CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

14-602/S056

Trade Name: Celestone® Soluspan®

Generic Name: Betamethasone acetate; betamethasone sodium phosphate

Sponsor: Schering Corporation

Approval Date: 3/13/2013

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

14-602/S056

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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 14602/S-056

APPROVAL LETTER

Merck Sharp & Dohme Corp.
Attention: David Young
Senior Specialist, Global Regulatory Affairs
2000 Galloping Hill Rd
Kenilworth NJ 07033

Dear Mr. Young:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 18, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Celestone Soluspan (betamethasone sodium phosphate and betamethasone acetate) Injection.

This "Changes Being Effected" supplemental new drug application provides proposes the change in storage condition and extension in the recertification period for the Betamethasone Sodium Phosphate drug substance.

We have completed our review of this supplemental new drug application. This supplement is 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 Youbang Liu, Regulatory Project Manager, at (301) 796-1926.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Acting 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
03/13/2013

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

14-602/S056

CHEMISTRY REVIEW(S)

Chemistry Review #1	**1. Division** ONDQA HFD-170	**2. NDA/Suppl. Number** 14-602/SCS-056
3. Name and Address of Applicant Schering Corporation Attention: David Young, Senior Specialist Global Regulatory Affairs, CMC 2000 Galloping Hill Road Kenilworth, NJ 07033		**4. Date of** **Sub.** **User Fee** 9/18/12 3/18/13
5. Name of Drug Celeston Soluspan	**6. Nonproprietary Name** Betamethasone Acetate/ Betamethasone Phosphate	
7. Supplement, CBE-0, Provides for: Increase the retesting period from (b) (4) months to (b) (4) months for drug substance betamethasone acetate/betamethasone phosphate.		**8. Amendment(s)**
9. Pharmacological Category Anti inflammatory disorders	**10. How Dispensed:** Rx	**11. Related Documents**:
12. Dosage Form Injection	**13. Potency(ies):** 6 mg/mL	
15. Comments: The storage of the drug substance was reduced from 25°C/65%RH to 2-8°C. An increase in stability was demonstrated at the refrigerated conditions. Firm is proposing an increase of recertification period from (b) (4) months to (b) (4) months for the Betamethasone Sodium Phosphate drug substance based on increase in stability.		
16. Conclusions and Recommendations: Recommend Approval.		
17. Name **Date** **Review Chemist** **Signature** **Date** Bart Ho, Chemist **Acting Branch Chief** **Signature** **Date** Ramesh Raghavachari, Ph.D.		

Doc ID: 14602SCS56 retest API Schering

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/s/

BARTHOLOME C HO
03/08/2013

RAMESH RAGHAVACHARI
03/08/2013

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

14-602/S056

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 14602/S-056

CBE-0 SUPPLEMENT

Merck Sharp & Dohme Corp.
Attention: David Young
Senior Specialist, Global Regulatory Affairs
2000 Galloping Hill Rd
Kenilworth NJ 07033

Dear Mr. Young:

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

NDA Number:	14602
Supplement Number:	S-056
Product Name:	Celestone Soluspan (betamethasone sodium phosphate and betamethasone acetate) Injection
Date of Submission:	September 18, 2012
Date of Receipt:	September 18, 2012

This supplemental application, submitted as a "Changes Being Effected" supplement, proposes the change in storage condition and extension in the recertification period for the Betamethasone Sodium Phosphate drug substance.

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 November 17, 2012, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be March 18, 2013.

Cite the application number listed above at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Pulmonary, Allergy and Rheumatology Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you have questions, call me, at (301) 796-1926.

Sincerely,

{See appended electronic signature page}

Youbang Liu
Regulatory Project Manager
Division III of New Drug Quality Assessment
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

YOUBANG LIU
10/17/2012