CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

016466Orig1s032

Trade Name:	ARISTOSPAN
Generic or Proper Name:	triamcinolone hexacetonide
Sponsor:	Wyeth-Ayerst Laboratories
Approval Date:	February 12, 2002
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).

CENTER FOR DRUG EVALUATION AND RESEARCH

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Reviews / Information Included in this NDA Review.

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APPLICATION NUMBER:

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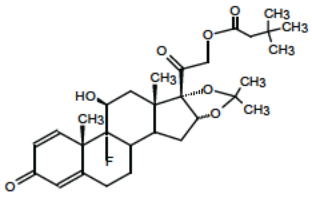
PRODUCT QUALITY REVIEW(S)

Chemistry Review Review #1	1. Division HFD-550	2. NDA Number 16-466
3. Name and Address of Applicant Wyeth-Ayerst Research P.O. Box 8299 Philadelphia, PA 19101-3710		4. Supplement Number Date SCS-032 29-AUG-01
5. Name of Drug ARISTOSPAN®	6. Nonproprietary Name Triamcinolone hexacetonide	
7. Supplement Provides for: Change to an HPLC test for benzyl alcohol determination in vehicle and (b) (4) CHANGES BEING EFFECTED—CBE-30		8. Amendment(s) 21-JAN-02/BC
9. Pharmacological Category Used for (b) (4) (b) (4) and intralesional indications	10. How Dispensed Rx	11. Related Documents
12. Dosage Form Sterile Suspension	13. Potency(ies) Triamcinolone hexacetonide, Intralesional use, 5 mg/mL; (b) (4)	

14. Chemical Name and Structure see USAN



$C_{30}H_{41}FO_7$
Mol. Wt.: 532.65
9-Fluoro-11β,16α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione cyclic 16,17-acetal with acetone 21-(3,3-dimethylbutyrate)

TRIAMCINOLONE HEXACETONIDE CAS-5611-51-8

15. Comments: The sponsor seeks approval to use with the product vehicle a modification of the approved HPLC method for the drug product used to determine benzyl alcohol [BzOH] content. Another request regards approval to change manufacturing instructions to permit (b) (4) (b) (4).

16. Conclusions and Recommendations: To support this request to replace the approved GC method for determining BzOH content in the product vehicle with a modification of an HPLC method approved for the drug product, the modified procedure and relevant studies from the validation of drug product HPLC method are presented. The only change in the method is a (b) (4) (b) (4) (b) (4). Experimental details and system suitability criteria are acceptable as presented for the analyst in Monograph 24285 for use with the manufacture of the Sterile Vehicle for Aristospan. Test results in all cases are acceptable. See attached review notes for details.

17. Name Signature	Date
Allan Fenselau, Review Chemist	
Concurrence Signature	Date
John L. Smith, Chemistry Team Leader	

cc: NDA 16-466
HFD-550/Division File
HFD-550/CSO/B.Gould
HFD-550/CHEM/A.Fenselau
HFD-550/CHEM/TeamLdr/J.L.Smith
HFD-550/Dep.Dir./L.Goldkind
HFD-830/C.-w.Chen

Doc ID: n16466s.032

5 Pages have been Withheld in Full as b4 (CCI/TS) immediately following this page

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/s/

Allan Fenselau
2/11/02 09:11:45 AM
CHEMIST

I included Goldkind on list of recipients and not Simon. What protocol should I follow?

John Smith
2/11/02 09:27:43 AM
CHEMIST

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APPLICATION NUMBER:

016466Orig1s032

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

NDA Number: 16-466/S-032 **Applicant: Wyeth-Ayerst Research**
Drug Name: ARISTOSPAN® **10-JAN-02**

These comments are being provided to you prior to completion of our review of the application to give you preliminary notice of issues that have been identified. Per the user fee reauthorization agreements, these comments do not reflect a final decision on the information reviewed and should not be construed to do so. These comments are preliminary and are subject to change as the review of your application is finalized. In addition, we may identify other information that must be provided prior to approval of this application. If you choose to respond to the issues raised in this letter during this review cycle, depending on the timing of your response, as per the user fee reauthorization agreements, we may or may not be able to consider your response prior to taking an action on your application during this review cycle.

NOTE: If your response can be found in the contents of your submission, just cite those sections of the submission that are relevant to the issue under consideration. Otherwise, please provide the appropriate information as an amendment to the submission.

Chemist's Concerns

1. Please include on p. 5 of Monograph No. 24053 the System Suitability criteria for the HPLC method used to determine benzyl alcohol content in the Sterile Aristospan Vehicle.

2. Please indicate where in the manufacturing batch record are the instructions that request removal of a sample for determining benzyl alcohol content. Please indicate where the results are later recorded.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Allan Fenselau
1/10/02 03:58:39 PM
CHEMIST

John Smith
1/16/02 09:05:41 AM
CHEMIST

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-466/S-032 **CBE-0 SUPPLEMENT**

Lederle Laboratories, Inc.
Attention: Patricia Foti Mann
Associate Director, Worldwide Regulatory Affairs
P.O.Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Mann:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Aristospan Suspension (sterile triamcinolone hexacetonide) 5mg/ml, (b) (4)

NDA Number: 16-466

Supplement number: S-032

Date of supplement: August 29, 2001

Date of receipt: August 30, 2001

This supplemental application was submitted as a "Supplement - Changes Being
appropriateness of reporting the proposed change(s) as changes being effected is under review.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on October 28, 2001 in accordance with 21 CFR 314.101(a).

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:
Center for Drug Evaluation and Research
Division of DAAODP, HFD-550
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of DAAODP HFD-550

Attention: Document Room
9201 Corporate Blvd.
Rockville, Maryland 20850

If you have any question, call Mary jane Walling, Regulatory Project Manager, at (301)827-2268.

Sincerely yours,

Mary jane Walling
ADRA, ODE V

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Mary Jane Walling
8/31/01 11:44:33 AM