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SUBMITTED ELECTRONICALLY

Division of Dockets Management
U.S. Food and Drug Administration
Department of Health and Human Services
Room 1061, HFA-305
5630 Fishers Lane
Rockville, Maryland 20852

Dear Sir or Madam:

Hyman, Phelps & McNamara, P.C., on behalf of a client, submits this petition pursuant to section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), and 21 C.F.R. § 314.93, and in accordance with 21 C.F.R. § 10.20 and 21 C.F.R. § 10.30, to request that the U.S. Food and Drug Administration ("FDA") determine that Cefazolin for Injection USP, 2 g vial—administered via intramuscular injection, intravenous direct (bolus) injection, and intravenous infusion—is suitable for submission in an Abbreviated New Drug Application ("ANDA").

A. Action Requested

Petitioner requests that FDA determine that Cefazolin for Injection USP, 2 g vial—administered via intramuscular injection, intravenous direct (bolus) injection, and intravenous infusion—is suitable for submission as an ANDA. The Reference Listed Drug ("RLD") upon which this petition is based is ANCEF® (Cefazolin for Injection), 1 g (single-dose vials), which FDA approved under NDA 050461 for intramuscular injection, intravenous direct (bolus) injection, and intravenous infusion.[1] Petitioner seeks to introduce a new 2 g vial strength.[2]

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1 ANCEF® (NDA 050461) is approved in several strengths—250 mg, 500 mg, 1 g, 5 g, and 10 g—each of which is identified in the Discontinued Drug Product List section of the Orange Book as a RLD.

2 In May 2007, FDA received a petition requesting the Agency's permission to submit an ANDA for Cefazolin for Injection, USP 2 g Vials. See ANDA Suitability Petition, Docket

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B. Statement of Grounds

FDC Act § 505(j)(2)(A)(iii) permits the submission of an ANDA for a drug product that differs in strength from the RLD after FDA has approved a petition submitted pursuant to FDC Act § 505(j)(2)(C). ANCEF®, the RLD for the proposed drug product, is indicated for use in the treatment of certain specified serious infections—including Respiratory Tract Infections, Urinary Tract Infections, Skin and Skin Structure Infections, Biliary Tract Infections, Bone and Joint Infections, Septicemia, Endocarditis, and Perioperative Prophylaxis—due to specified susceptible organisms. A copy of the current Orange Book entry for ANCEF® is included as ***Attachment 1*** and a copy of the most recent available labeling for ANCEF® (dated 2004) is included as ***Attachment 2***.

The proposed drug products in different strengths do not pose questions of safety or effectiveness: the indications, route of administration,[3] intended patient population, and recommendations for use of the proposed drug products are the same as that of the RLD. Draft labeling for the proposed Cefazolin for Injection USP, 2 g vial, drug product—administered via intramuscular injection, intravenous direct (bolus) injection, and intravenous infusion—is provided as ***Attachment 3***.

The proposed drug product is consistent with the RLD labeling in various respects:

- First, the current approved labeling for ANCEF® stipulates that in rare instances up to 12 g of Cefazolin have been used in one day (divided into 3 or 4 doses every 6 or 8 hours). For patients with higher body weight (>80 kg), the dose in standard indications such as preoperative infection prophylaxis is 2 g as a single dose. Moreover, the use of a 2 g dose has been reported in the

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No. FDA-2007-P-0406. According to FDA, a decision as to that petition is pending. Although this suitability petition also requests permission to submit an ANDA for a new 2 g vial, the previously submitted suitability petition concerns only an intravenously administered drug product.

[3] ANCEF® (NDA 050461) is identified in the Orange Book with a dosage form and route of administration nomenclature of "INJECTABLE;INJECTION." However, according to the ANCEF® Prescribing Information, the drug product is approved for intramuscular injection, intravenous direct (bolus) injection, and intravenous infusion. According to conventional FDA route of administration nomenclature standards, the Orange Book should separately reflect these various routes of administration as "INTRAMUSCULAR," "INTRAVENOUS," and "IV (INFUSION)."

literature. Specifically, in a relatively recent publication from the American Society of Health-System Pharmacists (***Attachment 4***), a single dose of Cefazolin up to 2 g and 3 g for patients that are ≤120kg and ≥120kg, respectively, is recommended.

- Second, a 2 g vial presentation would provide further flexibility for the various routes of administration for which the RLD is approved: intramuscular injection, intravenous direct (bolus) injection, and intravenous infusion.

- Third, a 2 g vial presentation would provide for safer handling for drug preparation and administration, particularly when preparing doses at higher concentrations, as fewer vials need to be combined for reconstitution leading to fewer preparation errors. In addition, fewer drug preparations reduce the probability of compromising a sterile drug product prior to administering to the patient.

The Pediatric Research Equity Act ("PREA"), enacted in December 2003, amended the FDC Act by requiring certain applications for a drug submitted under Section 505 to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is deferred or waived. See FDC Act § 505B(a)(I)(A)(i). Specifically, PREA applies to all applications for a new active ingredient, dosage form, indication, route of administration, or dosing regimen. See id. ANDAs submitted under an approved suitability petition for a change in strength are not subject to PREA requirements. See FDA, Draft Guidance for Industry, How to Comply with the Pediatric Research Equity Act, 4 (Sep. 2005). Petitioner asserts that PREA is not applicable to the proposed Cefazolin for Injection USP, 2 g vial, drug product, administered via intramuscular injection, intravenous direct (bolus) injection, and intravenous infusion, because the proposed change concerns only a new strength.

C. Environmental Impact

Petitioner claims a categorical exclusion under 21 C.F.R. § 25.31.

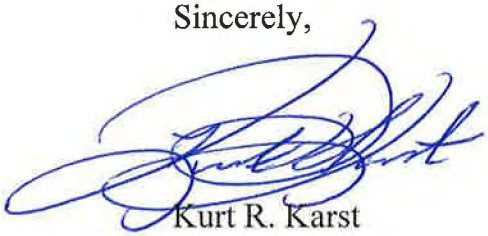
D. Economic Impact Statement

Petitioner will, upon request by the Commissioner, submit economic impact information, in accordance with 21 C.F.R. § 10.30(b).

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 are unfavorable to the Petition.

Sincerely,



Kurt R. Karst

KRK/eam
Attachments