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

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OVERNIGHT COURIER 12/10/01

2966 '01 DEC 11 P2:22

December 10, 2001

Dockets Management Branch
Food and Drug Administration (HFA-305)
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 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Nitroglycerin Aerosol (sublingual), 0.4 mg / spray (metered dose aerosol containing Nitroglycerin in CFC propellant) by Pohl Boskamp has been voluntarily withdrawn or withheld from sale for safety or efficacy reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products, which are eligible for submission as abbreviated new drug applications. That list, referred to as the "Orange Book", contains all FDA-approved drug products. The Orange Book currently lists Nitroglycerin Aerosol Spray containing Nitroglycerin in propellants as a Discontinued Product based on the listing in Cumulative Supplement 7 of the Approved Drug Products with Therapeutic Equivalence Evaluations, 21st Edition (Orange Book). A listing in this section of the Orange Book indicates that the specific drug product is the subject of an approved application. However, based on a survey of the marketplace and the recent listing as a discontinued drug product in the Orange Book, Nitroglycerin Aerosol Spray (metered dose aerosol containing Nitroglycerin), is not available for sale to the consumer.

Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug's application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn, discontinued from marketing or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved {21 CFR 314.161(a)(1)].

As stated, Pohl Boskamp's Nitroglycerin Aerosol Spray, 0.4 mg / spray (metered dose aerosol containing Nitroglycerin in CFC propellant) was discontinued from marketing and is not available for sale in the marketplace. Because there is no current commercial distribution of this drug product, it is requested that the FDA determine whether Pohl Boskamp's decision not to market Nitroglycerin Aerosol Spray, 0.4 mg / spray (metered dose aerosol containing Nitroglycerin in CFC propellant) was for reasons of safety or effectiveness.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 CFR 25.31.

D. Economic Impact

Pursuant to 21 CFR 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided, if so requested.

E. Certification

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

Respectfully submitted,

Gordon R. Johnston
Associate

GRJ/pk

Enclosure: Page 1-44, Cumulative Supplement 7, Approved Drug Products with Therapeutic Equivalence Evaluations

GCK1344

NETILMICIN SULFATE							
INJECTABLE; INJECTION							
NETROMYCIN							
@ SCHERING	EQ 100MG BASE/ML	N50544	003	FEB 28, 1983	MAY	DISC	
NIFEDIPINE							
CAPSULE; ORAL							
NIFEDIPINE							
@ CHASE LABS NJ	10MG	N72409	001	JUL 04, 1990	FEB	WDRP	
@	20MG	N73421	001	JUN 19, 1991	FEB	WDRP	
TABLET, EXTENDED RELEASE; ORAL							
ADALAT CC							
AB1 BAYER	30MG	N20198	001	APR 21, 1993	APR	CTEC	
NIFEDIPINE							
AB2 BIOVAIL	30MG	N75289	002	FEB 06, 2001	FEB	NEWA	
PROCARDIA XL							
AB2 + PFIZER	30MG	N19684	001	SEP 06, 1989	FEB	CTEC	
NITROFURAZONE							
OINTMENT; TOPICAL							
NITROFURAZONE							
@ CLAY PARK	0.2%	N84968	001	JAN 25, 1978	MAY	DISC	
POWDER; TOPICAL							
FURACIN							
@ ROBERTS LABS	0.2%	N83791	001	OCT 17, 1975	FEB	WDRP	
SOLUTION; TOPICAL							
NITROFURAZONE							
@ CLAY PARK	0.2%	N85130	001	NOV 02, 1978	MAY	DISC	
+ WENDT	0.2%	N87081	001	JUL 22, 1981	MAY	CTEC	
NITROGLYCERIN							
AEROSOL; SUBLINGUAL							
NITROLINGUAL							
@ POHL BOSKAMP	0.4MG/SPRAY	N18705	001	OCT 31, 1985	APR	DISC	
NORETHINDRONE ACETATE							
TABLET; ORAL							
NORETHINDRONE ACETATE							
AB BARR	5MG	N75951	001	MAY 25, 2001	MAY	NEWA	
NORTRIPTYLINE HYDROCHLORIDE							
CAPSULE; ORAL							
PAMELOR							
AB TYCO HLTHCARE	EQ 10MG BASE	N18013	001	AUG 01, 1977	JUN	CAHN	
AB	EQ 25MG BASE	N18013	002	AUG 01, 1977	JUN	CAHN	
AB	EQ 50MG BASE	N18013	004	JUN 14, 1979	JUN	CAHN	
AB +	EQ 75MG BASE	N18013	003	JUN 14, 1979	JUN	CAHN	
SOLUTION; ORAL							
AA TYCO HLTHCARE	EQ 10MG BASE/5ML	N18012	001	AUG 01, 1977	JUN	CAHN	

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- [ ] FedEx 2Day — Second business day. FedEx Envelope rate not available. Minimum charge: One-pound rate
- [ ] FedEx Express Saver — Third business day
- [ ] **NEW** FedEx Extra Hours — Later drop-off with next business afternoon delivery for select locations

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- [ ] FedEx 3Day Freight — Third business day

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5 Packaging

* Declared value limit $500

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

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- [ ] **HOLD Saturday at FedEx Location** — Available only for FedEx Priority Overnight and FedEx 2Day to select locations

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- [ ] Yes — Shipper's Declaration not required
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			Credit Card Auth.

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