B|BRAUN

May 10, 2006

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 161
Rockville, MD 20862

Citizen Petition

The undersigned submits this petition under 21 CFR 10.25(a) and 21 CFR 10.30 to request the Commissioner of the Food and Drug Administration to determine whether a listed drug (Cefotan®, manufactured by AstraZeneca under NDA 50-588), that has been discontinued, was not discontinued for safety or effectiveness reasons. In addition, the undersigned submits this petition to request permission of filing an abbreviated new drug application (ANDA) if the listed drug was discontinued for reasons other than for safety and effectiveness.

A. Action Requested

The petitioner (B. Braun Medical Inc.) requests that the Commissioner of the Food and Drug Administration determine whether Cefotan® (cefotetan injection), equivalent 1 g base/vial and 2 g base/vial, NDA 50-588, manufactured by AstraZeneca has been voluntarily withdrawn from sale for safety and efficacy reasons.

B. Statement of Grounds

The Food and Drug Administration's Orange Book lists Cefotan® as an active reference listed drug. According to information received online at www.factsandcomparisons.com and FDA's drug shortages website (www.fda.gov/cder/drug/shortages/default.com) under discontinuations, this product was discontinued as of March 31, 2006. Copies of online web pages are enclosed.

Under FDA regulations, the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety and effectiveness before an ANDA referencing the listed drug may be approved (21 CFR 314.161(a)(1)).

B. Braun Medical Inc. has no information or evidence concerning the reason that AstraZeneca discontinued marketing Cefotan®, but nonetheless contends that the reasons were unrelated to safety and effectiveness. B. Braun Medical Inc. petitions FDA to determine that AstraZeneca's decision to discontinue marketing Cefotan® was for reasons other safety or effectiveness.

C. Environmental Impact

A claim for categorical exclusion of the requirement for submission of an environmental assessment or environmental impact statement is made pursuant to 21 CFR 25.31.

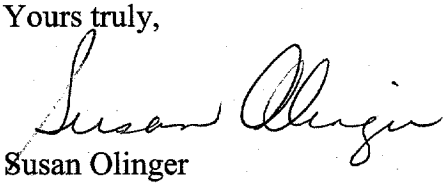
D. Economic Impact

In accordance with 21 CFR 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition. B. Braun Medical Inc., hereby commits to promptly provide this information, if so requested.

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 which are unfavorable to the petition.

Yours truly,



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AstraZeneca Discontinues *Cefotan*

11/21/2005
AstraZeneca Pharmaceuticals is discontinuing *Cefotan* (cefotetan injection) and expects the remaining inventory to be depleted by March 31, 2006, with no additional plans to manufacture or distribute the drug. Health care providers with questions should contact AstraZeneca's Corporate Information Center at 1-800-236-9933.

U.S. Food and Drug Administration

Department of Health and Human Services

CENTER FOR DRUG EVALUATION AND RESEARCH

Drug Shortages

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Drug Shortages Email Alert: To receive email notification of drug products added to the Current Drug Shortages, and Resolved Drug Shortages lists, link to http://list.nih.gov/cgi-bin/wa?SUBED1=drug-shortages&A=1 and complete the Drug Shortages listserv form.

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Drug Shortages RSS feed.
XML Find out more about RSS.

Introduction

It is FDA's policy to help prevent or alleviate shortages primarily of medically necessary drug products, since these can have significant public health consequences. A drug shortage may involve either an actual or a potential shortage of a drug product.

A 1997 FDA Consumer article "Inside FDA: When a Drug is in Short Supply" provides background information and an example of how FDA manages drug shortages. The article "FDA's Role in Responding to Drug Shortages" published in the American Journal of Health Systems Pharmacists {2002 Aug 1;59(15):1423-5}, provides additional information.

Frequently Asked Questions

Current Drug Shortages

Drug Name	Company Information	Reason for Shortage	Related Information
Albuterol Metered Dose Inhalers- (3/9/2006) Albuterol metered dose inhalers, both HFA and CFC inhalers, are made by multiple manufacturers. Beginning in early 2006, there have been temporary outages of albuterol inhaler products from some manufacturers. However other manufacturers continue to supply the market at previous or increased levels. Therefore, albuterol inhaler products continue to be available and additional supplies are anticipated over the next several weeks. Even though total albuterol supplies (HFA and CFC) are anticipated to meet demand, supplies of HFA albuterol metered dose inhalers are anticipated to increase relative to supplies of			

CFC inhalers over the next several months. Therefore, HFA inhalers may need to be substituted for CFC inhalers as the shift towards increased HFA inhalers continues to occur. Please note CFC albuterol inhalers will be completely withdrawn from the market by December 31, 2008 -see http://www.fda.gov/cder/mdi/mdifaqs.htm for further information.

The following firms are currently producing albuterol and levalbuterol metered dose inhalers. FDA considers all of these inhalers as options for patients who cannot otherwise get their preferred albuterol brand or product:

Albuterol metered dose inhalers:
Schering Plough is not experiencing a shortage at this time. Schering Plough's products are as follows:

Proventil (NDC 00085-0614-02), Proventil-HFA (NDC 00085-1132-01)
Warrick - albuterol MDI (NDC 59930-1560-01). Schering Customer Service: 1-877-432-7768.

GlaxoSmithKline - Ventolin-HFA (NDC# 0173-0682-00) - additional supplies anticipated to be available mid 2006. Customer service number 1-888-825-5249

IVAX is shipping supplies of albuterol metered dose inhalers (NDC 00172-4390-18) and Albuterol-HFA (NDC 59310-579-20) as they become available

Armstrong Pharmaceuticals albuterol metered dose inhalers (NDC 17270-0721-01). Customer service- 1 (800) 423-4136

Levalbuterol metered dose inhalers:
Sepracor - Xopenex HFA (levalbuterol tartrate) Inhalation Aerosol metered dose inhalers (NDC 63402-510-01). Customer

service 1-888-394-7377 FDA will continue to closely monitor this situation and will continue to work with the manufacturers on issues related to increasing supplies.			
BiCNU (carmustine) Injection updated 11/8/2005	Bristol-Myers Squibb 1-800-631-5244	Manufacturing pending	Update from BMS (updated 11/8/2005)
Maxipime (cefepime)	Elan Pharmaceuticals	Manufacturing delays	You may contact Elan at 1-800-859-8586 for additional information
Proglycem oral suspension 3/17/2006	IVAX/TEVA	Temporary delay	Supplies are anticipated to continue to meet demand. In order to continue to meet patient needs until normal distribution returns, pharmacies can call 1-800-445-2455

			to obtain an emergency supply of Proglycem to fill a prescription for an individual patient.
Valstar (valrubicin) Solution for Intravesical Instillation 4/24/2006 New!!	Valera Pharmaceuticals, Inc Cranbury, NJ Customer Service: 1-888-282-5372	Product was previously discontinued	As of April 2006, Valera acquired the rights to manufacture, market and distribute Valstar, and plans on re-introducing the product in the U.S. in the fourth quarter of 2006.

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Resolved Drug Shortages

Drug Name	Company Information	Related Information
Amphotericin B injection 2/23/2005	X-GEN (formerly Pharma-Tek), Sandoz	Amphotericin B injection is now available through normal distribution.
Avonex (interferon Beta 1a)	Biogen Idec (800) 456-2255	No further supply issues are anticipated.

4/12/2005		
Cortrosyn Injection (Cosyntropin) 0.25mg/vial 1/19/2005	Amphastar	Cortrosyn is now available through normal distribution. Please call Customer Service at 1-800-423-4136 for additional information.
Celestone Soluspan 4/6/2006	Schering-Plough Corp. 2000 Galloping Hill Rd. Kenilworth, NJ 07033-0530 908-298-4000 800-526-4099	Celestone Soluspan is now available through normal distribution channels.
Coreg (carvedilol) tablets 5/3/2006 New!!	GlaxoSmithKline	Coreg is now available through normal distribution channels. (please see attached letter for additional information)
Cytovene (ganciclovir) Powder for Injection 4/5/2005	Roche Professional Product Information Department 1-800-526-6367	Cytovene IV shortage has been resolved and no further supply problems are anticipated

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Fluorouracil Injection 4/10/2006 UPDATED	APP	5FU Available Presentations: NDC#: 63323-117-10 Strength = 500mg Vial Size = 10 mL NDC#: 63323-117-20 Strength = 1 gm Vial Size = 20 mL NDC#: 63323-117-51 Strength = 2.5g Vial Size = 50 mL NDC#: 63323-117-61 Strength = 5g Vial Size = 100mL
Marplan (isocarboxazid) 10 mg 5/20/2005	Oxford Pharmaceutical (877) 284-9120	Marplan will resume normal distribution 5/27/2005
MERREM IV (meropenem for injection) 4/6/2006 New!!	AstraZeneca Pharmaceuticals LP (Corporate Information Center 1-800-236-9933)	AstraZeneca has removed the allocation for MERREM for the 1gram/30 ml vials (NDC 0310-0321-30) and the 500 mg/20 ml vials (NDC 0310-0325-20.
Methotrexate injection	Mayne Pharma 1-866-594-8420	Please be sure to use new NDC numbers

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updated 3/17/2006	Bedford 1-800-562-4797	
	American Pharmaceutical Partners 1-888-386-1300	Methotrexate injection available from APP: NDC#: 63323-123-02 Strength = 25mg/ml Vial Size = 2mL NDC#: 63323-123-10 Strength = 25mg/ml Vial Size = 10 mL
Solu-Cortef (Hydrocortisone sodium succinate) for injection 4/6/2005	Pfizer	All presentations of Solu-Cortef are now available without restrictions.
Solu-Medrol (methylprednisolone sodium succinate) for injection 1/3/2006	Pfizer, American Pharmaceutical Partners (APP), Hospira	Pfizer reports availability of Solu-Medrol (methylprednisolone sodium succinate) injection. Please call Customer Service (800) 533-4535 if Solu-Medrol injection is NOT available through wholesale channels. American Pharmaceutical Partners (APP) has methylprednisolone

		sodium succinate injection available in 1 gram vials (63323-265-30). 125 mg vials (NDC #63323-258-03) and 40 mg vials (NDC 63323-255-03) are currently unavailable. Please call APP at 1-888-386-1300 for additional information. (updated 1/3/2006). Hospira has A-Methapred (methylprednisolone sodium succinate) injection available in 125 mg vials, NDC #00074-5685-02. Please call Hospira at 1-877-946-7747 for additional information.
TABLOID (Thioguanine) 40 mg Tablets 1/26/2005	GlaxoSmithKline	Please call GSK for additional information at 1-888-527-6933
Thiola (tiopronin) 100 mg tablets 1/3/2005	Mission Pharmacal Customer Service	Thiola is now available from pharmacies through normal distribution. Please

	(800) 292-7364	contact Mission Pharmacal at 1-800-292-7364 for additional information.
Trecator SC (ethionamide) 250 mg tablets 4/1/2005	Wyeth	Trecator SC is now available through normal distribution.
Zemuron (rocuronium bromide) injection, 5 ml and 10 ml vials 2/7/2005	Organon Pharmaceuticals USA Inc. (800) 241-8812	Please call Organon Customer Service at 1-800-241-8812 for additional information
Zyflo Filmtab (Zileuton) Tablets 11/17/2005	Critical Therapeutics (866) 835-8216	Zyflo is now available through Clinical Therapeutics.

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Discontinuations

The Food, Drug and Cosmetic Act requires companies to give FDA a six-month notification of the discontinuation of sole source products that are life-supporting, life-sustaining or for use in the prevention of a debilitating disease or condition.. From time to time, FDA also receives notification

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for other products. These discontinuations are provided below for informational purposes only.

To locate drugs that have already been discontinued, please consult the following:
Drugs@FDA
Orange Book Query
Orange Book Monthly Additions and Deletions

Drug Name	Company Information	Related Information
Agenerase (amprenavir) 150mg capsule 9/17/2004	GlaxoSmithKline 1-888-825-5249	Letter from GlaxoSmithKline
Calciferol injection in oil (ergocalciferol) 3/19/2004	Schwarz Pharma 6140 W. Executive Drive Mequon, WI 53092 1-800-558-5114	Schwarz has discontinued manufacturing of calciferol
CEFOTAN (cefotetan injection) 11/15/2005	AstraZeneca Pharmaceuticals LP (AstraZeneca) - Contact Corporate Information Center at 1-800-236-9933.	The remaining inventory of CEFOTAN (cefotetan injection) will be depleted by March 31, 2006. AstraZeneca has no further plans to manufacture or distribute CEFOTAN (cefotetan injection) after March 31, 2006. For further

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		questions, the AstraZeneca Corporate Information Center may be contacted at 1-800-236-9933.
Cylert (pemoline) tablets and chewable tablets, all strengths 5/25/2005	Abbott Laboratories	Abbott has made the decision to discontinue Cylert tablets and chewable tablets Letter from Abbott
ELAVIL (amitriptyline hydrochloride) Tablets and Injection. 5/15/2003	AstraZeneca Pharmaceuticals LP (AstraZeneca) – Contact Corporate Information Center at 1-800-236-9933	ELAVIL Injection is no longer available at AstraZeneca. The remaining inventory of ELAVIL Tablets will be depleted by December 31, 2003. AstraZeneca has no further plans to manufacture ELAVIL (amitriptyline hydrochloride) Tablets or Injection.
Flovent Rotadisk (fluticasone propionate inhalation powder)	GlaxoSmithKline 1-888-825-5249	Please see Dear Healthcare Professional letter for additional information.

8/31/2004		
Fortovase (saquinavir) capsules 200 mg 6/2/2005	Roche	Fortovase 200 mg capsules will be discontinued by February 15, 2006. Please see attached DHP letter for additional information. Dear Healthcare Professional Letter
Humulin U ULTRALENTE (HUMAN INSULIN [rDNA ORIGIN] EXTENDED ZINC SUSPENSION) 7/6/2005	Eli Lilly and Company	Dear Doctor Letter Patient Information
Humulin L LENTE (HUMAN INSULIN [rDNA ORIGIN] ZINC SUSPENSION) 7/6/2005	Eli Lilly and Company	Dear Doctor Letter Patient Information
Inulin in Sodium Chloride Injection, USP 9/26/2003	Questcor Pharmaceuticals, Inc.	Letter

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Kefzol (cefazolin) all presentations 2/28/2003	Eli Lilly and Company	Letter
Kefurox (cefuroxime) all presentations 2/28/2003	Eli Lilly and Company	Letter
Lanoxin Elixir (digoxin) 6/3/2005	GlaxoSmithKline	This product has been discontinued by GSK. Roxane is producing digoxin elixir.
Mandol (cefamandole) all presentations 2/28/2003	Eli Lilly and Company	Letter
Nolvadex (tamoxifen citrate) 4/10/2006 New!!	AstraZeneca (1-800-236-9933)	Letter
Novolin L, Lente, human insulin zinc suspension [rDNA origin] 7/15/2003	Novo Nordisk Pharmaceuticals, Inc. Contact: 1-800-727-6500 Customer Service	Letter

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NPH Iletin II (ISOPHANE INSULIN SUSPENSION, USP, PURIFIED PORK) 7/6/2005	Eli Lilly and Company	• Dear Doctor Letter • Patient Information • Frequently Asked Questions
ORLAAM (Levomethadyl hydrochloride acetate) Oral Solution, 10 mg/mL 9/2/2003	Roxane Laboratories	Letter
Panrease (pancrelipase) capsules 3/29/2006 New!!	McNeil Consumer and Specialty Pharmaceuticals, 1-888-440-7903	Other pancrelipase products continue to be available
Perchloracap (potassium perchlorate) 200 mg capsules 6/2/2005	Tyco Healthcare	Perchloracap capsules have been discontinued and supplies are anticipated to be depleted by the end of 2005.
Pre-Pen (benzylpenicilloyl polylysine) injection 4/13/2005	Hollister-Stier (800) 992-1120	Pre-Pen is no longer available.

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Regular Iletin II (INSULIN INJECTION, USP, PURIFIED PORK) 7/6/2005	Eli Lilly and Company	• Dear Doctor Letter • Patient Information • Frequently Asked Questions
Serevent Inhalation Aerosol 6/10/2003	GlaxoSmithKline 1-800-340-3236	GSK anticipates that SEREVENT Inhalation Aerosol will no longer be available starting in June 2003. Dear Health Care Professional Letter from GlaxoSmithKline
Stelazine (trifluoperazine) oral concentrate 10mg/ml Stelazine (trifluoperazine) tablets (1mg, 2mg, 5mg, 10mg) Stelazine (trifluoperazine) Injection 2mg/ml 12/18/2003	GlaxoSmithKline 1-888-825-5249	Stelazine was discontinued and withdrawn from the market. The final lots were distributed by GSK August 2003 and the final expiry date of all products in the marketplace is no later than January 31, 2004.
Suprax (cefixime)	Lederle/Wyeth Pharmaceuticals	Discontinued July 2002. Stock will be distributed until exhausted or until

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updated 2/25/2004		March 2003, whichever comes first. For additional information, please call customer service (800) 666-7248 Lupin Pharmaceuticals recently received approval for cefixime 400 mg tablets and cefixime 100 mg/5 ml suspension. For further information, please contact Lupin Pharmaceuticals at 410-576-2000 (2/25/2004)
Valstar (valrubicin) Solution for Intravesical Instillation 1/30/2004	Formerly distributed by Celltech (Celltech Customer Service 1-888-963-3382)	No further availability planned at this time.
Velosulin BR Human, Buffered Regular Human Insulin Injection [rDNA origin] 11/3/2003	Novo Nordisk Pharmaceuticals, Inc. Contact: 1-800-727-6500 Customer Service	Dear Healthcare Professional Letter
1.5% Xylocaine - MPF with	AstraZeneca (1-800-842-9920)	1.5% Xylocaine® -MPF with Dextrose 7.5%

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Dextrose 7.5% Injection (lidocaine HCl and dextrose anhydrous Injection ampules) 8/29/2005		Injection is no longer available at AstraZeneca. The remaining inventory of 1.5% Xylocaine® -MPF with Dextrose 7.5% Injection Ampules will be depleted by August 31, 2005. AstraZeneca has no further plans to manufacture 1.5% Xylocaine® -MPF with Dextrose 7.5% Injection Ampules
Zovirax (acyclovir sodium) for injection 1000mg/20ml vial 1/6/2004	GlaxoSmithKline Customer Service 1-800-877-1158	Letter from GSK

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Additional Communications

Distribution Changes for Lamprene (clofazimine) (5/4/2005) Please see the attached letter from Novartis Pharmaceuticals Corporation for information about distribution changes for Lamprene (clofazimine). • Letter to Doctors

On May 20, 2005, Praecis Pharmaceuticals announced that it is voluntarily discontinuing the sale of Plenaxis to new patients in the United States for economic reasons. Patients currently on Plenaxis therapy may continue to receive the drug. Please see Plenaxis Information page for additional information. (6/3/2005)

Drug Shortage Manual of Policies and Procedures (MaPP)

MaPPs are approved instructions for internal practices and procedures followed by CDER staff to help standardize the new drug review process and other activities. MaPPs define external activities as well. All MaPPs are available for the public to review to get a better understanding of office policies, definitions, staff responsibilities, and procedures.

- 4730.1 Drug Shortage Management (11/21/96). This describes CDER's Office of Compliance policy and procedures on drug shortage management. A CDER-wide MaPP is under development.

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Medical Necessity

A product is considered to be medically necessary, or a medical necessity, if it is used to treat or prevent a serious disease or medical condition, and there is no other available source of that product or alternative drug or therapy that is judged by medical staff to be an adequate substitute. Patient "inconvenience" alone is an insufficient basis to classify a product as a medical necessity.

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How to Report a Drug Shortage

To report a CDER product by email: drugshortages@cder.fda.gov

To report a CDER product by phone:

CDER Drug Information (888) INFOFDA or (888) 463-6332, or (301) 827-4570

To report a CBER product shortage (biological and related products including blood, vaccines, tissue, allergenics), by e-mail: CBERProductshortages@cber.fda.gov

To report a CBER product shortage (biological and related products including blood, vaccines, tissue, allergenics), by phone during business hours, biological product manufacturers and healthcare personnel may report a real or suspected biological product shortage by calling (301) 827-6220.

To report a CDRH or CFSAN shortage to FDA, see listings under FAQs

To report a shortage to ASHP you may use the Drug Product Shortages Report form (non-FDA site) available from the American Society of Health-Systems Pharmacists (ASHP) web page. When you use this form, you are reporting a drug shortage to ASHP, not FDA. CDER partners with ASHP to minimize drug shortages and report rapid accurate drug shortage information.

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Practical Steps for Practitioners Facing Drug Shortage Situations

ASHP Guideline on Managing Drug Shortages. The American Society of Health-System Pharmacists guideline describes the contributing factors to drug product shortages and recommends a general process for inventory management in preparation for and working through shortage situations.

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More Information on Drug Shortages, Product Recalls and Warnings

FDA Product Recalls, Alerts, and Warnings. FDA posts press releases and other notices of recalls from the firms involved as a service to consumers, the media, and other interested parties.

Cderrecalls@cder.fda.gov or phone (301) 827-9039

Other Drug Shortage Links

For more detailed information on all drug shortages we refer you to the following sites:

American Society of Health-System Pharmacists [External non-FDA Site]

For information on shortages of biological products, including blood and vaccines, we refer you to the Center for Biologics Evaluation and Research (CBER) shortage site: http://www.fda.gov/cber/shortage/shortage.htm

Comments on this Web Page
We ask you to take time to communicate with CDER about this website. Please e-mail us at drugshortages@cder.fda.gov with feedback about this site.

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FDA/Center for Drug Evaluation and Research