Chesapeake Regulatory Group, Inc.

March 29, 2013

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Division of Dockets Management,
Food and Drug Administration,
Department of Health and Human Services,
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852.

CITIZEN PETITION

Chesapeake Regulatory Group, Inc. (CRG) submits this petition pursuant to Section 505(b) and 505(j) of the Federal Food Drug and Cosmetic Act (FDC Act), among other provisions of law, and according to 21 CFR 10.25 and 10.30, to request that the Commissioner of Food and Drugs designate certain approved drug products as the Reference Listed Drugs.

A. Action Requested

The petitioner requests that the Commissioner of Food and Drugs designate the following approved drug products as the Reference Listed Drugs in order to allow the sponsors of future 505(j) applications to reference these products:

Intraperitoneal Solutions (Peritoneal Dialysis Fluids) for which Reference Listed Drug Status is Requested							
Appl No	Proprietary Name	Applicant	Active Ingredients and Strength				
			Calcium Chloride (mg)	Dextrose (g)	Magnesium Chloride (mg)	Sodium Chloride (mg)	Sodium Lactate (mg)
			Weight/100 mL				
N017512	Dianeal PD-2 w/1.5% Dextrose in plastic container	Baxter Healthcare	25.7	1.5	5.08	538	448
N020163	Dianeal PD-2 w/1.5% Dextrose in plastic container	Baxter Healthcare	25.7	1.5	5.08	538	448
N020163	Dianeal PD-2 w/2.5% Dextrose in plastic container	Baxter Healthcare	25.7	2.5	5.08	538	448
N017512	Dianeal PD-2 w/2.5% Dextrose in plastic container	Baxter Healthcare	25.7	2.5	5.08	538	448
N017512	Dianeal PD-2 w/3.5% Dextrose in plastic container	Baxter Healthcare	25.7	3.5	5.08	538	448
N020163	Dianeal PD-2 w/4.25% Dextrose in plastic container	Baxter Healthcare	25.7	4.25	5.08	538	448
N017512	Dianeal PD-2 w/4.25% Dextrose in plastic container	Baxter Healthcare	25.7	4.25	5.08	538	448
N020183	Dianeal Low Calcium w/1.5% Dextrose in plastic container	Baxter Healthcare	18.3	1.5	5.08	538	448
N020183	Dianeal Low Calcium w/2.5% Dextrose in plastic container	Baxter Healthcare	18.3	2.5	5.08	538	448
N020183	Dianeal Low Calcium w/3.5% Dextrose in plastic container	Baxter Healthcare	18.3	3.5	5.08	538	448
N020183	Dianeal Low Calcium w/4.25% Dextrose in plastic container	Baxter Healthcare	18.3	4.25	5.08	538	448

B. Statement of grounds

According to the FDA, "(a) reference listed drug (21 CFR 314.94(a)(3)) means the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its ANDA."[1] "A drug company seeking approval to market a generic equivalent must refer to the Reference Listed Drug in its Abbreviated New Drug Application (ANDA). By designating a single reference listed drug as the standard to which all generic versions must be shown to be bioequivalent, FDA hopes to avoid possible significant variations among generic drugs and their brand name counterpart."[2]

In addition, the regulations state that "(a)n abbreviated new drug application must refer to a listed drug. Ordinarily, that listed drug will be the drug product selected by the agency as the reference standard for conducting bioequivalence testing."[3]

Therefore a sponsor cannot submit an ANDA for approval unless FDA has selected a reference listed drug to which the sponsor may compare its generic product. "A firm wishing to market a generic version of a listed drug that is not designated as the reference listed drug may petition the Agency through the Citizen Petition procedure (see 21 CFR 10.25(a) and CFR 10.30)."[4]

There are currently no peritoneal dialysis fluids designated as Reference Listed Drugs in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). The Baxter Dianeal line of products is being recommended for RLD designation because it is estimated that these product account for a majority the total U.S. sales for this type of bagged peritoneal dialysis fluid products.

C. Environmental impact

An environmental assessment on the action requested in this petition qualifies for a categorical exclusion under 21 CFR $25.3 1. Therefore, an environmental assessment is not required for the requested action.

D. Economic impact

According to 21 CFR $10.30(b), economic impact information is to be submitted only when requested by the Commissioner. We will provide such information if requested.

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1 Approved Drug Products with therapeutic Equivalence Evaluations, 33nd Edition, pg x at http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf
2 Drugs@FDA Glossary of Terms at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#R
3 21 C.F.R. § 314.94(a)(3)
4 Approved Drug Products with therapeutic Equivalence Evaluations, 33nd Edition, pg x at http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf

E. Certification

I certify that, to the best of my knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to me that are unfavorable to the petition.

Sincerely,

David Zuchero, M.S., J.D.
President
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