LACHMAN CONSULTANT SERVICES, INC.
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

1600 STEWART AVENUE
WESTBURY, NY 11590
(516) 222-6222 • FAX (516) 683-1887

August 15, 2001

OVERNIGHT COURIER

Dockets Management Branch
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane Room 1061
Rockville, MD 20852

Citizen Petition

Dear Sir or Madam:

The undersigned submits this petition, in quadruplicate, pursuant to 21 CFR 10.30, and in accordance with the regulations at 21 CFR 314.93, on behalf of a client requesting the Commissioner of the Food and Drug Administration to amend the "Approved Drug Products with Therapeutic Equivalence Evaluation" list (the "Orange Book"), 21st Edition, as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration amend the "Orange Book" to designate Pharmacia and Upjohn's product, NDA #08-697, Cortef Tablets (hydrocortisone) 5 mg, 10 mg, and 20 mg a second reference-listed drug product.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products that are eligible for submission as abbreviated new drug applications. That list, referred to as the "Orange Book", contains all FDA approved drug products. The FDA has decided through the comment and rule-making process that it will designate all reference listed drug (RLD) products, and that the designated reference-listed drug products will be the same drug products selected by the Agency as the reference standard for bioequivalence testing for a duplicate generic version of the RLD (57 FR 17954). The FDA's intention in this regard was to designate a single reference listed drug against which all generic versions must be shown to be bioequivalent, and thus avoid possible variations among generic drugs and their brand name counterparts (57 FR 17954). For multiple-source NDA drug products or multiple source drug products without an NDA, the FDA has decided to generally designate the market leader as the reference-listed drug (57 FR 17958).

However, for multiple source drug products, a product **not** designated as the reference-listed drug and **not** shown to be bioequivalent to the designated reference listed drug product selected by the Agency may be shielded from direct generic competition. This is indeed the situation in regard to this request.

OIP-0356 CP1

In the current edition of the Orange Book (relevant page attached), there are five manufacturers listed for Hydrocortisone Tablets. Two of the manufacturers, Merck and Pharmacia / Upjohn, have approved NDAs for the product and three manufacturers hold ANDAs (approved prior to the Hatch-Waxman Act that required all generic products be bioequivalent to the RLD). The products are all rated BP in that they are considered to contain an active ingredient in a dosage form where there is a potential for causing a bioequivalence problem. None of the manufacturers have to date submitted in vivo data to support a showing of bioequivalence. The Agency on its own accord has designated NDA 08-506 held by Merck for Hydrocortone (hydrocortisone) Tablets as the reference listed drug product. Therefore, at this point in time, any ANDA applicant seeking approval of a hydrocortisone tablet product must cite the Merck product as the RLD and perform bioequivalence testing against the Merck product. This effectively shields the Pharmacia / Upjohn product from direct competition. The petitioner believes that the market share for Cortef is significant and against which it would like to compete.

Designation by the Agency of Cortef Tablets, 5 mg, 10 mg, and 20 mg, as a second reference-listed drug product in this situation will allow for generic competition in that currently protected market.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

D. Economic Impact

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis, if requested by the Agency.

E. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

Respectfully submitted,

Robert W. Pollock
PK

Robert. W. Pollock
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, New York 11590

RWP/pk

Attachment: "Orange Book" Page No. 3-188

cc: L. Lachman

SMP1127

HYDROCORTISONE

LOTION; TOPICAL

	ALA-CORT			
AT	DEL RAY LABS	1%	**N83201 001**	
	ALA-SCALP			
	DEL RAY LABS	2%	N83231 001	
	BETA-HC			
AT	BETA DERMAC	1%	**N89495 001**	JAN 25, 1988
	CETACORT			
AT	HEALTHPOINT	0.5%	**N80426 002**	
AT		1%	**N80426 001**	
	EPICORT			
AT	BLULINE	0.5%	**N83219 002**	
	GLYCORT			
AT	HERAN	1%	**N87489 001**	OCT 03, 1983
	HYDROCORTISONE			
AT	ALTANA	2.5%	**N40351 001**	JUL 25, 2000
AT	MERICON	0.5%	**N85282 001**	
AT		1%	**N85282 002**	FEB 26, 1987
AT	THAMES	2.5%	**N40247 001**	JUL 23, 1999
	HYTONE			
AT +	DERMIK LABS	1%	**N80473 003**	
AT +		2.5%	**N80473 004**	NOV 30, 1982
	NUTRACORT			
AT	HEALTHPOINT	1%	**N80443 003**	
AT		2.5%	**N87644 001**	AUG 24, 1982
	STIE-CORT			
AT	STIEFEL	1%	**N89066 001**	NOV 25, 1985
AT		2.5%	**N89074 001**	NOV 26, 1985

OINTMENT; TOPICAL

	CORTRIL			
AT +	PFIPHARMECS	1%	**N09176 001**	
AT +		2.5%	**N09176 002**	
	HC (HYDROCORTISONE)			
AT	C AND M PHARMA	1%	**N80481 002**	
	HYDROCORTISONE			
AT	ALTANA	1%	**N80489 003**	
AT		1%	**N80692 001**	

HYDROCORTISONE

OINTMENT; TOPICAL

	HYDROCORTISONE			
AT	CLAY PARK	2.5%	**N85027 001**	
AT	FOUGERA	2.5%	**N81203 001**	MAY 28, 1993
AT	NMC	1%	**N87796 001**	OCT 13, 1982
AT	THAMES	1%	**N86257 001**	
AT		2.5%	**N40310 001**	DEC 29, 2000
	HYDROCORTISONE IN ABSORBASE			
AT	CAROLINA MEDCL	1%	**N88138 001**	SEP 06, 1985

POWDER; FOR RX COMPOUNDING

	H-CORT			
AA	TORCH	100%	**N87834 001**	MAR 29, 1982
	HYDROCORTISONE			
AA	PADDOCK	100%	**N88082 001**	APR 08, 1983
AA	PHARMA TEK	100%	**N85982 001**	

SOLUTION; TOPICAL

	PENECORT			
AT	ALLERGAN HERBERT	1%	**N88214 001**	JUN 06, 1984
	TEXACORT			
AT +	BIOGLAN PHAR	1%	**N80425 001**	
+		2.5%	N81271 001	APR 17, 1992

TABLET; ORAL

	CORTEF			
BP	PHARMACIA AND UPJOHN	10MG	N08697 001	
BP		20MG	N08697 002	
		5MG	N08697 003	
	HYDROCORTISONE			
BP	IMPAX LABS	20MG	N80781 001	
BP	LANNETT	20MG	N85070 001	
BP	WEST WARD	20MG	N83365 001	
	HYDROCORTONE			
BP	MERCK	10MG	N08506 007	
BP +		20MG	N08506 011	

HYDROCORTISONE; *MULTIPLE*
SEE ACETIC ACID, GLACIAL; HYDROCORTISONE
SEE ACETIC ACID, GLACIAL; HYDROCORTISONE; NEOMYCIN SULFATE

94

100

FedEx Express USA Airbill

FedEx Tracking Number 8300 7205 1840

Form I.D. No. 0215

Recipient's Copy

RECIPIENT: PEEL HERE

1 From This portion can be removed for Recipient's records.

Date 8/15/01 FedEx Tracking Number 830072051840

Sender's Name R. Pollock Phone 516 222-6222

Company LACHMAN CONSULTANT SERVICE INC

Address 1600 STEWART AVE STE 604 Dept./Floor/Suite/Room

City WESTBURY State NY ZIP 11590

2 Your Internal Billing Reference

3 To

Recipient's Name DOCKETS MANAGEMENT Phone

Company FOOD + DRUG ADMIN.

Address 5630 FISHERS LANE, RM 1061

To "HOLD" at FedEx location, print FedEx address. We cannot deliver to P.O. boxes or P.O. ZIP codes.

HEALTH + HUMAN SERVICES Dept./Floor/Suite/Room

City ROCKVILLE State MD ZIP 20852

8300 7205 1840

0159279037

4a Express Package Service *Packages up to 150 lbs.* Delivery commitment may be later in some areas.

- [X] FedEx Priority Overnight — Next business morning
- [ ] FedEx Standard Overnight — Next business afternoon
- [ ] FedEx First Overnight — Earliest next business morning delivery to select locations
- [ ] FedEx 2Day — Second business day
- [ ] FedEx Express Saver — Third business day
- [ ] **NEW** FedEx Extra Hours — Later drop-off with next business afternoon delivery for select locations

FedEx Envelope rate not available. Minimum charge: One-pound rate

4b Express Freight Service *Packages over 150 lbs.* Delivery commitment may be later in some areas.

- [ ] FedEx 1Day Freight* — Next business day
- [ ] FedEx 2Day Freight — Second business day
- [ ] FedEx 3Day Freight — Third business day

* Call for Confirmation:

5 Packaging *Declared value limit $500

- [X] FedEx Envelope*
- [ ] FedEx Pak* — Includes FedEx Small Pak, FedEx Large Pak, and FedEx Sturdy Pak
- [ ] Other Pkg. — Includes FedEx Box, FedEx Tube, and customer pkg.

6 Special Handling Include FedEx address in Section 3.

- [ ] **SATURDAY Delivery** — Available only for FedEx Priority Overnight and FedEx 2Day to select ZIP codes
- [ ] **SUNDAY Delivery** — Available only for FedEx Priority Overnight to select ZIP codes
- [ ] **HOLD Weekday at FedEx Location** — Not available with FedEx First Overnight
- [ ] **HOLD Saturday at FedEx Location** — Available only for FedEx Priority Overnight and FedEx 2Day to select locations

Does this shipment contain dangerous goods? One box must be checked.

- [ ] No
- [ ] Yes — As per attached Shipper's Declaration
- [ ] Dry Ice — Dry Ice, 9, UN 1845 ____ x ____ kg
- [ ] Cargo Aircraft Only

Dangerous Goods (incl. Dry Ice) cannot be shipped in FedEx packaging or with FedEx Extra Hours service.

7 Payment *Bill to:* Enter FedEx Acct. No. or Credit Card No. below. [ ] Obtain Recip. Acct. No.

- [X] Sender — Acct. No. in Section 1 will be billed.
- [ ] Recipient
- [ ] Third Party
- [ ] Credit Card
- [ ] Cash/Check

Total Packages	Total Weight	Total Charges
		Credit Card Auth.

*Our liability is limited to $100 unless you declare a higher value. See the *FedEx Service Guide* for details.

8 Release Signature *Sign to authorize delivery without obtaining signature.*

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.

406

Questions? Visit our Web site at fedex.com or call 1-800-Go-FedEx® (800)463-3339.

SRS•Rev. Date 12/00•Part #155816S•©1994–2000 FedEx•PRINTED IN U.S.A.