Information:</b> Product Code: 6592-S; Lots: 62154 EXP 02/19/2019
<b>Product Description:</b> Oral Cleansing & Suctioning System with 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse q4, Contains 1 Covered Yankauer and Y-Connector, 2 Untreated Suction Toothbrush packages, 2 Single dose bottles of 0.12% CHG Oral Rinse, 4 Packages Suction Oral Swab with sodium bicarbonate, Perox-A-Mint solution and Mouth Moisturizer, 2 Oropharyngeal Suction Catheter packages. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6594 UPC 6 18029 82134 1
<b>Product Quantity:</b> 5138 Cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0387-2018
<b>Code Information:</b> Product Code: 6594; Lots: 53018, 53824, EXP 08/08/2017; 53023, EXP 08/31/2017; 53833, EXP 09/30/2017; 53949, EXP 10/03/2017; 54045, EXP 10/31/2017; 55087, 55169, EXP 11/30/2017; 54708, 55699; 55730; 55952; 56028; 56042, EXP 12/31/2017; 56540; 56945; 57345, EXP 02/28/2018; 57632; 57672, EXP 03/31/2018; 58428, EXP 04/30/2018; 58463, 58506, 58539, 58590, EXP 06/30/2018; 59137, 59395, 59442, EXP 07/31/2018; 60244, EXP 08/31/2018; 60709, 60778, EXP 09/30/2018; 61828, EXP 12/31/2018.
<b>Product Description:</b> Oral Cleansing & Suctioning System with 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse q2, Contains 1 Covered Yankauer and Y-Connector, 2 Untreated Suction Toothbrush packages, 2 Single dose bottles of 0.12% CHG Oral Rinse, 4 Packages Suction Oral Swab with sodium bicarbonate, Perox-A-Mint solution and Mouth Moisturizer, 2 Oropharyngeal Suction Catheter packages. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6594-S UPC 6 18029 82134 1
<b>Product Quantity:</b> 20 Cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0388-2018
<b>Code Information:</b> Product Code: 6594-S; Lots:52348, EXP 08/08/2017.
<b>Product Description:</b> Toothette Oral Care Q Care & Suctioning System. Contains 1 Covered Yankauer, Suction Handle and Y-Connector, 2 Suction Toothbrush packages with Perox-A-Mint solution, 10 Suction Oral Swab packages with Perox-A-Mint solution, 4 Oropharyngeal Suction Catheter packages. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6602 UPC 6 18029 84116 2
<b>Product Quantity:</b> 2408 Cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0389-2018
<b>Code Information:</b> Product Code: 6602; Lots: 52005, EXP 09/12/2017; 52917, EXP 11/07/2017; 53327, EXP 12/05/2017; 54186, EXP 02/06/2018; 55327, EXP 04/17/2018; 56169, EXP 06/12/2018; 57385, EXP 08/29/2018; 58564, EXP 10/30/2018; 60205, EXP 11/27/2018; 61033, EXP 03/19/2019; 61443, EXP 04/09/2019.
<b>Product Description:</b> Toothette Oral Care Suction Swabs with Perox-A-Mint solution. Contains 2 Suction Swabs with sodium bicarbonate, 0.25 fl oz/ 7ml Perox-A-Mint solution, 0.07 oz/2g Mouth Moisturizer, 1 Applicator Swab. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6613
<b>Product Quantity:</b> 4650 Cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products

products
<b>Recall Number:</b> D-0390-2018
<b>Code Information:</b> Product Code: 6613; Lots: 51330, EXP 08/08/2017; 52400, EXP 10/03/2017; 53198, EXP 11/28/2017; 54582, EXP 02/27/2018; 55837, EXP 05/22/2018, 57007, EXP 08/07/2018; 57904, EXP 09/25/2018; 58931, EXP 11/06/2018.
<b>Product Description:</b> Toothette Oral Care Suction Toothbrush with Perox-A-Mint solution. Contains 1 Suction Toothbrush with sodium bicarbonate, 0.25 fl oz/ 7ml Perox-A-Mint solution, 0.07 oz/2g Mouth Moisturizer, 1 Applicator Swab. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6671
<b>Product Quantity:</b> 4255 Cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0391-2018
<b>Code Information:</b> Product Code: 6671; Lots: 51716, EXP 08/22/2017; 52904, EXP 11/07/2017; 53686, EXP 01/03/2018; 54601, 54617, EXP 03/06/2018; 55377, EXP 04/24/2018; 56658, 07/17/2018; 57927, EXP 09/25/2018; 58936, EXP 11/06/2018; 59805, EXP 01/08/2019; 60691, EXP 03/05/2019; 61141, EXP 03/26/2019.
<b>Product Description:</b> Toothette Oral Care Suction Toothbrush with Antiseptic Oral Rinse. Contains 1 Suction Toothbrush with sodium bicarbonate, 0.25 fl oz/ 7ml Antiseptic Oral Rinse, 0.07 oz/2g Mouth Moisturizer, 1 Applicator Swab. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6673
<b>Product Quantity:</b> 672 Cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0392-2018
<b>Code Information:</b> Product Code: 6673; Lots: 57938, EXP 09/19/2017; 59802, EXP 01/08/2018; 61329, EXP 03/05/2018.
<b>Product Description:</b> Q.Care Petite Size Oral Cleansing & Suctioning System. Contains 1 Covered Yankauer, Suction Handle and Y-Connector, 2 Petit Size Suction Toothbrush packages with Antiseptic Oral Rinse, 4 Petit Size Untreated Suction Oral Swab packages with Antiseptic Oral Rinse, 2 8 French Oropharyngeal Suction Catheter packages. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6704 UPC 6 18029 84123 0
<b>Product Quantity:</b> 6726 Cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0393-2018
<b>Code Information:</b> Product Code: 6704; Lots: 58121, EXP 09/19/2017; 58771, EXP 10/09/2017; 59394, EXP 11/15/2017; 59400, EXP 12/15/2017; 60389, EXP 01/08/2018; 60453, 61087, EXP 01/22/2018; 61121, EXP 03/05/2018; 61579, EXP 04/17/2018.
<b>Product Description:</b> Q.Care Petite Size Oral Cleansing & Suctioning System. Contains 1 Covered Yankauer, and Y-Connector, 2 Petit Size Suction Toothbrushes, 7ml Antiseptic Oral Rinse, Applicator Swab and 2g Mouth Moisturizer, 4 Petit Size Untreated Suction Oral Swabs, 7ml Antiseptic Oral Rinse, Applicator Swab and 2g Mouth Moisturizer, 2 8 French Oropharyngeal Suction Catheter. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6714 UPC 6 18029 83038 8
<b>Product Quantity:</b> 2017 Cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0394-2018
<b>Code Information:</b> Product Code: 6714; Lots: 57979, EXP 09/19/2017; 58845, EXP 10/09/2017; 60215, EXP 01/08/2018; 61235, EXP 03/05/2018.
<b>Product Description:</b> Q.CareOral Cleansing & Suctioning System q2. Contains 1 Covered Yankauer Suction Handle and Y-Connector, 2 Suction Toothbrush packages with Antiseptic Solution,, 4 Suction Oral Swab packages with Perox-A-Mint solution, 6 Suction Oral Swab packages with Alcohol-Free Mouthwash, 4 Oropharyngeal Suction Catheter packages. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6802 UPC 6 18029 84120 9
<b>Product Quantity:</b> 2970 Cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0395-2018
<b>Code Information:</b> Product Code: 6802; Lots: 57509, EXP 08/14/2017; 58122, EXP 09/11/2017; 58203, EXP 10/02/2017; 58978, EXP 11/03/2018; 59724, EXP 11/27/2017; 6055

6, EXP 02/05/2018; 61241, EXP 02/23/2018;

**Product Description:**

Q.CARE Oral Cleansing & Suctioning System q4. Contains 1 Covered Yankauer, Suction Handle and Y-Connector, 2 Toothbrush packages with Antiplaque solution. 4 Suction Oral Swab packages with Perox-A-Mint solution. 2 Oropharyngeal Suction Catheter packages, Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6804 UPC 6 18029 84121 6

**Product Quantity:**

5085 Cases

**Reason for Recall:**

Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products

**Recall Number:**

D-0396-2018

**Code Information:**

Product Code: 6804; Lots: 57567, EXP 08/14/2017; 58163, EXP 09/11/2017; 59009, EXP 11/03/2017; 59637, EXP 11/27/2017; 60241, 60263, EXP 01/02/2018; 60631, EXP 02/05/2018; 61294,EXP 02/23/2018; 61321, EXP 03/30/2018.

**Product Description:**

Q.Care Oral Cleansing & Suctioning System q8. Contains 1 Covered Yankauer Suction Handle and Y-Connector, 2 Suction Toothbrush packages with Antiseptic Solution,, 1 Suction Oral Swab packages with Perox-A-Mint solution, 1 Oropharyngeal Suction Catheter package. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6808 UPC 6 18029 84122 3

**Product Quantity:**

2468 Cases

**Reason for Recall:**

Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products

**Recall Number:**

D-0397-2018

**Code Information:**

Product Code: 6808; Lots: 57592, EXP 08/14/2017; 58202, EXP 10/02/2017; 59213, EXP 11/13/2017; 60274, EXP 01/02/2018; 60718 EXP 02/05/2018; 61745, EXP 03/21/2018.

**Product Description:**

Q.Care Oral Cleansing & Suctioning System with 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse q4. Contains 1 Suction Handle, Covered Yankauer and Y-Connector, 2 Untreated Suction Toothbrush packages, 2 Single dose bottles of 0.12% CHG Oral Rinse, 4 Suction Oral Swab packages with Perox-A-Mint solution, 2 Oropharyngeal Suction Catheter packages. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6904 UPC 6 18029 83008 1

**Product Quantity:**

6130 Cases

**Reason for Recall:**

Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products

**Recall Number:**

D-0398-2018

**Code Information:**

Product Code: 6904; Lots: 52850, 53281, EXP 08/31/2017; 53300, 53579, EXP 09/30/2017; 54320, EXP 10/31/2017; 54960, EXP 11/30/2017; 55753, EXP 12/31/2017; 56914, EXP 02/28/2018; 57352, EXP 04/30/2018; 57836, EXP 03/31/2018; 58349, EXP 04/30/2018; 59578, EXP 07/31/2018; 60712, EXP 09/30/2018; 61274, EXP 12/31/2018.

**Product Description:**

Q.Care Oral Cleansing & Suctioning System with 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse q2. Contains 1 Covered Yankauer and Y-Connector, 2 Untreated Suction Toothbrush packages, 2 Single dose bottles of 0.12% CHG Oral Rinse, 4 Suction Oral Swab packages with Perox-A-Mint solution, 6 Suction Oral Swab packages with Alcohol-Free Mouthwash, 4 Oropharyngeal Suction Catheter packages. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6912-S UPC 6 18029 83016 6

**Product Quantity:**

60 Cases

**Reason for Recall:**

Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products

**Recall Number:**

D-0399-2018

**Code Information:**

Product Code: 6912-S; Lots: 54675, EXP 03/06/2018; 60933, EXP 03/12/2019.

**Product Description:**

Q.Care Oral Cleansing & Suctioning System with 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse q4. Contains 1 Covered Yankauer and Y-Connector, 2 Untreated Suction Toothbrush packages, 2 Single dose bottles of 0.12% CHG Oral Rinse, 4 Suction Oral Swab packages with Perox-A-Mint solution, 2 Suction Oral Swab packages with Alcohol-Free Mouthwash, 4 Oropharyngeal Suction Catheter packages. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6914 UPC 6 18029 83017 3

**Product Quantity:**

82072 Cases

**Reason for Recall:**

Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products

**Recall Number:**

D-0400-2018

**Code Information:**

Product Code: 6914; Lots: 52775, 52877, 52932, 53050, 53143, 53290, 53337, EXP 08/31/2017; 53345, 53418, 53454, 53488, 53609, 53830, 55373 EXP 09/30/2017; 53869, 53982, 53991, 53992, 53995, 54004, 54016, 54025, 54126, 54241, 54292, 54380, 54471, 54490, EXP 10/31/2017; 54504, 54594, 54674,

EXP 12/31/2017; 54841, 54867, 54974, 55108, EXP 11/30/2017; 55237, 55307, 55362, 55392, 55652, 55684, 55774, 55842, 56003, 56099, 56149, 56212, 56244, EXP 12/31/2017; 56285, 56467, 56538, 56545, 56553, 56563, 56578, 56720, 56747, 56758, 56768, 56779, 56798, 56811, 56881, 56935, 56990, 57038, 57103, 57266, 57470, 57327, EXP 02/28/2018; 57380, 57444, 57476, 57640, 57699, 57769, 57810, EXP 03/31/2018; 57862, 57990, 58055, 58128, 58172, 58333, 58390, 58418, EXP 04/30/2018; 58460, 58538, 58589, 58645, 58887, 58941, EXP 06/30/2018; 59171, 59275, 59350, 59403, 59616, 59684, EXP 07/31/2018; 59745, 59916, 59964, 60015, 60095, 60180, 60254, EXP 08/31/2018; 60451, 60521, 60763, 60833, 60885, 61045, EXP 09/30/2018; 61069, 61618, 61697, 61879, 61932, 61979, 62026, 62057, 62246, 61128, EXP 12/31/2018

<b>Product Description:</b> Q.Care Oral Cleansing & Suctioning System with 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse q4. Contains 1 Covered Yankauer and Y-Connector, 2 Untreated Suction Toothbrush packages, 2 Single dose bottles of 0.12% CHG Oral Rinse, 4 Suction Oral Swab packages with Perox-A-Mint solution, 2 Suction Oral Swab packages with Alcohol-Free Mouthwash, 4 Oropharyngeal Suction Catheter packages. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6914-S UPC 6 18029 83017 3
<b>Product Quantity:</b> 60 Cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0401-2018
<b>Code Information:</b> Product Code: 6914-S; Lots: 52435, EXP 10/03/2017, 57750, EXP 09/18/2018.

<b>Product Description:</b> Q.Care Oral Cleansing & Suctioning System Suction Toothbrush Compatible with Chlorhexidine Gluconate (CHG) Oral Rinse q2. Contains 1 Covered Yankauer and Y-Connector, 2 Untreated, CHG Compatible Suction Toothbrush packages, 4 Suction Oral Swab packages with Perox-A-Mint solution, 6 Suction Oral Swab packages with Alcohol-Free Mouthwash, 4 Oropharyngeal Suction Catheter packages. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6922 UPC 6 18029 83032 6
<b>Product Quantity:</b> 6461 Cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0402-2018
<b>Code Information:</b> Product Code: 6922; Lots: 51408, EXP 08/10/2017; 51701, EXP 08/22/2017; 52782, EXP 10/31/2018; 53083, EXP 11/14/2017; 53746, EXP 01/09/2018; 54210, EXP 02/06/2018; 54868, EXP 03/21/2018; 55294, XP 04/17/2018; 55930, EXP 05/30/2018;56555, EXP 07/12/2018; 57519, EXP 09/05/2018; 58373, EXP 10/16/2018; 59542, EXP 12/11/20178; 60611, EXP 02/26/2019; 61148, EXP 03/26/2019; 61623, EXP 04/17/2019

<b>Product Description:</b> Q.Care Oral Cleansing & Suctioning System Suction Toothbrush Compatible with Chlorhexidine Gluconate (CHG) Oral Rinse q2. Contains 1 Covered Yankauer and Y-Connector, 2 Untreated, CHG Compatible Suction Toothbrush packages, 4 Suction Oral Swab packages with Perox-A-Mint solution, 6 Suction Oral Swab packages with Alcohol-Free Mouthwash, 4 Oropharyngeal Suction Catheter packages. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6922-B UPC 6 18029 83032 6
<b>Product Quantity:</b> 480 Cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0403-2018
<b>Code Information:</b> Product Code: 6922-B; Lots: 53070, EXP 08/31/2017; 54452, EXP 10/31/2017; 56283, EXP 12/31/2017; 57710, EXP 02/28/2018; 58350, EXP 04/30/2018; 59528, 59539 EXP 07/31/2018; 60468, EXP 08/31/2018.

<b>Product Description:</b> Q.Care Oral Cleansing & Suctioning System Suction Toothbrush Compatible with Chlorhexidine Gluconate (CHG) Oral Rinse q4. Contains 1 Covered Yankauer and Y-Connector, 2 Untreated Suction Toothbrush packages, 4 Suction Oral Swab packages with Perox-A-Mint solution, 2 Oropharyngeal Suction Catheter packages. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6924 UPC 6 18029 83033 3
<b>Product Quantity:</b> 16639 Cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0404-2018
<b>Code Information:</b> Product Code: 6924; Lots: 51601, EXP 08/15/2017; 52138, EXP 09/19/2017; 52836, 52935, EXP 11/07/2017; 53531, EXP 12/12/2017; 53788, EXP 01/09/2018; 54388, EXP 02/20/2018; 54796, 54816, EXP 3/13/2018; 55130, 55171, EXP 04/03/2018; 55323, EXP 04/17/2018; 55400, EXP 04/24/2018; 56049, EXP 06/05/2018; 56191, EXP 06/12/2018; 56330, EXP 06/19/2018; 56856, EXP 07/31/2018; 57437, EXP 08/29/2018; 57876, EXP 09/25/2018; 58707, EXP 11/06/2018; 59126, EXP 11/13/2018; 59607, EXP 12/11/2018; 60255, EXP 11/27/2018; 60273, EXP 01/22/2019; 60871, 03/05/2019; 61058, EXP 03/19/2019; 61676, EXP 04/23/2019.

<b>Product Description:</b> Q.Care Oral Cleansing & Suctioning System Suction Toothbrush Compatible with Chlorhexidine Gluconate (CHG) Oral Rinse q4. Contains 1 Covered Yankauer and Y-Connector, 1 Untreated Suction Toothbrush packages, 2 Single dose bottles of 0.12% CHG Oral Rinse, 4 Suction Oral Swab packages with Corinz Antiseptic Cleansing and Moisturizing Oral Rinse, 2 Oropharyngeal Suction Catheter packages. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6964 UPC 6 18029 83075 3
<b>Product Quantity:</b> 3928 Cases

<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0405-2018
<b>Code Information:</b> Product Code: 6964; Lots: 56718, EXP 09/26/2017; 57387, 57414, 57423, EXP 11/13/2017; 58272, EXP 04/03/2018; 59592, EXP 07/16/2018; 60142, EXP 08/02/2018; 60541, EXP 09/04/2018; 60767, EXP 09/06/2018; 61159, EXP 09/11/2018; 61467, EXP 10/16/2018; 62075, EXP 11/12/2018.
<b>Product Description:</b> Q Care RX Petite Oral Cleansing & Suctioning System with 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse. Contains 1 Covered Yankauer and Y-Connector, 2 Untreated Petite Suction Toothbrush packages, 2 Single dose bottles of 0.12% CHG Oral Rinse, 4 Petite Suction Oral Swab packages with Corinz Antiseptic Cleansing and Moisturizing Oral Rinse, 2 Oropharyngeal Suction Catheter packages. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6974 UPC 6 18029 83097 5
<b>Product Quantity:</b> 633 Cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0406-2018
<b>Code Information:</b> Product Code: 6974; Lots: 58322, 58649, EXP 04/03/2018; 60186, EXP 08/02/2018; 60747, EXP 09/06/2018.
<b>Product Description:</b> Q Care RX Petite Oral Cleansing & Suctioning System with 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse. Contains 1 Covered Yankauer and Y-Connector, 2 Untreated Petite Suction Toothbrush packages, 2 Single dose bottles of 0.12% CHG Oral Rinse, 4 Petite Suction Oral Swab packages with Corinz Antiseptic Cleansing and Moisturizing Oral Rinse, 2 Oropharyngeal Suction Catheter packages. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6974-S UPC 6 18029 83097 5
<b>Product Quantity:</b> 25 Cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0407-2018
<b>Code Information:</b> Product Code: 6974-S; Lots: 58317, EXP 04/03/2018.
<b>Product Description:</b> Q Care Oral Cleansing & Suctioning System compatible with 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse. Contains 1 Covered Yankauer and Y-Connector, 2 Untreated Suction Toothbrush packages, 4 Suction Oral Swab packages with Corinz Antiseptic Cleansing and Moisturizing Oral Rinse, 2 Oropharyngeal Suction Catheter packages. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 6994 UPC 6 18029 83094 4
<b>Product Quantity:</b> 1273 Cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0408-2018
<b>Code Information:</b> Product Code: 6994; Lots: 58092, EXP 12/11/2017; 60090, EXP 07/30/2018; 60663, EXP 09/06/2018; 61261, EXP 09/11/2018; 61947, EXP 11/12/2018
<b>Product Description:</b> Q Care RX Oral Cleansing & Suctioning System with 0.12% Chlorhexidine Gluconate (CHG) Oral Rinse. Contains 1 Covered Yankauer and Y-Connector, 1 Untreated Suction Toothbrush packages, 1 Single dose bottle of 0.12% CHG Oral Rinse, 2 Suction Oral Swab packages with Perox-A-Mint, 1 Oropharyngeal Suction Catheter packages. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 9002 UPC 6 18029 83025 8
<b>Product Quantity:</b> 4298 Cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0409-2018
<b>Code Information:</b> Product Code: 9002; Lots: 52886, EXP 08/31/2017; 53688, EXP 09/30/2017; 54468, EXP 10/31/217; 55221, 55230, EXP 11/30/2017; 56320, EXP 2/28/2018; 57367, 58083, EXP 04/30/2018; 58969, EXP 06/30/2018; 59906, EXP 08/31/2018; 61138, EXP 12/31/2018; 61881, EXP 12/13/2018
<b>Product Description:</b> Skin antisepsis and oral cleansing. Contains Three 2-packs of 2% Chlorhexidine Gluconate Cloth Patient Preoperative Skin Preparation and One 7ml Burst Pouch of Corinz Antiseptic Cleansing and Moisturizing Oral Rinse, I Ultra-Soft Toothbrush, 1 Applicator Swab treated with Sodium Bicarbonate. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 9009 UPC 6 18029 79140 5
<b>Product Quantity:</b> 150 Cases
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products

<b>Recall Number:</b> D-0410-2018
<b>Code Information:</b> Product Code: 9009; Lots: 60354, EXP 04/01/2018.

<b>Product Description:</b> Nose to Toes Skin Antisepsis, Oral Cleansing and Nasal Antisepsis System. Contains: Three 2-packs of 2% Chlorhexidine Gluconate Cloth Patient Preoperative Skin Preparation and One 7ml Burst Pouch of Corinz Antiseptic Cleansing and Moisturizing Oral Rinse, I Ultra-Soft Toothbrush, 1 Applicator Swab treated with Sodium Bicarbonate. 1 Bottle of 3M Skin and Nasal Antiseptic (Povidone-Iodine Solution 5%w/w (0.5%available iodine) USP) Patient Preoperative Skin Preparation 0.14 fl oz (4ml), 4 sterile swabs. Sage Products, Inc., 3909 Three Oaks Road, Cary, IL 60013. Product Code 9010 UPC 6 18029 79139 9
<b>Product Quantity:</b>
<b>Reason for Recall:</b> Cross Contamination With Other Products: Oral care solutions were manufactured by a third party supplier on equipment shared with non-pharmaceutical products
<b>Recall Number:</b> D-0411-2018
<b>Code Information:</b> Product Code: 9010; Lots: 60298, 60352, EXP 04/01/2018

Class II Drugs Event

<b>Event ID:</b> 78811	<b>Product Type:</b> Drugs
<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 12/22/2017	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated
<b>Center Classification Date:</b> 02/15/2018	<b>Initial Firm Notification of Consignee or Public:</b> Letter
<b>Recalling Firm:</b> Hetero Labs Limited Unit V Unit V (SEZ Unit I in APIIC SEZ) Surv. No. 439-441, 458, Polepally Vill. Jadcherla Mandal, Mahaboob Nagar India	
<b>Distribution Pattern:</b> Nationwide in the USA.	

Associated Products

<b>Product Description:</b> Famciclovir Tablets, 500 mg, 30-count bottles, Rx Only, Manufactured For: Camber Pharmaceuticals. Inc. Piscataway, NJ 08854 By: HETERO, Hetero Labs Limited, Unit V, Polepally, Jadcherla, Mahaboob Nagar-509 301, India. NDC 31722-708-30
<b>Product Quantity:</b> 8,436 bottles
<b>Reason for Recall:</b> Temperature Abuse: Complaints of tablets being wet and stuck together with tablet coating peeled and disintegrated.
<b>Recall Number:</b> D-0415-2018
<b>Code Information:</b> Lot # FMC17039, Exp 07/2019.

Class III Drugs Event

<b>Event ID:</b> 78666	<b>Product Type:</b> Drugs
<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 11/30/2017	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated
<b>Center Classification Date:</b> 02/12/2018	<b>Initial Firm Notification of Consignee or Public:</b> Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit
<b>Recalling Firm:</b> BYL Solutions Inc. 1301 10th St E Ste A Palmetto FL United States	
<b>Distribution Pattern:</b> Nationwide	

Associated Products

<b>Product Description:</b> Bull Capsules, 1800 mg/grain, 30 count per tin, Hongkong Jiuyuejiu Biology Technology CO., LTD, BYL Solutions, Inc. dba Nutra Labs, Inc., Palmetto, FL
<b>Product Quantity:</b> 329 tins

<b>Reason for Recall:</b> Marketed without an Approved NDA/ANDA; product found to be tainted with sildenafil
<b>Recall Number:</b> D-0414-2018
<b>Code Information:</b> All lots remaining within expiry.

Class III Drugs Event

<b>Event ID:</b> 79080	<b>Product Type:</b> Drugs
<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 02/02/2018	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated
<b>Center Classification Date:</b> 02/09/2018	<b>Initial Firm Notification of Consignee or Public:</b> Letter
<b>Recalling Firm:</b> ALLERGAN 1 Giralda Farms Madison NJ United States	
<b>Distribution Pattern:</b> Nationwide in the USA	

Associated Products

<b>Product Description:</b> NORCO (Hydrocodone Bitartrate and Acetaminophen) Tablets, USP, 10 mg/325 mg, 100-count bottles, Rx Only, Distributed by: Allergan USA, Inc., Irvine, CA 92612, NDC 0023-6022-01.
<b>Product Quantity:</b> 8 bottles
<b>Reason for Recall:</b> Labeling: Not Elsewhere Classified: does not have the required "CII" controlled drug classification indication on the primary label.
<b>Recall Number:</b> D-0413-2018
<b>Code Information:</b> Lot # 544821A, Exp 07/19

Class III Drugs Event

<b>Event ID:</b> 79145	<b>Product Type:</b> Drugs
<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 02/05/2018	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated
<b>Center Classification Date:</b> 02/13/2018	<b>Initial Firm Notification of Consignee or Public:</b> Letter
<b>Recalling Firm:</b> Sun Pharmaceutical Industries, Inc. 270 Prospect Plains Rd Cranbury NJ United States	
<b>Distribution Pattern:</b> Nationwide	

Associated Products

<b>Product Description:</b> Azelastine HCl Nasal Solution (Nasal Spray) 0.1% (137 mcg per spray), 30 mL, Rx only, Distributed by: Sun Pharmaceutical Ind. Inc. Cranbury, NJ 08512 Manufactured by: Sun Pharmaceutical Ind. Ltd. Halol-Baroda Highway, Halol - 389 350, Gujarat, India --- NDC 47335-779-91
<b>Product Quantity:</b> 17554 bottles
<b>Reason for Recall:</b> Sun Pharmaceutical is recalling Azelastine HCl Nasal Solution, 0.1% (30 mL Bottle) following a failure to meet the % RSD requirement in the test for Droplet Size during the 6 month long term stability test station
<b>Recall Number:</b> D-0417-2018
<b>Code Information:</b> JKR7706A December 2018 JKR7705A November 2018

Class III Drugs Event



<b>Event ID:</b> 79172	<b>Product Type:</b> Drugs
<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 02/07/2018	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated
<b>Center Classification Date:</b> 02/14/2018	<b>Initial Firm Notification of Consignee or Public:</b> Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit
<b>Recalling Firm:</b> Webbrx dba RxPalace.com 501 N Beneva Rd Ste 550 Sarasota FL United States	
<b>Distribution Pattern:</b> NY	

Associated Products

<b>Product Description:</b> BonaDur For Men (lidocaine) spray, 10 mg per spray, Net Contents .25 fl. oz. (7.4 mL) spray bottles, Manufactured by WebRx Pharmacy Palace, Sarasota, FL 34232; NDC 70582-999-74
<b>Product Quantity:</b> 1 bottle
<b>Reason for Recall:</b> CGMP Deviations: not manufactured according to current good manufacturing practices.
<b>Recall Number:</b> D-0421-2018
<b>Code Information:</b> Lot: 17JXIII, Exp. 12/31/2019

Class III Drugs Event

<b>Event ID:</b> 79175	<b>Product Type:</b> Drugs
<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 02/05/2018	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated
<b>Center Classification Date:</b> 02/13/2018	<b>Initial Firm Notification of Consignee or Public:</b> Letter
<b>Recalling Firm:</b> Genentech, Inc. 1 Dna Way South San Francisco CA United States	
<b>Distribution Pattern:</b> Distributed throughout the United States	

Associated Products

<b>Product Description:</b> Klonopin (clonazepam) 0.5 mg Tablets, 100-count bottle, Rx only. Made in Canada, Distributed by Genentech USA, Inc. A Member of the Roach Group, 1 DNA Way South San Francisco, CA 94080-4990. NDC 0004-0068-01
<b>Product Quantity:</b> 3,192 bottles
<b>Reason for Recall:</b> Labeling: Not Elsewhere Classified: Schedule IV controlled substance indicator of CIV being omitted from the product carton, primary label is correct.
<b>Recall Number:</b> D-0416-2018
<b>Code Information:</b> Lot # 3141989, EXP 08/31/2019

Not Yet Classified Drugs Event

<b>Event ID:</b> 79036	<b>Product Type:</b> Drugs
<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 01/19/2018	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated
<b>Center Classification Date:</b>	<b>Initial Firm Notification of Consignee or Public:</b> Letter
<b>Recalling Firm:</b> AMERICAN HEALTH PACKAGING	

2550 John Glenn Ave Ste A  
Columbus OH United States

**Distribution Pattern:**  
Nationwide in the USA

Associated Products

<b>Product Description:</b> Aripiprazole Tablets, USP, 10 mg, 100 Tablets (10 x 10) unit dose blisters [NDC60687-179-11; UPC (01) 003 60687 179 11 7] per carton (NDC 60687-179-01), Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217.
<b>Product Quantity:</b> 270 cartons
<b>Reason for Recall:</b> Failed Dissolution Specifications: Sub-recall of the manufacturer's recall due to dissolution failure.
<b>Recall Number:</b>
<b>Code Information:</b> Lot #: 174096, Exp 05/31/19

Not Yet Classified Drugs Event

<b>Event ID:</b> 79118	<b>Product Type:</b> Drugs
<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 02/05/2018	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated
<b>Center Classification Date:</b>	<b>Initial Firm Notification of Consignee or Public:</b> Letter
<b>Recalling Firm:</b> Teva Pharmaceuticals USA 1090 Horsham Rd North Wales PA United States	
<b>Distribution Pattern:</b> Distributed throughout the United States	

Associated Products

<b>Product Description:</b> Fluoxetine Tablets USP, 10 mg, 30-count bottle, Rx only, Manufactured in Israel by: Teva Pharmaceuticals IND, LTD, Jerusalem, 9777402, Israel, Manufactured for: Teva Pharmaceuticals USA, INC., North Wales, PA 19454, NDC 0093-7188-56
<b>Product Quantity:</b> 1,157,095 bottles
<b>Reason for Recall:</b> Failed impurities/ degradation specifications: Teva Pharmaceuticals USA, Inc. is voluntarily recalling all lots within expiry due to out of specification (OOS) test result for the lactoside impurity obtained during routine stability testing activities.
<b>Recall Number:</b>
<b>Code Information:</b> All lots within expiry. Lot # 732259, 732260, 732261, 732262, 732263, 732264, 732265, 732266, 732267, 732268, 732269, 732270, 732272, 732273, 732274, 732275, 732276, 732277, 732278, 732280, 732281, 732282, 732283, 732284, 732285, 732286, 732287, 732288, 732289, 732293, 732294, 732296, 732297, 732295, 732298, 732299, 732300, 732301

Not Yet Classified Drugs Event

<b>Event ID:</b> 79168	<b>Product Type:</b> Drugs
<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 01/12/2018	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated
<b>Center Classification Date:</b>	<b>Initial Firm Notification of Consignee or Public:</b> Letter
<b>Recalling Firm:</b> The Compounding Pharmacy of America 6216 Highland Place Way Ste 101-A Knoxville TN United States	
<b>Distribution Pattern:</b> TN, SC	

Associated Products

<b>Product Description:</b> HCG 5,000 IU/mL + Methylcobalamin 500 mc/mL Injection **5 mL Multi-Dose Vial, Sterile, Refrigerate** 6216 Highland Place Way, Ste. 101A Knoxville, TN 37919 Ph (855) 277-2488 Fax (888) 689-9892
<b>Product Quantity:</b> 5 vials

**Reason for Recall:**  
Lack of sterility assurance.

**Recall Number:**

**Code Information:**  
Lot: 01052018@46 Use By: 2/9/2018