LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P.C.
700 THIRTEENTH STREET, N.W.
SUITE 1200
WASHINGTON, D.C. 20005-5929
(202) 737-5600
FACSIMILE
(202) 737-9329
www.hpm.com

KURT R. KARST

Direct Dial (202) 737-7544
KKarst@hpm.com

July 11, 2013

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

Citizen Petition

The undersigned submits this Citizen Petition, in quadruplicate, pursuant to Section 505(j)(2)(c) of the Federal Food, Drug and Cosmetic Act ("FDC Act"), and in accordance with 21 C.F.R. §§ 10.20(a), 10.30 and 314.93 to request that FDA amend the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") to designate Ampicillin for Injection 1g and 2g in ADD-Vantage Vial approved under Abbreviated New Drug Application ("ANDA") No. 062738 as a Reference Listed Drug ("RLD"). The product currently designated as the RLD is Ampicillin for Injection 1g and 2g in Flip-Top Vial approved under ANDA No. 061395.

A. ACTION REQUESTED

The undersigned requests that FDA designate ANDA No. 062738 as an RLD for purposes of submitting an ANDA for a generic version of this drug product.

B. STATEMENT OF GROUNDS

FDC Act § 505(j) allows the marketing of generic versions of previously approved drug products when the generic drug product is the subject of an ANDA. To obtain ANDA approval, the application sponsor must show, among other things, that with respect to a listed drug (i.e., a previously approved drug product), the generic drug product has the same active ingredient(s) in the same strength, has essentially identical labeling, and is bioequivalent.

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A "listed drug" is a new drug product that has an effective approval under FDC Act § 505(j), that has not been withdrawn or suspended under FDC Act §§ 505(e)(1) through (5) or (j)(5), and that has not been withdrawn from sale for reasons of safety or effectiveness. See 21 C.F.R. § 314.3. Listed drugs are identified in FDA's Orange Book. An RLD is the listed drug identified by FDA as the drug product on which ANDA applicants should rely in seeking approval of their applications.

FDA stated its policy for designating a second RLD in the preamble to the Agency's 1992 final ANDA Regulations. Specifically, in response to comments asking FDA to explain how the Agency determines which drugs should be RLDs, FDA stated:

> FDA will designate [RLDs]. Generally, the [RLD] 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 [RLD] 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 [RLD], it should consult FDA.

FDA, Final Rule, ANDA Regulations, 57 Fed. Reg. 17,950, 17,958 (Apr. 28, 1992). In addition, FDA states in the preface to the Orange Book that:

> [I]n some instances when listed drugs are approved for a single drug product, a product not designated as the [RLD] and not shown to be bioequivalent to the [RLD] may be shielded from generic competition. A firm wishing to market a generic version of a listed drug that is not designated as the [RLD] may petition the Agency through the Citizen Petition procedure. . . . When the Citizen Petition is approved, the second listed drug will be designated as an additional [RLD] and the petitioner may submit an [ANDA] citing the designated [RLD].

Orange Book Preface at x (33rd ed. 2013).

There is a sound basis for designating Ampicillin for Injection 1g and 2g in ADD-Vantage Vial (ANDA No. 062738) as an RLD. The current identified RLD, approved under ANDA No. 061395, is a glass Flip-Top Vial approved with IM and IV routes of administration. ANDA No. 062738 covers a bioequivalent drug product approved with

only the IV route of administration in the ADD-Vantage Container/Closure system. This product should also be designated as a RLD, thereby allowing generic competition to the Ampicillin for Injection 1g and 2g in ADD-Vantage Vial product approved for IV administration.

C. ENVIRONMENTAL IMPACT

An environmental assessment report on the action requested in this petition is not required under 21 C.F.R. § 25.31.

D. ECONOMIC IMPACT

In accordance with 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition. We hereby commit 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 is unfavorable to the petition.

Sincerely,

Kurt R. Karst

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