CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

018892Orig1s038

Trade Name:	SODIUM PHOSPHATES
Generic or Proper Name:	(Disodium Hydrogen Phosphate (Dibasic Sodium Phosphate) and Monosodium Phosphate Monohydrate (Monobasic Sodium Phosphate)
Sponsor:	HOSPIRA INC.
Approval Date:	November 30, 2023
Indication:	Sodium Phosphates Injection, USP, 3 mM P/mL is indicated as a source of phosphorus, for addition to large volume intravenous fluids, to prevent or correct hypophosphatemia in patients with restricted or no oral intake. It is also useful as an additive for preparing specific parenteral fluid formulas when the needs of the patient cannot be met by standard electrolyte or nutrient solutions. The concomitant amount of sodium (Na+ 4 mEq/mL) must be calculated into total electrolyte dose of such prepared solutions.

CENTER FOR DRUG EVALUATION AND RESEARCH

018892Orig1s038

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APPLICATION NUMBER:

018892Orig1s038

APPROVAL LETTER

See List of Applications

APPROVAL LETTER

Hospira Inc
Attention: Angela LeCaptain
Director, Pfizer Global Regulatory Affairs
275 North Field Drive
Bldg H1
Lake Forest, IL 60045

Dear Angela LeCaptain:

Please refer to your supplemental New Drug Application(s) (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA), and your supplemental Abbreviated New Drug Application(s) (sANDAs) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following products:

Supplemental Application	Product Information	Submit Date	FDA Received Date
NDA 018800/S-041	Bacteriostatic 0.9% Sodium Chloride Injection, USP	June 2, 2023	June 2, 2023
NDA 018801/S-056	Sterile Water for Injection, USP	June 2, 2023	June 2, 2023
NDA 018802/S-042	Bacteriostatic Water for Injection, USP	June 2, 2023	June 2, 2023
NDA 018803/S-062	0.9% Sodium Chloride Injection, USP	June 2, 2023	June 2, 2023
NDA 018892/S-038	Sodium Phosphates Injection, USP	June 2, 2023	June 2, 2023
NDA 018893/S-043	Sodium Acetate Injection, USP	June 2, 2023	June 2, 2023
NDA 018895/S-031	TPN Electrolytes Injection	June 2, 2023	June 2, 2023
NDA 018896/S-036	Potassium Acetate Injection, USP	June 2, 2023	June 2, 2023
NDA 018897/S-041	14.6% Sodium Chloride Injection, USP	June 2, 2023	June 2, 2023
NDA 018959/S-030	Zinc Chloride Injection, USP	June 2, 2023	June 2, 2023
NDA 018960/S-027	Copper Chloride (Cupric Chloride Injection, USP)	June 2, 2023	June 2, 2023

NDA 018961/S-029	Chromium Trichloride (Chromic Chloride Injection, USP)	June 2, 2023	June 2, 2023
NDA 018962/S-029	Manganese Chloride Injection, USP	June 2, 2023	June 2, 2023
ANDA 080205/S-109	Potassium Chloride for Injection Concentrate, USP	June 2, 2023	June 2, 2023
ANDA 202432/S-009	Sodium Bicarbonate Injection	June 2, 2023	June 2, 2023
ANDA 202981/S-006	Sodium Bicarbonate Injection	June 2, 2023	June 2, 2023

These "Changes Being Effected in 30 days" supplemental new drug applications provide for:

- Addition of an alternate Elastomeric Closure (b) (4) (b) (4) for drug products packaged in glass and plastic vials manufactured at the Hospira manufacturing facility in Rocky Mount, North Carolina.
- Removal of the (b) (4) (b) (4).

APPROVAL

We have completed our review of these supplemental applications. These supplements are approved.

We remind you that you must comply with reporting requirements for an approved NDA and ANDA set forth under 21 CFR 314.80 and 314.81.

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website as https://www.uspnf.com/.

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements

regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas.

If you have any questions, contact Megan Nguyen, Regulatory Business Process Manager, at Megan.Nguyen@fda.hhs.gov or (301) 796 - 7826.

Sincerely,

{See appended electronic signature page}

David B. Lewis, Ph.D.
Branch Chief, B2
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

David
Lewis

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APPLICATION NUMBER:

018892Orig1s038

LABELING

ADVERSE REACTIONS

OVERDOSAGE

DOSAGE AND ADMINISTRATION

HOW SUPPLIED

Unit of Sale	Concentration	Unit of Use
[illegible]	[illegible]	[illegible]

Hospira

SODIUM PHOSPHATES

Injection, USP

45 mM P in 15 mL

(3 mM P and 4 mEq Na^+/mL)

FOR ADDITIVE USE ONLY AFTER DILUTION IN I.V. FLUIDS

Plastic Vial

Rx only

DESCRIPTION

EN-5840

(b) (4)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

018892Orig1s038

PRODUCT QUALITY REVIEW(S)

U.S. FOOD & DRUG ADMINISTRATION

CHAPTER VII: MICROBIOLOGY

For more details about the items in this template, please see Chapter VII (Microbiology) of the NDA IQA Guide

Product Information	Indicated only for diluting or dissolving drugs for intravenous, intramuscular, or subcutaneous injection, according to instructions of the manufacturer of the drug to be administered.
NDA Number	018800/S-041 (Grouped supplement, see list below)
Assessment Cycle Number	MR01
Drug Product Name/ Strength	NDA 018800 Bacteriostatic 0.9% Sodium Chloride Injection, USP NDA 018801 Sterile Water for Injection, USP NDA 018802 Bacteriostatic Water for Injection, USP NDA 018803 0.9% Sodium Chloride Injection, USP NDA 018892 Sodium Phosphates Injection, USP NDA 018893 Sodium Acetate Injection, USP NDA 018895 TPN Electrolytes Injection NDA 018896 Potassium Acetate Injection, USP NDA 018897 14.6% Sodium Chloride Injection, USP NDA 018959 Zinc Chloride Injection, USP NDA 018960 Copper Chloride (Cupric Chloride Injection, USP) NDA 018961 Chromium Trichloride (Chromic Chloride Injection, USP) NDA 018962 Manganese Chloride Injection, USP
Route of Administration	Intravenous, intramuscular, subcutaneous injections
Applicant Name	Hospira, Inc.
Therapeutic Classification/ OND Division	CDER/OND/OII/DHN
Manufacturing Site	Hospira, Inc., Highway 301 North, Rocky Mount, NC 27801
Method of Sterilization	(b) (4)

Assessment Recommendation: **Adequate**

Assessment Summary: **The applicant proposes adding alternate stoppers and removing** [redacted]

List Submissions Being Assessed (table):

Document(s) Assessed	Date Received
eCTD sequence #0040	06/02/2023

Highlight Key Issues from Last Cycle and Their Resolution: N/A

Remarks: This is a grouped CBE-30 covering multiple [redacted] **injectable products manufactured at the Rocky Mount, NC facility.**

Concise Description of Outstanding Issues *(list bullet points with key information and update as needed)*: None

Supporting Documents: None

CHANGES PROPOSED IN THE SUPPLEMENTAL APPLICATION

In this grouped CBE-30, the applicant proposes the following changes:

1. Adding alternate stoppers with [redacted] for all drug products packaged in glass and plastic vials manufactured at Rocky Mount, NC facility. The approved stoppers have [redacted]
2. Removing the [redacted]

INFORMATION TO SUPPORT CHANGES

Summary of approved and proposed stoppers
(eCTD seq #0040, Section 1.11.1: summ-changes, pages 2-7/10)

Comparison of the approved and proposed stoppers are provided in the tables below. These stoppers have identical near/identical dimensions and differ in formulation only.

Formulation	(b) (4)
	(b) (4)

Formulation	(b) (4) (b) (4)

Assessment: *Adequate*

The applicant provided an adequate description of the proposed stoppers.

Container/closure and package integrity

Container closure integrity test results for the proposed alternate stoppers are not provided.

Note to reviewer: Because the dimensions of the approved and proposed stoppers are identical/near identical, new studies will not be requested.

Assessment: *Adequate*

The stoppers are adequate to support container closure integrity.

Component Depyrogenation
(eCTD seq #0040, Section 1.11.1: summ-changes, page 9/10)

The approved stopper (b) (4) (b) (4) The applicant proposes (b) (4)

(b) (4) Per the applican (b) (4) (b) (4)

Assessment: *N/A*

Release and stability testing
(eCTD seq #0040, Section 3.2.P.5.4, batch-analyses-018800, pages 1-4/4; Section 3.2.P.8.1, stabilty-summary-018800, pages 1-10/10)

The applicant provided results from release and stability testing for three pilot scale batches of representative products for the subject drug products. The representative products were selected based on (b) (4) (b) (4) (b) (4) The three batches are 42-203-SB (NDA 018961), 38-290-SB (NDA 018892), and 42-277-SB (NDA 018801).

All three batches met the acceptance criteria for sterility and endotoxin testing at release and throughout stability under long-term (b) (4) and accelerate (b) (4) conditions.

Assessment: *Adequate*

The applicant provided release and stability data to support the change in stoppers.

MICROBIOLOGY LIST OF DEFICIENCIES

None

Primary Microbiology Assessor Name and Date: Renee A. Marcsisin, Ph.D., 10/30/2023

Secondary Assessor Name and Date (and Secondary Summary, as needed): Bethanie Lee, Ph.D., 10/30/2023

Renee Marcsisin

Digitally signed by Renee Marcsisin
Date: 10/31/2023 01:00:15PM
GUID: 58a215b40087203411c81698f83c8632

Bethanie Lee

Digitally signed by Bethanie Lee
Date: 10/31/2023 01:03:23PM
GUID: 5a9d84b3000e5ae45e6f6044896c5811

Office of Lifecycle Drug Products
Division of Post-Marketing Activities I
Review of Chemistry, Manufacturing, and Controls

1. **NDA Supplement Number:** NDA-018800-SUPPL-41 (lead), NDA-018801-SUPPL-56, NDA-018802-SUPPL-42, NDA-018803-SUPPL-63, NDA-018892-SUPPL-38, NDA-018893-SUPPL-43, NDA-018895-SUPPL-31, NDA-018896-SUPPL-36, NDA-018897-SUPPL-41, NDA-018959-SUPPL-30, NDA-018960-SUPPL-27, NDA-018961-SUPPL-29, NDA-018962-SUPPL-29, and ANDA group 1992135. Group ID 1992411. ANDA group 1992135 includes ANDA-080205-SUPPL-109, ANDA-202432-SUPPL-9, and ANDA-202981-SUPPL-6.
   sNDA Recommendation: Approval
   sNDA Managed by: OPQ

2. **Submission(s) Being Reviewed**:

Submission	Type	Submission Date	CDER Stamp Date	Assigned Date	PDUFA Goal Date	Review Date
Original Supplement	CBE-30	06/02/2023	06/02/2023	06/07/2023	12/02/2023	11/30/2023

   Group 1992411 includes NDA-018800-SUPPL-41 (lead), NDA-018801-SUPPL-56, NDA-018802-SUPPL-42, NDA-018803-SUPPL-63, NDA-018892-SUPPL-38, NDA-018893-SUPPL-43, NDA-018895-SUPPL-31, NDA-018896-SUPPL-36, NDA-018897-SUPPL-41, NDA-018959-SUPPL-30, NDA-018960-SUPPL-27, NDA-018961-SUPPL-29, NDA-018962-SUPPL-29, and ANDA group 1992135. ANDA group 1992135 includes ANDA-080205-SUPPL-109, ANDA-202432-SUPPL-9, and ANDA-202981-SUPPL-6.

3. **Provides For:**
   - Addition of an alternate Elastomeric Closur (b) (4) (b) (4) for drug products packaged in glass and plastic vials manufactured at the Hospira manufacturing facility in Rocky Mount, North Carolina.
   - Removal o (b) (4) (b) (4)

4. **Review #**: 1

5. **Clinical Review Division**: CDER/OND/ON/DHN

6. **Name and Address of Applicant**:
   Hospira, Inc.
   275 North Field Drive
   Bldg. H1
   Lake Forest, IL 60045
   USA

7. Drug Product:

Drug Name	Dosage Form	Strength	Route of Administration	Rx or OTC	Special Product
Bacteriostatic 0.9% Sodium Chloride Injection, USP	Injectable	9 mg/mL	Injection (I.V., I.M., S.C.)	Rx	No

8. Chemical Name and Structure of Drug Substance:

NaCl	USAN: Sodium chloride, USP Chemical name: Sodium chloride Molecular formula: NaCl Molecular weight: 58.44 g/mol CAS No.: *7647-14-5*

9. Indication: This parenteral preparation is indicated only for diluting or dissolving drugs for intravenous, intramuscular or subcutaneous injection, according to instructions of the manufacturer of the drug to be administered.

10. Supporting/Relating Documents: See pages 5 to 11.

11. Consults:

- Request the Microbiology to review of the Section P.2.3 and Section P.3.3.
  The supplement is recommended for approval from the sterile assurance standpoint based on the microbiology review by Renee A. Marcsisin, Ph.D., dated 10/30/23.

- Request Pharmacology/Toxicology consult to evaluat (b) (4) Extractables Study Report, Extractables and Leachables Assessment, safety assessment report in Section P.2.4
  From a nonclinical perspective, each of the submitted NDA manufacturing supplements should be approved based on the Pharmacology/Toxicology consult review by Rosalyn A. Jurjus, dated 11/07/2023.

  Division of Pharmacology/Toxicology Review (DPTR) in the Office of Generic Drugs concludes that extractables originating from the (b) (4) stopper identified in the submitted extractable study do not pose a safety risk at their respective exposures in the following generic applications: A080205 (potassium chloride for injection concentrate), A202432 (8.4% sodium bicarbonate injection), and A202981 (4.2% sodium bicarbonate injection) based on the Pharmacology/Toxicology consult review by Vincent Crowley, PhD, dated 11/30/2023.

12. Executive Summary:
This grouped Changes Being Effected in 30 days (CBE-30) supplement provides for the addition of an alternate Elastomeric Closure (b) (4) for drug products packaged in glass and plastic vials manufactured at the Hospira facility in Rocky Mount, North Carolina. Currently, these products are packaged in vials closed with (b) (4) In addition, the applicant provides for

removal o [redacted] For the purpose of this drug product review, NDA-018800-SUPPL-41 is serving as the lead supplement for Group 1992411, which also includes NDA-018801-SUPPL-56, NDA-018802-SUPPL-42, NDA-018803-SUPPL-63, NDA-018892-SUPPL-38, NDA-018893-SUPPL-43, NDA-018895-SUPPL-31, NDA-018896-SUPPL-36, NDA-018897-SUPPL-41, NDA-018959-SUPPL-30, NDA-018960-SUPPL-27, NDA-018961-SUPPL-29, NDA-018962-SUPPL-29, and ANDA group 1992135. ANDA group 1992135 includes ANDA-080205-SUPPL-109, ANDA-202432-SUPPL-9, and ANDA-202981-SUPPL-6.

The supplement is recommended for approval from the sterile assurance standpoint based on the microbiology review by Renee A. Marcsisin, Ph.D., dated 10/30/23. From a nonclinical perspective, each of the submitted NDA manufacturing supplements should be approved based on the Pharmacology/Toxicology consult review by Rosalyn A. Jurjus, dated 11/07/2023. DPTR concludes that extractables originating from the [redacted] stopper identified in the submitted extractable study do not pose a safety risk at their respective exposures in the following generic applications: A080205, A202432, and A202981 based on the Pharmacology/Toxicology consult review by Vincent Crowley, PhD, dated 11/30/2023. The proposed use of the [redacted] stopper in the container closure systems is acceptable based on the microbiology reviewer's evaluation, the Pharmacology/ Toxicology reviewer's evaluation, and this CMC reviewer's evaluation.

[redacted] stopper is [redacted] wherea [redacted] stopper and [redacted] stopper are [redacted] and are supplied by the same vendor, [redacted] > testing has been carried out by the Vizag facility o [redacted] stopper to demonstrate conformance to the acceptance criteria for physicochemical tests, biological and functional tests. DMF [redacted] was evaluated and found adequate by the microbiology reviewer Refer to microbiology review [redacted] M64R01.docx by Dacie R. Bridge, Ph.D., dated 8/22/2023. The extractables study, the available toxicology data, and the USP <381> test results provide a reasonable assurance of safety for the proposed use of th [redacted] stopper in the container closure systems for the Drug Products (Group 3: SWFI and Electrolytes in vials).

The batch analytical results of the product manufactured wit [redacted] stopper met acceptance criteria in the drug product specifications.

The applicant has performed risk assessment in accordance with the International Conference on Harmonization (ICH) Q3D: Guideline for Elemental Impurities and USP <232> Elemental Impurities – Limits to assess for potential presence and control of elemental impurities for the product which use th [redacted] stopper presentation. The risk assessment report [redacted]-2018-AR-800.02, supports the previous conclusion using current stopper that the concentration of elemental impurities is less than the control threshold (30% of the ICH permitted daily exposure) and no additional control measures are warranted. The provided elemental impurities risk assessment is acceptable. No additional control of elemental

impurities in the drug product using the proposed stopper is acceptable from the CMC standpoint.

Rational for the selection of the worst-case Group 3 products (Group 3: SWFI and Electrolytes in vials as outlined in the Type C Briefing Package Amendment) products used in the stability study is acceptable from the CMC standpoint. One batch each of 3-months accelerated and long term stability data for exhibit batch products (Chromium (Chromic Chloride Injection, USP), Sodium Phosphates Injection, USP and Sterile Water for Injection, USP) manufactured using alternative stopper (b) (4)) at Rocky Mount, North Carolina facility demonstrates that the SWFI and simple electrolyte products with proposed (Alternative) stopper are stable at 3 months stability interval as all the analytical test results are meeting the specification limit. Based on the stability data generated for the stability bracket for the three Group 3 (SWFI and Electrolytes in Vials) products presented above, the applicant proposes that the expiration dating for Bacteriostatic 0.9% Sodium Chloride Injection, USP be maintained at twenty-four (24) months for all presentations of the subject drug product, when stored at controlled room temperature (20° C – 25° C; 68° F – 77° F). The Post-approval stability Protocol & Stability commitment are acceptable.

13. Conclusions & Recommendations:
This grouped supplement is recommended for **Approval**.

14. Comments/Deficiencies to be Conveyed to Applicant:
None

15. Primary Reviewer:
Le Zhang, Ph.D., CMC reviewer, Branch 2, Division of Post-Marketing Activities I, Office of Lifecycle Drug Products, Office of Pharmaceutical Quality (OPQ)

16. Secondary Reviewer:
David B. Lewis, Branch Chief, Branch 2, Division of Post-Marketing Activities I, Office of Lifecycle Drug Products, OPQ

7 Pages have been Withheld in Full as CCI/TS immediately following this page.

Le Zhang

Digitally signed by Le Zhang
Date: 11/30/2023 11:28:24AM
GUID: 594abf46003a4cb7cc12cf6cfd6d8751

David Lewis

Digitally signed by David Lewis
Date: 11/30/2023 11:30:40AM
GUID: 508da72000029f287fa31e664741b577
Comments: concur; recommend approval from the standpoint of CMC

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

018892Orig1s038

ADMINISTRATIVE AND CORRESPONDENCE DOCUMENTS

See List of Applications

CBE SUPPLEMENT - ACKNOWLEDGEMENT

Hospira, Inc.
Attention: Angela LeCaptain
Director, Pfizer Global Regulatory Affairs
275 North Field Drive
Bldg H1
Lake Forest, IL 60045

Dear Angela LeCaptain:[1]

Please refer to your supplemental New Drug Application(s) (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA), and your supplemental Abbreviated New Drug Application(s) (sANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following products:

Supplemental Application	Product Information	Submit Date	FDA Received Date
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NDA 018801/S-056	Sterile Water for Injection, USP	June 2, 2023	June 2, 2023
NDA 018802/S-042	Bacteriostatic Water for Injection, USP	June 2, 2023	June 2, 2023
NDA 018803/S-062	0.9% Sodium Chloride Injection, USP	June 2, 2023	June 2, 2023
NDA 018892/S-038	Sodium Phosphates Injection, USP	June 2, 2023	June 2, 2023
NDA 018893/S-043	Sodium Acetate Injection, USP	June 2, 2023	June 2, 2023
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NDA 018959/S-030	Zinc Chloride Injection, USP	June 2, 2023	June 2, 2023
NDA 018960/S-027	Copper Chloride (Cupric Chloride Injection, USP)	June 2, 2023	June 2, 2023

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NDA 018962/S-029	Manganese Chloride Injection, USP	June 2, 2023	June 2, 2023
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ANDA 202432/S-009	Sodium Bicarbonate Injection	June 2, 2023	June 2, 2023
ANDA 202981/S-006	Sodium Bicarbonate Injection	June 2, 2023	June 2, 2023

These supplemental applications, submitted as "Changes Being Effected in 30 Days" supplements, propose the following change:

- Addition of an alternate Elastomeric Closure with (b) (4) (b) (4) to the current Elastomeric Closures with (b) (4) for drug products packaged in glass and plastic vials manufactured at Rocky Mount, North Carolina facility.
- Removal o (b) (4) (b) (4)

Unless we notify you within 60 days of the receipt date that the applications are not sufficiently complete to permit a substantive review, we will file the applications on August 1, 2023, in accordance with 21 CFR 314.101(a).

If the applications are filed, the user fee goal date will be December 2, 2023.

Cite the application number listed above at the top of the first page of all submissions to this application.

If you have any questions, please contact me at Megan.Nguyen@fda.hhs.gov or (301) 796 - 7826.

Sincerely,

{See appended electronic signature page}
Megan Nguyen
Regulatory Business Process Manager
Division of Regulatory and Business Process Management III (DRBPMIII)
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Megan Nguyen

Digitally signed by Megan Nguyen
Date: 6/14/2023 07:14:40AM
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