CENTER FOR DRUG EVALUATION AND RESEARCH

SPECIAL INTEREST TOPIC

TITLE: OFFICE OF GENERIC DRUGS LVP LETTERS

DATE: 8/26/97

ANDA 18-465 Soyacal 10% (Soybean Oil Injection)
18-786 Soyacal 20% (Soybean Oil Injection)

AUG 26 1997

Alpha Therapeutic Corp.
Attention: Dan Classen
5555 Valley Blvd.
Los Angeles, CA 90032

Dear Sir:

This is in reference to your new drug applications submitted pursuant to Section 505 of the Federal Food, Drug, and Cosmetic Act (Act).

Effective August 23, 1997, your applications were transferred from the Division of Metabolic and Endocrine Drug Products (HFD-510) to the Office of Generic Drugs (HFD-600).

The Code of Federal Regulations, Title 21, Section 310.509(a) established that any parenteral drug product packaged in a plastic immediate container is a new drug under section 201(p) of the Act and requires an approved new drug application as a condition for marketing. Section 310.509 took effect when 505(b) was the only provision in the Act for submission of a new drug application. The subsequent enactment of the Drug Price Competition and Patent Term Restoration Act of 1984 (Waxman-Hatch Amendments) replaced 505(b) with 505(b)(1), 505(b)(2) and 505(j), thereby creating three distinct types of applications for approval of new drugs depending on the nature and the source of the evidence required to demonstrate the safety and effectiveness of the new drug product.

On September 6, 1996 the Center for Drug Evaluation and Research (CDER) issued MAPP 6020.2 which addressed applications for parenteral products in plastic immediate containers. In this MAPP, an application of a parenteral product in a plastic immediate container may be filed as an Abbreviated New Drug Application (ANDA) under section 505(j) or, for antibiotics, an Abbreviated Antibiotic Drug Application (AADA) under section 507 provided that, 1) the product duplicates an approved product listed in the current edition of *Approved Drug Products with Therapeutic Equivalence Evaluations* ("The Orange Book") and 2) approval of the product in the plastic immediate container does not require studies beyond limited confirmatory testing and the testing described in the USP. Your applications have been

determined to meet the criteria above or have been determined to meet the requirements of an ANDA under section 505(j) of the Act.

This change in Center policy now permits the Office of Generic Drugs to assume the administrative and review functions of these applications as ANDAs pursuant to section 505(j) of the Act. They will, however, retain the same application number that is currently assigned.

As of August 23, 1997, please submit all correspondence for the referenced applications to:

Office of Generic Drugs
CDER, FDA
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

If you have any questions concerning the transfer of these applications to OGD, please call Peter Rickman, Chief, Regulatory Support Branch, at 301-527-5862.

Sincerely yours,

Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 18-465
18-786
Division File
HFD-600/RF
HFD-610/JPhillips
HFD-510/EGalliers
Field Copy
njg/8/26/97/x:/new/firmsam/alpha/ltrs&rev/lvptx.897
Letter Out

ON

ANDA 19-971 Dextrose 5% Injection AUG 26 1997

Haemonetics Corporation
Attention: Alicia R. Lopez
400 Wood Road
Braintree, MA 02184-9114

Dear Sir:

This is in reference to your new drug application, submitted pursuant to Section 505 of the Federal Food, Drug, and Cosmetic Act (Act).

Effective August 23, 1997, your application was transferred from the Division of Metabolic and Endocrine Drug Products (HFD-510) to the Office of Generic Drugs (HFD-600).

The Code of Federal Regulations, Title 21, Section 310.509(a) established that any parenteral drug product packaged in a plastic immediate container is a new drug under section 201(p) of the Act and requires an approved new drug application as a condition for marketing. Section 310.509 took effect when 505(b) was the only provision in the Act for submission of a new drug application. The subsequent enactment of the Drug Price Competition and Patent Term Restoration Act of 1984 (Waxman-Hatch Amendments) replaced 505(b) with 505(b)(1), 505(b)(2) and 505(j), thereby creating three distinct types of applications for approval of new drugs depending on the nature and the source of the evidence required to demonstrate the safety and effectiveness of the new drug product.

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not require studies beyond limited confirmatory testing and the testing described in the USP. Your application has been determined to meet the criteria above or have been determined to meet the requirements of an ANDA under section 505(j) of the Act.

This change in Center policy now permits the Office of Generic Drugs to assume the administrative and review functions of this application as an ANDA pursuant to section 505(j) of the Act. It will, however, retain the same application number that is currently assigned.

As of August 23, 1997, please submit all correspondence for the referenced application to:

Office of Generic Drugs
CDER, FDA
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

If you have any questions concerning the transfer of this application to OGD, please call Peter Rickman, Chief, Regulatory Support Branch, at 301-527-5862.

Sincerely yours,

Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 19-971
Division File
HFD-600/RF
HFD-610/JPhillips
HFD-510/EGalliers
Field Copy
njg/8/26/97/x:/new/firmsam/dhl/ltrs&rev/lvptx.897
Letter Out

(DFile)

AUG 26 1997

Baxter Healthcare Corp.
Attention: Marcia Marconi
Rte 120 & Wilson Road
Round Lake, IL 60073-0490

Dear Madam:

This is in reference to your new drug applications (see attachment), submitted pursuant to Section 505 of the Federal Food, Drug, and Cosmetic Act (Act).

Effective August 23, 1997, your applications were transferred from the Division of Metabolic and Endocrine Drug Products (HFD-510) to the Office of Generic Drugs (HFD-600).

The Code of Federal Regulations, Title 21, Section 310.509(a) established that any parenteral drug product packaged in a plastic immediate container is a new drug under section 201(p) of the Act and requires an approved new drug application as a condition for marketing. Section 310.509 took effect when 505(b) was the only provision in the Act for submission of a new drug application. The subsequent enactment of the Drug Price Competition and Patent Term Restoration Act of 1984 (Waxman-Hatch Amendments) replaced 505(b) with 505(b)(1), 505(b)(2) and 505(j), thereby creating three distinct types of applications for approval of new drugs depending on the nature and the source of the evidence required to demonstrate the safety and effectiveness of the new drug product.

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determined to meet the criteria above or have been determined to meet the requirements of an ANDA under section 505(j) of the Act.

This change in Center policy now permits the Office of Generic Drugs to assume the administrative and review functions of these applications as ANDAs pursuant to section 505(j) of the Act. They will, however, retain the same application number that is currently assigned.

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If you have any questions concerning the transfer of these applications to OGD, please call Peter Rickman, Chief, Regulatory Support Branch, at 301-527-5862.

Sincerely yours,

Jerry Phillips 8/26/97

Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

Attachment: ANDA list

cc:
Division File
HFD-600/RF
HFD-610/JPhillips
HFD-510/EGalliers
Field Copy
njg/8/26/97/x:/new/firmsam/baxter/ltrs&rev/lvptx.897
Letter Out

ANDA 16-694	DEXTROSE 10% INJ,USP,PL-146
16-673	DEXTROSE 5% IN PLASTIC CONT. INJ
18-629	DEXTROSE 5%, 0.33% NACL, & KCL INJ
20-047	DEXTROSE INJ, USP 50%, 60%, 70%
20-179	DEXTROSE MINI-BAG PLUS 5% INJ
20-178	SODIUM CHL INJ USP IN MINI-BAG PLUS
18-632	STERILE WATER FOR INJ USP PL 146
20-107	NOVAMINE 15% SULFITE FREE INJECTION
20-177	TRAVASOL 3.5% W/ELECTROLYTES
20-173	TRAVASOL 5.5% & 8.5% INJECTION
18-523	ACETIC ACID 0.25% IRRIGATION SOLUTION
18-921	LACTATED RINGER'S IRRIGATION IN PL-146
18-495	RINGER'S SOLUTION FOR IRRIGATION
17-864	SODIUM CHL 0.45% IN PLASTIC 146 IRRIGATION
17-867	SODIUM CHL 0.9% IN PLASTIC 146 IRRIGATION
17-427	SODIUM CHL 0.9% IRRIGATION SOLUTION
17-428	STERILE WATER FOR IRRIGATION USP
17-866	STERILE WATER FOR IRRIGATION USP PL 146
18-508	TIS-U-SOL IRRIGATION SOLUTION (PL 325)
18-931	Travasol Injection

"DW

AUG 26 1997

Abbott Laboratories
Hospital Products Division
Attention: Jill Sackett
200 Abbott Park Road
Dept 389 AP30
Abbott Park, IL 60064-3537

Dear Madam:

This is in reference to your new drug applications (see attachment), submitted pursuant to Section 505 of the Federal Food, Drug, and Cosmetic Act (Act).

Effective August 23, 1997, your applications were transferred from the Division of Metabolic and Endocrine Drug Products (HFD-510) to the Office of Generic Drugs (HFD-600).

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not require studies beyond limited confirmatory testing and the testing described in the USP. Your applications have been determined to meet the criteria above or have been determined to meet the requirements of an ANDA under section 505(j) of the Act.

This change in Center policy now permits the Office of Generic Drugs to assume the administrative and review functions of these applications as ANDAs pursuant to section 505(j) of the Act. They will, however, retain the same application number that is currently assigned.

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If you have any questions concerning the transfer of these applications to OGD, please call Peter Rickman, Chief, Regulatory Support Branch, at 301-527-5862.

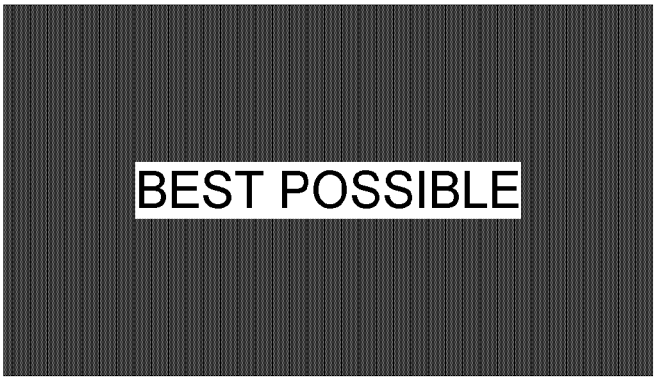
Sincerely yours,

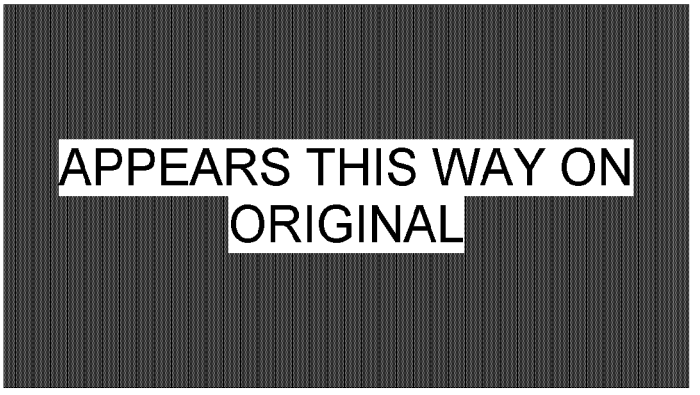
Jerry Phillips 8/26/97

Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

Attachment: ANDA list

cc: Division File
HFD-600/RF
HFD-610/JPhillips
HFD-510/EGalliers
Field Copy
njg/8/26/97/x:/new/firmsam/abbott/ltrs&rev/lvptx.897
Letter Out





ANDA	18-080	DEXTROSE 10% IN WATER IN FLEX CONT
	18-096	DEXTROSE 2.5% & .45% NACL INJ, USP, PL
	18-564	DEXTROSE 20% INJ IN FLEX CONT
	19-345	DEXTROSE 30% INJ IN FLEX CONT
	18-562	DEXTROSE 40% INJ FLEX CONT
	18-254	DEXTROSE 5% AND RINGERS INJ
	17-607	DEXTROSE 5% IN HALF STRENGTH SALINE
	17-608	DEXTROSE 5% IN LACTATED RINGERS
	17-585	DEXTROSE 5% IN SALINE 0.9%
	19-466	DEXTROSE 5% INJ ADD-VAN FLEX CONT
	19-479	DEXTROSE 5% INJ IN 250 ML ADD-VAN
	18-371	DEXTROSE 5% W/.15,.15,.224, OR .3% KCL INJ FC
	18-362	DEXTROSE 5% WITH NACL & KCL IN FLEX CONT
	19-894	DEXTROSE 50% INJ USP PHARMACY BULK PACK
	18-563	DEXTROSE 50% INJ IN FLEX CONT
	19-346	DEXTROSE 60% INJ IN FLEX CONT
	18-561	DEXTROSE 70% INJ IN FLEX CONT
	19-893	DEXTROSE 70% INJ USP PHARMACY BULK PACK
	19-691	KCL IN 5% DEXTROSE & 0.9% NACL INJ/PVC
	17-641	LACTATED RINGER'S INJ IN FLEX CONT
	19-603	MANNITOL 5% & 10% IV
	16-269	MANNITOL I.V./GLASS
	17-610	NORMOSOL M IN 5% DEXTROSE
	19-685	KCl IN 5% DEXTROSE & LACT RINGER'S INJ
	19-686	KCl IN 0.9% SODIUM CHL
	20-161	KCl INJ, USP IN PVC
	18-251	RINGER'S INJ IN FLEX CONT
	18-090	SODIUM CHL 0.45% IN FLEX CONT
	19-759	SODIUM CHL 0.45% INJ./ADD-VAN CONT
	19-465	SODIUM CHL 0.9% ADD-VAN FLEX
	16-366	SODIUM CHL 0.9% IN PLIA-LITER BAGS
	19-480	SODIUM CHL 0.9% INJ IN 250 ML ADD-VAN
	18-249	SODIUM LACTATE INJ USP 1/6 MOLAR
	19-869	STERILE WATER FOR INJ; Pharmacy Bulk Package
	20-015	AMINOSYN II 10% INJ; Pharmacy Bulk Package
	18-404	ACETIC ACID 0.25% IRRIGATION IN FLEX CONT
	17-633	GLYCINE 1.5% IRRIGATION
	18-315	GLYCINE 1.5% IRRIGATION IN FLEX CONT
	19-416	LACTATED RINGER'S IRRIG. PVC FLEX CONT
	18-380	SODIUM CHL 0.45% IRRIGATION IN FLEX
	17-514	SODIUM CHL 0.9% IRRIGATION/SEMI-RIGID
	18-314	SODIUM CHL 0.9% IRRIGATION IN FLEX
	18-316	SORBITOL MANNITOL IRRIGATION IN FLEX CONT
	17-513	STERILE WATER FOR IRRIGATION USP SR 73
	18-313	STERILE WATER FOR IRRIGATION USP FLEX
	18-904	UROLOGIC G IRRIGATION IN SEMI-RIGID CONT

ANDA 20-248 Intralipid 20% (Soybean Oil Injection)

AUG 26 1997

Pharmacia & Upjohn Company
Attention: James Chambers
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Sir:

This is in reference to your new drug application, submitted pursuant to Section 505 of the Federal Food, Drug, and Cosmetic Act (Act).

Effective August 23, 1997, your application was transferred from the Division of Metabolic and Endocrine Drug Products (HFD-510) to the Office of Generic Drugs (HFD-600).

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determined to meet the criteria above or have been determined to meet the requirements of an ANDA under section 505(j) of the Act.

This change in Center policy now permits the Office of Generic Drugs to assume the administrative and review functions of this application as an ANDA pursuant to section 505(j) of the Act. It will, however, retain the same application number that is currently assigned.

As of August 23, 1997, please submit all correspondence for the referenced application to:

Office of Generic Drugs
CDER, FDA
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

If you have any questions concerning the transfer of this application to OGD, please call Peter Rickman, Chief, Regulatory Support Branch, at 301-527-5862.

Sincerely yours,

Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 20-248
Division Files
HFD-600/RF
HFD-610/JPhillips
HFD-510/EGalliers
Field Copy
njg/8/26/97/X:\NEW\FIRMSN2\PHARMACE\LTRS&REV\LVPTX.897
Letter Out

AUG 26 1997

McGaw Inc.
Attention: John D'Angelo
2525 McGaw Avenue
Irvine, CA 92713

Dear Sir:

This is in reference to your new drug applications (see attachment), submitted pursuant to Section 505 of the Federal Food, Drug, and Cosmetic Act (Act).

Effective August 23, 1997, your applications were transferred from the Division of Metabolic and Endocrine Drug Products (HFD-510) to the Office of Generic Drugs (HFD-600).

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determined to meet the criteria above or have been determined to meet the requirements of an ANDA under section 505(j) of the Act.

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Sincerely yours,

Jerry Phillips 8/26/97

Jerry Phillips
Director
Division of Labeling and Program Support
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HFD-600/RF
HFD-610/JPhillips
HFD-510/EGalliers
Field Copy
njg/8/26/97/x:\new\firmsam\mcgaw\ltrs&rev\lvptx.897
Letter Out

ANDA	18-026	DEXTROSE 5% & 0.9% SODIUM CHL INJ
	18-046	DEXTROSE 10% INJ,USP,IN PLASTIC
	18-047	DEXTROSE 10%/NACL .9% IN PLASTIC CONT
	18-744	DEXTROSE 5% KCL INJ IN PLASTIC CONT(4)
	16-730	DEXTROSE 5% IN H2O IN PLASTIC CONT
	17-510	DEXTROSE 5% IN LACTATED RINGERS
	20-000	DEXTROSE 5% IN RINGER'S INJ IN EXCEL PLASTIC
	18-256	DEXTROSE 5% IN RINGER'S INJ
	18-867	ISOLYTE E 5% DEXTROSE IN EXCEL
	19-718	ISOLYTE E IN PLASTIC CONT
	19-844	ISOLYTE H IN 5% DEXTROSE
	19-870	ISOLYTE M
	19-873	ISOLYTE P 5% DEXTROSE
	18-252	ISOLYTE S
	19-711	ISOLYTE S IN PLASTIC CONT
	18-274	ISOLYTE S WITH 5% DEXTROSE
	19-843	ISOLYTE S WITH 5% DEXTROSE
	19-864	ISOLYTE R WITH 5% DEXTROSE IN EXCEL PLASTIC
	19-696	ISOLYTE S, PH 7.4 IN EXCEL PLASTIC CONT
	19-632	LACTATED RINGER'S INJ USP IN EXCEL
	18-023	LACTATED RINGER'S USP IN PLASTIC
	14-738	MANNITOL 20% IN H2O/GLASS
	20-006	MANNITOL INJ. USP 5%, 10%, 15%, 20%
	18-722	NACL 0.9% & KCL INJ PLASTIC CONT
	20-002	RINGER'S INJ USP IN EXCEL PLASTIC CONT
	18-721	RINGER'S INJ USP IN PLASTIC CONT
	19-635	SODIUM CHL 0.45,.9,3, & 5% INJ IN EXCEL
	18-186	SODIUM CHL 1/6 MOLAR INJ IN PLASTIC
	18-184	SODIUM CHL 0.45% INJ IN PLASTIC
	17-464	SODIUM CHL 0.9% INJ USP IN PLSTIC
	20-004	SODIUM CHL INJ 1/6 M USP IN EXCEL PLASTIC
	19-633	STERILE WATER FOR INJ USP IN EXCEL
	19-531	NUTRILIPID 10% & 20% IV FAT EMULSION
	18-161	ACETIC ACID 0.25% IRRIGATION IN PLASTIC
	18-681	LACTATED RINGER'S IRRIGATION IN PLSTIC CONT
	16-772	MANNITOL IN PLASTIC CONT IRRIGATION SOL
	18-156	RINGER'S SOLUTION NF IN PLASTIC CONT