DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV 2 9 2013

David Zuchero, M.S., J.D.
President
Chesapeake Regulatory Group, Inc.
6574 River Clyde Drive
Highland, Maryland 20777

Re: Docket No. FDA-2013-P-0408

Dear Mr. Zuchero:

This letter responds to your citizen petition dated March 29, 2013 (Petition). Your Petition requests that the Food and Drug Administration (FDA or the Agency) designate the following approved drug products, manufactured by Baxter Healthcare Corporation, as reference listed drugs (RLDs) for peritoneal dialysis solutions consisting of calcium chloride, dextrose, magnesium chloride, sodium chloride, and sodium lactate:

- Dianeal PD-2 w/1.5% Dextrose in plastic container (New Drug Application (NDA) 017512)
- Dianeal PD-2 w/1.5% Dextrose in plastic container (NDA 020163)
- Dianeal PD-2 w/2.5% Dextrose in plastic container (NDA 017512)
- Dianeal PD-2 w/2.5% Dextrose in plastic container (NDA 020163)
- Dianeal PD-2 w/3.5% Dextrose in plastic container (NDA 017512)
- Dianeal PD-2 w/4.25% Dextrose in plastic container (NDA 017512)
- Dianeal PD-2 w/4.25% Dextrose in plastic container (NDA 020163)
- Dianeal Low Calcium w/1.5% Dextrose in plastic container (NDA 020183)
- Dianeal Low Calcium w/2.5% Dextrose in plastic container (NDA 020183)
- Dianeal Low Calcium w/3.5% Dextrose in plastic container (NDA 020183)
- Dianeal Low Calcium w/4.25% Dextrose in plastic container (NDA 020183)

Your Petition indicates that, at this time, there is no peritoneal dialysis solution consisting of these active ingredients designated as an RLD in *FDA's Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book). For the reasons stated below, your Petition is granted.

I. BACKGROUND

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(j)) allows the marketing of generic versions of previously approved drug products when the generic drug product is the subject of an approved abbreviated new drug

application (ANDA). To obtain approval, the ANDA applicant must show, among other things, that with respect to a listed drug (i.e., a previously approved drug product), the generic drug product (1) has the same active ingredient(s) in the same strength, (2) has the same labeling (with certain permissible differences), and (3) is bioequivalent.

A *listed drug* is a drug product that has an effective approval under section 505(c) of the FD&C Act for safety and effectiveness or under section 505(j), that has not been withdrawn or suspended under section 505(e)(1) through (5) or (j)(5) of the FD&C Act, and that has not been withdrawn from sale for reasons of safety or effectiveness.[1] Listed drugs are identified as drugs with an effective approval in FDA's Orange Book. An RLD is the listed drug identified by FDA as the drug product on which an ANDA applicant relies in seeking approval of its application.[2]

Our policy on the designation of RLDs is stated in the preamble to the 1992 final rule establishing the requirements for ANDAs.[3] In response to comments, asking us to explain how we determine which drugs should be RLDs, we stated:

> FDA will designate all reference listed drugs. Generally, the reference listed drug will be the NDA drug product for a single source drug product. For multiple source NDA drug products or multiple source drug products without an NDA, the reference listed drug generally will be the market leader as determined by FDA on the basis of commercial data. FDA recognizes that, for multiple source products, a product not designated as the listed drug and not shown bioequivalent to the listed drug may be shielded from direct generic competition. If an applicant believes that there are sound reasons for designating another drug as a reference listed drug, it should consult FDA.[4]

II. DISCUSSION

In your Petition, you request that FDA designate the approved drug products listed above as RLDs (Petition at 1). Currently, there are no peritoneal dialysis solutions containing calcium chloride, dextrose, magnesium chloride, sodium chloride, and sodium lactate as active ingredients designated as RLDs in the Orange Book. Without designating these products as RLDs, ANDAs cannot be submitted for these drug products, effectively shielding them from generic competition.

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[1] See 21 CFR 314.3(b).

[2] Id.

[3] See *Abbreviated New Drug Application Regulations; Final Rule*, 57 FR 17950, 17958 (April 28, 1992).

[4] Id.

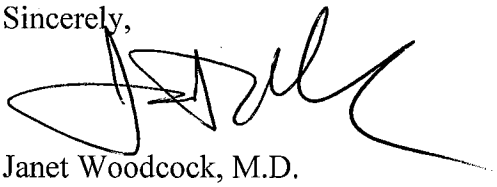
We have examined the issues presented in your Petition and have determined that you have stated grounds establishing that it is in the public interest to allow submission of ANDAs citing the drug products listed above.

Therefore, in accordance with the policy stated in the 1992 final rule, we will designate these drug products as RLDs. Applications submitted under section 505(j) of the FD&C Act may reference any of these products, provided all other legal and regulatory requirements are met.

III. CONCLUSION

For the reasons stated above, your Petition is granted.

Sincerely,



Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research