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April 2, 2020

**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

**Re: Cefazolin for Injection USP, 2 g and 3 g Vials**
**Suitability Petitions**
**Docket Nos. FDA-2019-P-4362 and FDA-2019-P-4363**

Dear Sir or Madam:

I write concerning two September 17, 2019 Suitability Petitions our firm submitted to FDA on behalf of a client pursuant to section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act ("FDC Act") requesting determinations that Cefazolin for Injection USP, 2 g and 3 g Vials, are suitable for submission in an Abbreviated New Drug Application ("ANDA"). These petitions were submitted more than 90 days ago. As such, I write to request that FDA act on both petitions promptly, or, at a minimum, provide an update as to their status and anticipated response timeframe.

Pursuant to FDA implementing regulations at 21 C.F.R. § 314.93, I submitted both petitions requesting permission to submit an ANDA for Cefazolin for Injection USP, 2 g and 3 g Vials, referencing ANCEF® (Cefazolin for Injection), 1 g (single-dose vials), (NDA 050461).[1] The new strengths do not raise questions of safety and effectiveness, and the proposed drug products are expected to be demonstrated to be bioequivalent to ANCEF®. Draft labeling for the proposed drug products was provided as part of the

[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 FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") as a Reference Listed Drug ("RLD").

suitability petitions to demonstrate that the proposed new strengths remain consistent with the RLD labeling.

The statute states, in relevant part, that:

> If a person wants to submit an [ANDA] for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph ***within ninety days*** of the date the petition is submitted.

FDC Act § 505(j)(2)(C) (emphasis added). Likewise, FDA's regulations implementing FDC Act § 505(j)(2)(C) state that the Agency is required to approve or disapprove a suitability petition "[n]o later than ***90 days*** after the date" of submission. 21 C.F.R. § 314.93(e) (emphasis added).

It has now been ***nearly 200 days*** since the submission of our Cefazolin for Injection USP, 2 g and 3 g Vials, suitability petitions. Therefore, in accordance with FDC Act § 505(j)(2)(C) and 21 C.F.R. § 314.93(e), I respectfully request that FDA issue a timely response to the petitions. After all, FDA's compliance by the 90-day deadline is mandatory and not merely a policy recommendation.[2]

Despite FDA's historical policy of not ruling on ANDA suitability petitions within the statutory deadline,[3] leading to a loss of faith in the process itself, FDA, in August 2013, published a Manual of Policies and Procedures ("MaPP")[4] establishing the policies and procedures for responding to suitability petitions, and that reiterates that "[u]nder

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2 *See In re Barr Laboratories, Inc.*, 930 F. 2d 72 (D. C. Cir. 1991).

3 A review of more than 1,300 ANDA suitability petitions submitted to FDA since the enactment of the Hatch-Waxman statutory provision creating them shows that FDA has been largely unable to meet the mandatory statutory 90-day goal of approving or disapproving a petition, particularly in recent years, and despite a decline in the number of petitions submitted to FDA. *See* Kurt Karst, *Letting the Devil Ride: Thirty Years of ANDA Suitability Petitions Under the Hatch-Waxman Act*, 40 WILLIAM MICHELL L. REV. 1260 (2014).

4 FDA, Manual of Policies and Procedures, Office of Generic Drugs: ANDA Suitability Petitions, MaPP 5240.5 (Aug. 21, 2013).

21 CFR 314.93(e), the Agency will approve or deny the petition no later than 90 days after the petition is submitted."[5] According to the MaPP:

> [The Office of Generic Drugs' ("OGD's")] goal is to respond to suitability petitions in an efficient and effective manner. To meet this goal, a number of parties within the Center for Drug Evaluation and Research (CDER) and throughout the Agency must work in a coordinated manner. OGD, the office primarily responsible for responding to suitability petitions, has developed procedures for enhancing communication among parties involved in addressing the request(s) in the suitability petitions.[6]

Unfortunately, in the nearly seven years since FDA issued MaPP 5240.5, little progress has been made. Curiously, the most recent version of MaPP 5240.5 omits any reference to the 90-day statutory period, as well as to OGD's goal to respond to suitability petitions in an efficient and effective manner.[7]

Perhaps as a result of FDA's failure to timely address suitability petitions, Congress expressed its expectation that FDA meet this 90-day target in Section 805 of the 2017 Food and Drug Administration Reauthorization Act ("FDARA"). In addition to a "sense of Congress" provision stating that FDA "shall meet the requirement under [FDC Act § 505(j)(2)(C)] and [21 C.F.R. § 314.93(e)] of responding to suitability petitions within 90 days of submission," Congress hoped to encourage FDA to expedite responses to such petitions by requiring a report of the number of outstanding suitability petitions and a report of the number of suitability petitions that remained outstanding 180 days after submission. FDARA § 805. In addition, the GDUFA II Performance Goals Letter states that "FDA aspires to respond to Suitability Petitions in a more timely and predictable manner." GDUFA II Performance Goals Letter at 23.

FDA has thus far not complied with this congressional mandate and GDUFA II Performance Goal. According to FDA's most recent FDARA § 805 activities report—from Fiscal Year 2018—148 suitability petitions are pending a substantive FDA response

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5 *Id.* at 1.

6 *Id.* at 2.

7 *See* FDA, Manual of Policies and Procedures, Office of Generic Drugs: ANDA Suitability Petitions, MaPP 5240.5 Rev. 1 (Aug. 10, 2018).

for more than 180 days from the date of receipt of the petition.[8] Certainly that number is significantly higher today.

I request that FDA provide a determination on the approvability of my petitions submitted well over 90 days ago seeking permission to submit an ANDA for Cefazolin for Injection USP, 2 g and 3 g Vials, in accordance with the statute, FDA's implementing regulations, FDARA § 805, and the GDUFA goals FDA agreed to meet.

Please contact me at 202.737.7544 if you have any questions concerning this submission.

Sincerely,

**/Kurt R. Karst/**

KRK/eam

[8] *See* FDA, Activities Reports of the Generic Drugs Program - FDARA Title VIII Sections 807 and 805 (FY 2018), available at https://www.fda.gov/drugs/generic-drugs/activities-reports-generic-drugs-program-fdara-title-viii-sections-807-and-805-fy-2018.