CENTER FOR DRUG EVALUATION AND RESEARCH

SPECIAL INTEREST TOPIC

TITLE: OFFICE OF GENERIC DRUGS LVP LETTERS

DATE: 8/26/97
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

BEST POSSIBLE
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 301-527-5062.

Sincerely yours,

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

BEST POSSIBLE

APPEARS THIS WAY ON ORIGINAL
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).

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BEST POSSIBLE
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:

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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
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).

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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
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/firamsam/baxter/ltssrev/1vptx.897
Letter Out

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<table>
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<tr>
<th>ANDA</th>
<th>Description</th>
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<tbody>
<tr>
<td>16-694</td>
<td>DEXTROSE 10% INJ, USP, PL-146</td>
</tr>
<tr>
<td>16-673</td>
<td>DEXTROSE 5% IN PLASTIC CONT. INJ</td>
</tr>
<tr>
<td>18-629</td>
<td>DEXTROSE 5%, 0.33% NAACL, &amp; KCL INJ</td>
</tr>
<tr>
<td>20-047</td>
<td>DEXTROSE INJ, USP 50%, 60%, 70%</td>
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<tr>
<td>20-179</td>
<td>DEXTROSE MINI-BAG PLUS 5% INJ</td>
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<tr>
<td>20-170</td>
<td>SODIUM CHL INJ USP IN MINI-BAG PLUS</td>
</tr>
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<td>18-632</td>
<td>STERILE WATER FOR INJ USP PL 146</td>
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<tr>
<td>20-177</td>
<td>NOVAMINE 15% SULFITE FREE INJECTION</td>
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<tr>
<td>20-173</td>
<td>TRAVASOL 3.5% W/ELECTROLYTES</td>
</tr>
<tr>
<td>18-523</td>
<td>TRAVASOL 5.5% &amp; 8.5% INJECTION</td>
</tr>
<tr>
<td>18-921</td>
<td>ACETIC ACID 0.25% IRRIGATION SOLUTION</td>
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<td>18-921</td>
<td>LACTATED RINGER'S IRRIGATION IN PL-146</td>
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<tr>
<td>18-955</td>
<td>RINGER'S SOLUTION FOR IRRIGATION</td>
</tr>
<tr>
<td>17-866</td>
<td>SODIUM CHL 0.45% IN PLASTIC 146 IRRIGATION</td>
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<tr>
<td>17-867</td>
<td>SODIUM CHL 0.9% IN PLASTIC 146 IRRIGATION</td>
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<td>17-427</td>
<td>SODIUM CHL 0.9% IRRIGATION SOLUTION</td>
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<td>17-428</td>
<td>STERILE WATER FOR IRRIGATION USP</td>
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<td>17-866</td>
<td>STERILE WATER FOR IRRIGATION USP PL 146</td>
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<tr>
<td>18-508</td>
<td>TIS-U-SOL IRRIGATION SOLUTION (PL 325)</td>
</tr>
<tr>
<td>18-931</td>
<td>Travasol Injection</td>
</tr>
</tbody>
</table>
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).

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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.

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

Attachment: ANDA list
| 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 |
| 19-254     | 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 |
| 10-563     | 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 |
| 19-466     | 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 |
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.

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

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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.997
Letter Out

BEST POSSIBLE

APPEARS THIS WAY ON ORIGINAL
McGaw Inc.
Attention: John D'Angelo
2525 McGaw Avenue
Irvine, CA 92713

Dear Sir:

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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%/NAACL .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 RINGRER'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  NAACL 0.9% & KCL INJ PLASTIC CONT
20-002  RINGRER'S INJ USP IN EXCEL PLASTIC CONT
18-721  RINGRER'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 PLASTIC
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 PLASTIC CONT
16-772  MANNITOL IN PLASTIC CONT IRRIGATION SOL
18-156  RINGRER'S SOLUTION NF IN PLASTIC CONT

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APPEARS THIS WAY ON ORIGINAL