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BY HAND DELIVERY

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 an additional Reference Listed Drug ("RLD") for Cefdinir for Oral Suspension.

A. ACTION REQUESTED

The undersigned requests that FDA designate one of the approved Abbreviated New Drug Applications ("ANDAs") listed in the Orange Book for Cefdinir for Oral Suspension an RLD for purposes of submitting an application 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A "listed drug" is a new drug product that has an effective approval under FDC Act § 505(j), that has not been withdrawn or suspended under FDC Act §§ 505(e)(1) through (5) or (j)(5), and that has not been withdrawn from sale for reasons of safety or effectiveness.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 an additional RLD for Cefdinir for Oral Suspension. The original RLD, OMNICEF, approved under New Drug Application No. 050749 (Abbvie), has been discontinued and is listed in the *Discontinued Drug Product List* section of the Orange Book. The current edition of the Orange Book lists ANDA No. 065337 (Sandoz) as the RLD (250mg/5mL strength); however, to the best of the

undersigned's knowledge, the drug product covered by this ANDA is no longer available in the market. The current edition of the Orange Book lists four additional companies with approvals to market Cefdinir for Oral Suspension: (1) ANDA No. 065259 (Lupin); (2) ANDA No. 065332 (Teva); (3) ANDA No. 065473 (Aurobindo); and (4) ANDA No. 065429 (Orchid). Each of these drug products is AB-rated to ANDA No. 065337. Accordingly, the undersigned requests that the Commissioner of the FDA designate one of these ANDA-approved drug products as a second RLD for Cefdinir for Oral Suspension.

C. ENVIRONMENTAL IMPACT

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

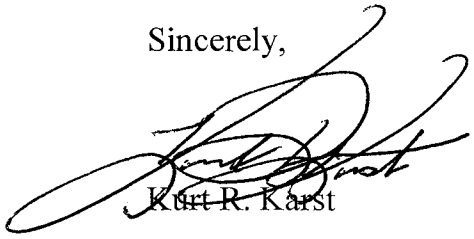
D. ECONOMIC IMPACT

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. Petitioner hereby commits 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

KRK/eam