



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

**FILE COPY**

August 1, 2001

Brian A. Green, MS  
Manager, Regulatory Affairs  
ASTA Medica, Inc.  
890 East Street  
Tewksbury, MA 01876-1496

Dear Mr. Green:

Your petition requesting that the Food and Drug Administration determine that the decision by Bristol-Myers Squibb not to market non-lyophilized form of Cytoxan was for reasons other than safety and/or efficacy was received by this office on 07/31/01. It was assigned docket number 01P-0333/CP 1 and it was filed on 08/01/01. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe  
Dockets Management Branch

01P-0333

ACK 1



8628 01 JUL 31 10:16

July 26, 2001

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
12420 Parklawn Drive  
Rockville, Maryland 20857

ASTA Medica, Inc.  
890 East Street  
Tewksbury, MA 01876-1496

Telephone 978.851.5981  
Telefax 978.851.7346

### CITIZEN PETITION

Dear Sir/Madam:

ASTA Medica, Inc. (ASTA) submits this petition, pursuant to 21 CFR §10.25(a) and 10.30 and in accordance with the regulations at 21 CFR §314.122, to request that the Commissioner of the Food and Drug Administration (Commissioner) make a determination that a drug listed in the Discontinued Drug Products section of the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) was voluntarily withdrawn from marketing for reasons other than safety or efficacy as outlined below.

#### A. Action Requested

The petitioner requests that the Commissioner make a determination that Bristol-Myers Squibb's non-lyophilized Cytoxan<sup>®</sup> (cyclophosphamide for injection, USP) 2 g vials, containing NaCl, was voluntarily withdrawn or withheld from sale for reasons other than safety or efficacy and that an Abbreviated New Drug Application (ANDA) may be submitted and approved pursuant to 21 CFR §314.122 and 314.161 using non-lyophilized Cytoxan as the Referenced Listed Drug (RLD).

#### B. Statement of Grounds

The Orange Book contains a list of all drug products approved by the Food and Drug Administration (FDA) which are eligible for submission as ANDAs. The current version of the Orange Book lists non-lyophilized Cytoxan under the Discontinued Drug Products section, indicating that this product formulation is no longer marketed. Prior to the 1984 Drug Price Competition and Patent Term Restoration Act (1984 Amendments), the FDA did not include discontinued products in the Orange Book. However, since the enactment of the 1984 Amendments, any approved drug, whether or not it is on the market, is included in the Orange Book and may support an ANDA as a referenced listed drug unless or until FDA finds that it is withdrawn for safety or effectiveness reasons. Pursuant to 21 CFR §314.161(a)(1), the FDA must make a determination as to whether a listed drug in the Discontinued Drug Product section was withdrawn from the market for reasons of safety or efficacy before an ANDA using that listed drug as a RLD may be approved.

As stated above, non-lyophilized Cytoxan is currently listed in the Orange Book under the Discontinued Drug Products section and are not available in the marketplace. The non-lyophilized and lyophilized forms of Cytoxan are approved under NDA 12-142, held by Bristol-Myers Squibb. The non-lyophilized forms were approved prior to January 1, 1982 (100, 200 and 500 mg vials) and August 30, 1982 (1 and 2 gram vials). The lyophilized forms were approved between January 4, 1984 and December 10, 1985. The non-lyophilized form of Cytoxan was moved to the Discontinued Products List in early 1997.

Significantly, there are two companies with non-lyophilized cyclophosphamide for injection, USP listed in the Orange Book under the Prescription Drug Products section.

The first company is Pharmacia and Upjohn (now called Pharmacia). Pharmacia's product, Neosar, is available in both non-lyophilized and lyophilized forms (according to the most recent package insert available from their website). Pharmacia has two applications for Neosar. The first is ANDA 87-442, approved February 16, 1982 (100, 200 and 500 mg vials), with supplemental approvals on July 8, 1983 (1 gram vial) and March 30, 1989 (2 gram vial). We believe that ANDA 87-442 is for the non-lyophilized form. The second application, NDA 40-014, was approved on April 29, 1993 (all strengths). We believe that NDA 40-014 is for the lyophilized form.

The second company is the petitioner, ASTA Medica, Inc. ASTA Medica has four ANDA's for non-lyophilized cyclophosphamide for injection, USP. ANDA's 88-371 (100 mg vial), 88-372 (200 mg vial) and 88-373 (500 mg vial) were approved on July 3, 1986. ANDA 88-374 (1 gram vial) was approved on September 24, 1986.

All three non-lyophilized products (the discontinued Cytoxan, Neosar, and ASTA Medica's cyclophosphamide for injection, USP) are (or were) manufactured by our parent company, ASTA Medica AG in Künsebeck, Germany.

In order to ensure that a waiver of an in vivo bioavailability study may be granted (pursuant to 21 CFR §320.22(b)(1)), ASTA Medica requests that the FDA determine that Bristol-Myers Squibb's decision not to market the non-lyophilized form of Cytoxan was for reasons other than safety and/or efficacy.

ASTA Medica would like to point out that this determination should have already been made. In accordance with 21 CFR §314.161(a)(2), the Agency is required to make a determination whether a listed drug that has been voluntarily withdrawn from sale was withdrawn for reasons of safety or effectiveness when ANDA's that referred to the listed drug have been approved. If a determination is made that the listed drug was withdrawn for reasons of safety or effectiveness, then in accordance with 21 CFR §314.153(b), the Agency will initiate procedures to determine if ANDA's based on the withdrawn listed drug should be suspended from marketing. ASTA Medica is not aware of any publication in the Federal Register concerning the determination of withdrawal pursuant to 21 CFR §314.161(a)(2) or the initiation of any procedures pursuant to 21 CFR §314.153(b).

Consistent with 21 §314.122(a) and §314.161(b), ASTA Medica has no information or evidence available to it that non-lyophilized Cytoxan is no longer on the market because of safety or effectiveness reasons. There are two other non-lyophilized cyclophosphamide for injection, USP products still in the Prescription Drug Products section of the Orange Book, and the non-lyophilized forms of Cytoxan were moved to the Discontinued Drug Products list approximately 13 years after the lyophilized forms of Cytoxan were approved, it is unlikely that the reason is due to a safety or effectiveness problem. We submit that the non-marketing of the non-lyophilized product was strictly an economic/strategic decision by Bristol-Myers Squibb, totally unrelated to safety or efficacy.

C. Environmental Impact

An environmental assessment on the action requested in this petition qualifies for a categorical exclusion under 21 CFR §25.31. Therefore, an environmental assessment is not required for the requested action.

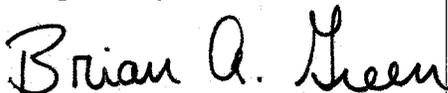
D. Economic Impact

Pursuant to 21 CFR §10.30(b), economic impact information is to be submitted only when requested by the Commissioner. ASTA Medica, Inc. will provide such information promptly, if so requested.

E. Certification

On behalf of ASTA Medica, I certify that, to the best of my knowledge and belief, this petition includes all information and views on which the petition relies as well as representative data and information known to the petitioner that are unfavorable to the petition.

Respectfully submitted,



Brian A. Green, MS  
Manager, Regulatory Affairs  
ASTA Medica, Inc.  
890 East Street  
Tewksbury, MA 01876-1496

Application Number: 012142  
Product Number: 009  
Approval Date: Dec 10, 1984  
Reference Listed Drug: Yes  
RX/OTC/DISCN: RX  
TE Code: **AP**  
Patent and Exclusivity Info for this product: [Click Here](#)

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Active Ingredient: CYCLOPHOSPHAMIDE  
Dosage Form;Route: Injectable; Injection  
Proprietary Name: LYOPHILIZED CYTOXAN  
Applicant: BRISTOL MYERS SQUIBB  
Strength: 1GM/VIAL  
Application Number: 012142  
Product Number: 010  
Approval Date: Sep 24, 1985  
Reference Listed Drug: Yes  
RX/OTC/DISCN: RX  
TE Code: **AP**  
Patent and Exclusivity Info for this product: [Click Here](#)

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## Search results from the "Disc" table for query on "012142."

Active Ingredient: CYCLOPHOSPHAMIDE  
 Dosage Form;Route: Injectable; Injection  
 Proprietary Name: CYTOXAN  
 Applicant: BRISTOL MYERS SQUIBB  
 Strength: 100MG/VIAL  
 Application Number: 012142  
 Product Number: 001  
 Approval Date: Approved prior to Jan 1, 1982  
 RX/OTC/DISCN: DISCN  
 Patent and Exclusivity Info for this product: [Click Here](#)

Active Ingredient: CYCLOPHOSPHAMIDE  
 Dosage Form;Route: Injectable; Injection  
 Proprietary Name: CYTOXAN  
 Applicant: BRISTOL MYERS SQUIBB  
 Strength: 200MG/VIAL  
 Application Number: 012142  
 Product Number: 002  
 Approval Date: Approved prior to Jan 1, 1982  
 RX/OTC/DISCN: DISCN  
 Patent and Exclusivity Info for this product: [Click Here](#)

Active Ingredient: CYCLOPHOSPHAMIDE  
 Dosage Form;Route: Injectable; Injection  
 Proprietary Name: CYTOXAN  
 Applicant: BRISTOL MYERS SQUIBB  
 Strength: 500MG/VIAL  
 Application Number: 012142  
 Product Number: 003  
 Approval Date: Approved prior to Jan 1, 1982  
 RX/OTC/DISCN: DISCN  
 Patent and Exclusivity Info for this product: [Click Here](#)

Active Ingredient: CYCLOPHOSPHAMIDE  
 Dosage Form;Route: Injectable; Injection  
 Proprietary Name: CYTOXAN  
 Applicant: BRISTOL MYERS SQUIBB  
 Strength: 1GM/VIAL  
 Application Number: 012142  
 Product Number: 004  
 Approval Date: Aug 30, 1982  
 RX/OTC/DISCN: DISCN  
 Patent and Exclusivity Info for this product: [Click Here](#)

Active Ingredient: CYCLOPHOSPHAMIDE

Dosage Form;Route:	Injectable; Injection
Proprietary Name:	CYTOXAN
Applicant:	BRISTOL MYERS SQUIBB
Strength:	2GM/VIAL
Application Number:	012142
Product Number:	005
Approval Date:	Aug 30, 1982
RX/OTC/DISCN:	DISCN
Patent and Exclusivity Info for this product:	<a href="#">Click Here</a>

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U.S. Food and Drug Administration  
Center for Drug Evaluation and Research

# Drug and Device Approvals-December 1995

December 1995 - FDA Drug and Device Product Approvals

\*\*\*ORIGINAL AND SUPPLEMENTAL NDAs\*\*\*  
FOR NEW DRUG PRODUCTS

20-628 INVIRASE  
06-DEC-95 (CAPSULE)  
(1 P, AA\*, E\*\*, H\*\*\*)

ROCHE  
NUTLEY, NJ  
07110

SAQUINAVIR MESYLATE  
EQ 200MG BASE  
(ANTIVIRAL)  
[TREATMENT OF ADVANCED HIV  
INFECTION IN SELECTED  
PATIENTS IN COMBINATION  
WITH NUCLEOSIDE ANALOGUES]

19-835 ZYRTEC  
08-DEC-95 (TABLET)  
(1 S)

PFIZER  
NEW YORK, NY  
10017

CETIRIZINE  
HYDROCHLORIDE  
5MG  
10MG  
(H1-RECEPTOR  
ANTAGONIST)  
[SEASONAL AND  
PERENNIAL  
ALLERGIC RHINITIS,  
CHRONIC URTICARIA]

20-221 ETHYOL  
08-DEC-95 (INJECTABLE)  
(1 P, V\*\*\*\*)

US BIOSCIENCE  
WEST CONSHOHOCKEN, PA  
19428

AMIFOSTINE  
500MG/VIAL  
(CYTOPROTECTIVE)  
[TO REDUCE THE CUMULATIVE  
RENAL TOXICITY ASSOCIATED  
WITH REPEATED ADMINISTRATION  
OF CISPLATIN IN PATIENTS  
WITH ADVANCED OVARIAN CANCER]

AA\* - Priority Classification AIDS Drug  
E\*\* - Drug for Severely Debilitating/Life Threatening Illness  
H\*\*\* - Accelerated Approval (drug is intended to treat a serious of life-  
threatening illness  
and provide a meaningful therapeutic benefit over existing treatments,  
and the NDA was approved under the provisions of 21 CFR 314 Subpart H)  
V\*\*\*\* - Designated Orphan Drug

20-363 FAMVIR  
11-DEC-95 (TABLET)  
(SUPPL-004)

SMITHKLINE BEECHAM  
PHILADELPHIA, PA  
19101

FAMCICLOVIR  
125MG  
(NEW INDICATION --  
TREATMENT OF ACUTE  
RECURRENT GENITAL HERPES)

20-553 OXYCONTIN  
12-DEC-95 (TABLET,  
EXTENDED RELEASE)  
(3 S)

PURDUE FREDERICK  
NORWALK, CT  
06850

OXYCODONE HYDROCHLORIDE  
10MG  
20MG  
40MG  
(OPIOID ANALGESIC)

20-599 RILUTEK  
12-DEC-95 (TABLET)

RHONE POULENC  
COLLEGEVILLE, PA

RILUZOLE  
50MG

14-DEC-95	(POWDER FOR RECONSTITUTION)	RES TRIANGLE PK, NC 27709	EQ 125MG BASE/5ML (LABELING REVISION -- DESCRIPTION; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
12-122 15-DEC-95	GLUCAGON (INJECTABLE)	LILLY INDIANAPOLIS, IN 46285	GLUCAGON HYDROCHLORIDE EQ 1MG BASE/VIAL (LABELING REVISION -- DESCRIPTION; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
10-187 15-DEC-95	RITALIN (TABLET)	CIBA SUMMIT, NJ 07901	METHYLPHENIDATE HYDROCHLORIDE 5MG 10MG 20MG (LABELING REVISION -- PRECAUTIONS)
18-029 15-DEC-95	RITALIN-SR (TABLET, EXTENDED RELEASE)	CIBA SUMMIT, NJ 07901	METHYLPHENIDATE HYDROCHLORIDE 20MG (LABELING REVISION -- PRECAUTIONS)
18-537 15-DEC-95	TRIDIL (INJECTABLE)	FAULDING ELIZABETH, NJ 07207	NITROGLYCERIN 0.5MG/ML 5MG/ML (LABELING REVISION -- PRECAUTIONS)
18-470 18-DEC-95	CIBACALCIN (INJECTABLE)	CIBA SUMMIT, NJ 07901	CALCITONIN, HUMAN 0.5MG/VIAL (LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS)
19-726 18-DEC-95	ZOLADEX (IMPLANT)	ZENECA WILMINGTON, DE 19850	GOSERELIN ACETATE EQ 3.6MG BASE (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
12-141 20-DEC-95	CYTOXAN (TABLET)	BRISTOL SYRACUSE, NY 13221	CYCLOPHOSPHAMIDE 25MG 50MG (LABELING REVISION -- WARNINGS; ADVERSE REACTIONS; HOW SUPPLIED)
12-142 20-DEC-95	CYTOXAN (INJECTABLE)	BRISTOL SYRACUSE, NY 13221	CYCLOPHOSPHAMIDE 100MG/VIAL 200MG/VIAL 500MG/VIAL 1GM/VIAL 2GM/VIAL (LABELING REVISION -- WARNINGS; ADVERSE REACTIONS;

*Both forms still available in 1995*

			HOW SUPPLIED)
12-142 20-DEC-95	LYOPHILIZED CYTOXAN (INJECTABLE)	BRISTOL SYRACUSE, NY 13221	CYCLOPHOSPHAMIDE 100MG/VIAL 200MG/VIAL 500MG/VIAL 1GM/VIAL 2GM/VIAL (LABELING REVISION -- WARNINGS; ADVERSE REACTIONS; HOW SUPPLIED)
50-441 20-DEC-95	CLEOCIN PHOSPHATE (INJECTABLE)	UPJOHN KALAMAZOO, MI 49001	CLINDAMYCIN PHOSPHATE EQ 150MG BASE/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
50-639 20-DEC-95	CLEOCIN PHOSPHATE IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	UPJOHN KALAMAZOO, MI 49001	CLINDAMYCIN PHOSPHATE EQ 6MG BASE/ML EQ 12MG BASE/ML EQ 18MG BASE/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
20-412 21-DEC-95	ZERIT (CAPSULE)	BRISTOL MYERS SQUIBB WALLINGFORD, CT 06492	STAVUDINE 15MG 20MG 30MG 40MG (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; PRECAUTIONS; ADVERSE REACTIONS)
19-684 26-DEC-95	PROCARDIA XL (TABLET, EXTENDED RELEASE)	PFIZER NEW YORK, NY 10017	NIFEDIPINE 30MG 60MG 90MG (LABELING REVISION -- PRECAUTIONS)
50-664 26-DEC-95	CEFZIL (TABLET)	BRISTOL MYERS SQUIBB WALLINGFORD, CT 06492	CEFPROZIL 250MG 500MG (LABELING REVISION -- WARNINGS)
50-665 26-DEC-95	CEFZIL (POWDER FOR RECONSTITUTION)	BRISTOL MYERS SQUIBB WALLINGFORD, CT 06492	CEFPROZIL 125MG/5ML 250MG/5ML (LABELING REVISION -- WARNINGS)
20-386 29-DEC-95	COZAAR (TABLET)	MERCK WEST POINT, PA	LOSARTAN POTASSIUM 25MG



**Prescription and Over-the-Counter Drug Product List - 17th Edition**

**Cumulative Supplement Number 5: Jan '97 - May '97**

**[Prescription - OTC]**

**ADDITIONS/DELETIONS FOR PRESCRIPTION DRUG PRODUCT LIST**

	ACARBOSE				
	TABLET; ORAL				
	PRECOSE				
> ADD >	BAYER	25MG		N20482 004	> ADD >
> ADD >				MAY 29, 1997	> ADD >
					> ADD >
					> ADD >
	ACETAMINOPHEN; HYDROCODONE BITARTRATE				
	TABLET; ORAL				
	LORTAB				
> DLT >	AA + GRAHAM DM	500MG;10MG		N40100 001	> DLT >
> DLT >				JAN 26, 1996	> DLT >
> ADD >	AA + UCB	500MG;10MG		N40100 001	> DLT >
> ADD >				JAN 26, 1996	> ADD >
					> ADD >
	ACETAZOLAMIDE				> ADD >
	TABLET; ORAL				> ADD >
	ACETAZOLAMIDE				> ADD >
> ADD >	AB TARO	125MG		N40195 001	> ADD >
> ADD >				MAY 28, 1997	> ADD >
> ADD >	AB	250MG		N40195 002	> ADD >
> ADD >				MAY 28, 1997	> ADD >
					> ADD >
	AMINOPHYLLINE				> DLT >
	TABLET; ORAL				> DLT >
	AMINOPHYLLINE				> DLT >
> DLT >	BD HALSEY	100MG		N84674 001	> DLT >
> ADD >	@	100MG		N84674 001	> DLT >
					> ADD >
					> ADD >
	AMITRIPTYLINE HYDROCHLORIDE				> DLT >
	TABLET; ORAL				> DLT >
	AMITRIPTYLINE HCL				> DLT >
> DLT >	BP HALSEY	10MG		N85923 001	> DLT >
> DLT >	BP	50MG		N85925 001	> DLT >

## Search results from the "Rx" table for query on "040015."

Active Ingredient:	CYCLOPHOSPHAMIDE
Dosage Form;Route:	Injectable; Injection
Proprietary Name:	NEOSAR
Applicant:	PHARMACIA AND UPJOHN
Strength:	100MG/VIAL
Application Number:	040015
Product Number:	001
Approval Date:	Apr 29, 1993
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	<b>AP</b>
Patent and Exclusivity Info for this product: <a href="#">Click Here</a>	

Active Ingredient:	CYCLOPHOSPHAMIDE
Dosage Form;Route:	Injectable; Injection
Proprietary Name:	NEOSAR
Applicant:	PHARMACIA AND UPJOHN
Strength:	200MG/VIAL
Application Number:	040015
Product Number:	002
Approval Date:	Apr 29, 1993
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	<b>AP</b>
Patent and Exclusivity Info for this product: <a href="#">Click Here</a>	

Active Ingredient:	CYCLOPHOSPHAMIDE
Dosage Form;Route:	Injectable; Injection
Proprietary Name:	NEOSAR
Applicant:	PHARMACIA AND UPJOHN
Strength:	500MG/VIAL
Application Number:	040015
Product Number:	003
Approval Date:	Apr 29, 1993
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	<b>AP</b>
Patent and Exclusivity Info for this product: <a href="#">Click Here</a>	

Active Ingredient:	CYCLOPHOSPHAMIDE
Dosage Form;Route:	Injectable; Injection
Proprietary Name:	NEOSAR
Applicant:	PHARMACIA AND UPJOHN
Strength:	1GM/VIAL

**Search results from the "Rx" table for query on "087442."**

Active Ingredient:	CYCLOPHOSPHAMIDE
Dosage Form;Route:	Injectable; Injection
Proprietary Name:	NEOSAR
Applicant:	PHARMACIA AND UPJOHN
Strength:	100MG/VIAL
Application Number:	087442
Product Number:	001
Approval Date:	Feb 16, 1982
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	<b>AP</b>
Patent and Exclusivity Info for this product:	<a href="#">Click Here</a>

Active Ingredient:	CYCLOPHOSPHAMIDE
Dosage Form;Route:	Injectable; Injection
Proprietary Name:	NEOSAR
Applicant:	PHARMACIA AND UPJOHN
Strength:	200MG/VIAL
Application Number:	087442
Product Number:	002
Approval Date:	Feb 16, 1982
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	<b>AP</b>
Patent and Exclusivity Info for this product:	<a href="#">Click Here</a>

Active Ingredient:	CYCLOPHOSPHAMIDE
Dosage Form;Route:	Injectable; Injection
Proprietary Name:	NEOSAR
Applicant:	PHARMACIA AND UPJOHN
Strength:	500MG/VIAL
Application Number:	087442
Product Number:	003
Approval Date:	Feb 16, 1982
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	<b>AP</b>
Patent and Exclusivity Info for this product:	<a href="#">Click Here</a>

Active Ingredient:	CYCLOPHOSPHAMIDE
Dosage Form;Route:	Injectable; Injection
Proprietary Name:	NEOSAR
Applicant:	PHARMACIA AND UPJOHN
Strength:	1GM/VIAL

Application Number: 087442  
Product Number: 004  
Approval Date: Jul 08, 1983  
Reference Listed Drug: No  
RX/OTC/DISCN: RX  
TE Code: **AP**  
Patent and Exclusivity Info for this product: [Click Here](#)

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Active Ingredient: CYCLOPHOSPHAMIDE  
Dosage Form;Route: Injectable; Injection  
Proprietary Name: NEOSAR  
Applicant: PHARMACIA AND UPJOHN  
Strength: 2GM/VIAL  
Application Number: 087442  
Product Number: 005  
Approval Date: Mar 30, 1989  
Reference Listed Drug: No  
RX/OTC/DISCN: RX  
TE Code: **AP**  
Patent and Exclusivity Info for this product: [Click Here](#)

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**Search results from the "Rx" table for query on "088371."**

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Active Ingredient:	CYCLOPHOSPHAMIDE
Dosage Form;Route:	Injectable; Injection
Proprietary Name:	CYCLOPHOSPHAMIDE
Applicant:	ASTA
Strength:	100MG/VIAL
Application Number:	088371
Product Number:	001
Approval Date:	Jul 03, 1986
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	<b>AP</b>
Patent and Exclusivity Info for this product:	<a href="#">Click Here</a>

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**Search results from the "Rx" table for query on "088372."**

Active Ingredient:	CYCLOPHOSPHAMIDE
Dosage Form;Route:	Injectable; Injection
Proprietary Name:	CYCLOPHOSPHAMIDE
Applicant:	ASTA
Strength:	200MG/VIAL
Application Number:	088372
Product Number:	001
Approval Date:	Jul 03, 1986
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	<b>AP</b>
Patent and Exclusivity Info for this product:	<a href="#">Click Here</a>

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**Search results from the "Rx" table for query on "088373."**

Active Ingredient:	CYCLOPHOSPHAMIDE
Dosage Form;Route:	Injectable; Injection
Proprietary Name:	CYCLOPHOSPHAMIDE
Applicant:	ASTA
Strength:	500MG/VIAL
Application Number:	088373
Product Number:	001
Approval Date:	Jul 03, 1986
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	<b>AP</b>
Patent and Exclusivity Info for this product:	<a href="#">Click Here</a>

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**Search results from the "Rx" table for query on "088374."**

Active Ingredient:	CYCLOPHOSPHAMIDE
Dosage Form;Route:	Injectable; Injection
Proprietary Name:	CYCLOPHOSPHAMIDE
Applicant:	ASTA
Strength:	1GM/VIAL
Application Number:	088374
Product Number:	001
Approval Date:	Sep 24, 1986
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	<b>AP</b>
Patent and Exclusivity Info for this product:	<a href="#">Click Here</a>

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From: KAREN HOMEN (978)858-2566  
MURO ASTA MEDICA, INC  
890 EAST STREET

SHIPPER'S FEDEX ACCOUNT #



TEWKSBURY, MA, 01876

To: Dockets Management Branch (301)827-2531

FDA

Department of Health and Human Services

12420 Parklawn Drive

Rockville, MD, 20857

SHIP DATE: 26JUL01  
WEIGHT: 1 LBS

Ref:



DELIVERY ADDRESS BARCODE(FEDEX-EDR)

FedEx STANDARD OVERNIGHT

FRI

TRK # 7916 2174 7407 6901

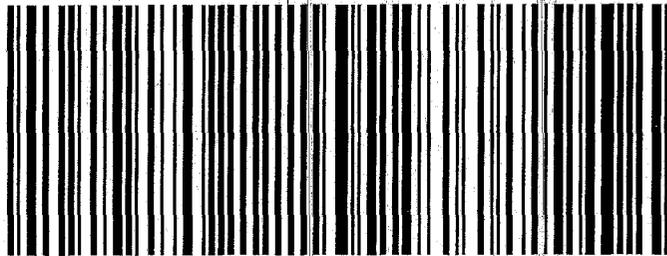
IAD

AA

20857-MD-US

ZM GAIA

Deliver by:  
27JUL01



Please fold this document in half and place it in the waybill pouch affixed to your shipment so that the barcode portion of the label can be read and scanned.

\*\*\*WARNING: Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges, along with the cancellation of your FedEx account number.

### Shipping Label

Schedule Courier

Find a Dropoff Location

Shipping History

Shipment Complete

Cancel Shipment

1. Use the "Print" feature from your browser to send this page to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping label pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.
4. To print a receipt of your shipment, please click on "Shipping History."

### Ship a New Package

Ship Inside U.S.

Ship Outside U.S.

Ship to Same Recipient

Use of this system constitutes your agreement to the service conditions in the current FedEx service Guide, available upon request.

FedEx will not be responsible for any claim in excess of \$100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of \$100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is \$500, e.g. jewelry, precious metals, negotiable instruments