CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

016466Orig1s045

Trade Name:	ARISTOSPAN
Generic or Proper Name:	triamcinolone hexacetonide
Sponsor:	Sandoz Canada, Inc.
Approval Date:	September 4, 2014
Indication:	The intralesional administration of Aristospan (triamcinolone hexacetonide injectable suspension, USP) 5 mg/mL is indicated for alopecia areata; discoid lupus erythematosus; keloids; localized hypertrophic, infiltrated, inflammatory lesions of granuloma annulare, lichen planus, lichen simplex chronicus (neurodermatitis), and psoriatic plaques; necrobiosis lipoidica diabeticorum. Aristospan may also be useful in cystic tumors of an aponeurosis or tendon (ganglia).

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016466Orig1s045

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Reviews / Information Included in this NDA Review.

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APPLICATION NUMBER:

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 12802/S-032, 16466/S-045, 21163/S-029, 21265/S-025, 21559/S-021, 21646/S-018

APPROVAL LETTER

Sandoz Canada, Inc.
Attention: Jean Domenico
Associate Director, Regulatory Affairs
2555 W Midway Blvd. P.O Box 446
Broomfield, CO 80038

Dear Mr. Domenico:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received March 7, 2014, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA NUMBER	SUPPLEMENT NUMBER	PRODUCT NAME
12802	S-032	Aristocort Forte (triamcinolone diacetate) Injectable Suspension
16466	S-045	Aristopan (triamcinolone hexacetonide) Injectable Suspension
21163	S-029	Infuvite Adult (Multiple Vitamins for Infusion) Injection
21265	S-025	Infuvite Pediatric (Multiple Vitamins for Infusion) Injection
21559	S-021	Infuvite Adult Pharmacy Bulk (Multiple Vitamins for Infusion) Injection
21646	S-018	Infuvite Pediatric Pharmacy Bulk (Multiple Vitamins for Infusion) Injection

These "Changes Being Effected" supplemental new drug applications provide for revision to the rubber stoppers code (b) (4) and code (b) (4) specifications to comply with the European Pharmacopeia (EP).

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

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

If you have any questions, call Priyanka Kumar, Regulatory Project Manager, at (240) 402-3722.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Branch Chief, Branch IX
Division of New Drug Quality Assessment III
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

RAMESH RAGHAVACHARI
09/04/2014

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

016466Orig1s045

PRODUCT QUALITY REVIEW(S)

Review of Chemistry, Manufacturing and Controls

Chemist's Review No. 1	**1. Organization** OND Division DMEP	**2. NDAs** Lead 12802 (see attachment I for the bundled supplements).

3. Name and Address of the Applicant	**4. Supplement Number: S032** **Letter Date**: 03/07/2014 **Stamped Date**: 03/07/2014 **Type:** CBE-0 **Due Date:** 09/07/2014 **Assignment Received Date:** 08/25/2014* (note this is a late assignment)
Sandoz Canada, Inc. 145 Jules Leger Street Boucherville, QC J4B 7K8 Canada	

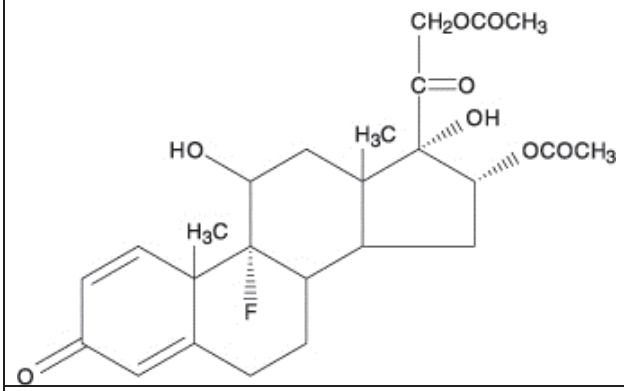
5. Established Name	**6.Proprietary Name**	**7. Amendments, Report, Date**
Triamcinolone Diacetate Injectable Suspension	Aristocort Forte	

8. Supplement Provides for:
This is a bundled supplement that provides for rubber stopper's specification update

9. Indication(s) for Use:	**10. How Dispensed**	**11a. Related Documents**
Allergic states, dermatologic diseases, endocrine disorders, gastrointestinal, and hematologic disorders, misc	Rx	

12. Dosage Form	**13. Strengths**	**11b. Submission Media**
Injectable	40 mg/mL	Electronic

14. Chemical Name and Structure
Triamcinolone 16a,21-diacetate
Chemically triamcinolone diacetate is 9-fluoro-11ß,16α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione 16,21-diacetate.
The molecular weight is 478.51.



15. Comments
This is a bundled supplement that provides for rubber stopper's specification update for the NDAs listed in Attachment I.
The applicant is revising the rubber stoppers code (b) (4) and code (b) (4) specifications to comply with the European Pharmacopeia (EP). The applicant states the EP specifications are not required by the USP. However, these specification sheets used by the Sandoz Canada site are universal for multiple countries, therefore, they included both the EP and USP requirements.
The proposed changes, as per the current official EP monograph, are listed as follows:

Rubber Stopper Code [redacted]

- [redacted]
- [redacted]

limits from [redacted]% to [redacted]%.

Rubber Stopper Code [redacted]

- [redacted]
- [redacted]

[redacted] limit of the test from [redacted]% to [redacted]%, the limits remain the same.

There are no changes made to the USP tests and USP specifications. The proposed changes are acceptable and do not impact the quality of the drug product.

16. Conclusion and Recommendation
Recommended for Approval

17. Name	18. Reviewer's Signature	19. Date Completed
Ping Jiang-Baucom	See appended electronic signature sheet	08/28/2014

Attachments

Attachment I. Listed of Bundled Supplements

Application Type and Number	Submission Type and Number	Product Name	Dosage Form
NDA-012802	Supplement-32	ARISTOCORT INJECTION	INJECTION
NDA-016466	Supplement-45	ARISTOSPAN (STERILE TRIAMCINOLONE HEXACE	INJECTION
NDA-021163	Supplement-29	INFUVITE ADULT	INJECTABLE
NDA-021265	Supplement-25	INFUVITE PEDIATRIC	INJECTION
NDA-021646	Supplement-18	INFUVITE PEDIATRIC PHARMACY BULK PACKAGE	INJECTION

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/s/

PING JIANG-BAUCOM
08/28/2014

RAMESH RAGHAVACHARI
08/28/2014

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APPLICATION NUMBER:

016466Orig1s045

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 12802/S-032, 16466/S-045, 21163/S-029, 21265/S-025, 21559/S-021, 21646/S-018

**CBE SUPPLEMENT –
ACKNOWLEDGEMENT**

Sandoz Canada, Inc.
Attention: Jean Domenico
Associate Director, Regulatory Affairs
2555 W Midway Blvd. P.O Box 446
Broomfield, CO 80038

Dear Mr. Domenico:

We have received your Supplemental New Drug Applications (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act) for the following:

NDA NUMBER	SUPPLEMENT NUMBER	PRODUCT NAME
12802	S-032	Aristocort Forte (triamcinolone diacetate) Injectable Suspension
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21646	S-018	Infuvite Pediatric Pharmacy Bulk (Multiple Vitamins for Infusion) Injection

DATE OF SUBMISSION: March 7, 2014

DATE OF RECEIPT: March 7, 2014

These supplemental applications, submitted as a "Changes being effected" supplement, propose revision to the rubber stoppers code (b) (4) and code (b) (4) specifications to comply with the European Pharmacopeia (EP).

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on May 6, 2014, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be September 7, 2014.

If you have questions, call me at (240) 402-3722.

Sincerely,

{See appended electronic signature page}

Priyanka Kumar, Pharm. D
Regulatory Health Project Manager
Division of New Drug Quality Assessment III
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

PRIYANKA KUMAR
03/27/2014