Guvam Pharma LLC

Date: December 6, 2019

Division of Dockets Management
U.S. Food and Drug Administration
Department of Health and Human Services
Room 1061, 1-IFA-305
5630 Fishers Lane
Rockville, MD 20852

ANDA Suitability Petition for Phenazopyridine Hydrochloride Tablets, 50 mg, 100 mg and 200 mg

Dear Sir or Madam,

Guvam Pharma LLC., submits this ANDA Suitability Petition 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, 10.30 and 314.93. The Suitability Petition requests that the FDA determine that Phenazopyridine Tablets, 50 mg, 100 mg and 200 mg is suitable for submission in an Abbreviated New Drug Application (ANDA).

A. Action Requested:

The Suitability Petition requests that the FDA determine that the proposed Phenazopyridine Tablets, 50 mg, 100 mg and 200 mg is suitable for submission in an ANDA. This Suitability Petition pursuant to Section 505(j)(2)(C) of the FDC Act and 21C.F.R. §314.93, is the appropriate mechanism for securing FDA authorization to submit an ANDA for a drug product that differs in one of the active ingredients in a listed combination drug from the Reference Listed Drug (RLD).

The Reference Listed Drug (RLD) upon which this petition is based are

- Azo Gantanol (Phenazopyridine Hydrochloride; Sulfamethoxazole, Tablets), which FDA approved on September 10, 1987 under NDA 013294, and is marketed in 100 mg (Phenazopyridine Hydrochloride); 500 mg (Sulfamethoxazole) as identified in the Orange Book.

- Azo Gantrisin (Phenazopyridine Hydrochloride; Sulfisoxzole, Tablets), which FDA approved on August 31, 1990 under NDA 019358, and is marketed in 50 mg (Phenazopyridine Hydrochloride); 500 mg (Sulfisoxzole) as identified in the Orange Book.

- Sulfamethoxazole, Trimethoprim and Phenazopyridine Hydrochloride, Tablets, which FDA approved on June 26, 2001 under NDA 021105, and is marketed in 800 mg; 160 mg (Sulfamethoxazole/Trimethoprim, Combination); 200 mg (Phenazopyridine Hydrochloride) strength as identified in the Orange Book.

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The relevant copies of the pages from the current Electronic Edition of the *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book) for Azo Gantanol, Azo Gantrisin, and Sulfamethoxazole, Trimethoprim and Phenazopyridine Hydrochloride, Tablets, are provided as ***Attachment 1***.

Approval of this Suitability Petition would allow Guvam Pharma LLC., to submit Phenazopyridine Hydrochloride Tablets, 50 mg, 100 mg and 200 mg as an ANDA, and would permit convenient dosing and administration by healthcare providers to treat patients with monotherapy in accordance with the approved indications for Phenazopyridine Hydrochloride, Tablets.

B. Statement of Grounds:

The FDC Act permits, at Section 505(j)(2)(A)(iii) and 21C.F.R. §314.93, the submission of an ANDA for a drug product that differs in one of the active ingredients in a listed combination drug from the RLD after FDA has approved a petition seeking permission to file such an application.

Azo Gantanol (Phenazopyridine Hydrochloride, Sulfamethoxazole) approved under NDA 013294 and Azo Gantrisin (Phenazopyridine Hydrochloride, Sulfisoxazole) approved under NDA 019358.

The Agency determined that Azo Gantanol (Phenazopyridine Hydrochloride, Sulfamethoxazole) Tablet, 100 mg/500 mg, and Azo Gantrisin (Phenazopyridine Hydrochloride, Sulfisoxazole) Tablet, 50 mg/500 mg, were not withdrawn from sale for reasons of Safety or Effectiveness as published in Federal Register. A copy of the notice published in Federal Register (June 12, 2014) is provided as ***Attachment 2***.

Sulfamethoxazole, Trimethoprim and Phenazopyridine Hydrochloride, Tablets approved under NDA 021105 consists of a blister card containing a combination tablets of trimethoprim/sulfamethoxazole double strength (160 mg/800 mg) and a separately blistered Phenazopyridine Hydrochloride 200 mg tablets in the same blister for oral administration.

Based on the above three referenced NDAs, proven safety and efficacy studies (where required) and subsequent approval of these three NDAs, it is our understanding that the monotherapy of Phenazopyridine Hydrochloride Tablets in the strengths of 50 mg, 100 mg and 200 mg would be safe and efficacious.

Guvam Pharma LLC., proposes Phenazopyridine Hydrochloride, Tablets administered for the approved indication separately or as a monotherapy. The following table 1 presents the comparison between approved and proposed drug product strengths:

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Table 1: Comparison of Approved Drug Product to Proposed Drug Product

Product Names as approved and as listed in the Orange Book (Reference NDA's)	Dosage Form	Route of Administration	Proposed Strength of Phenazopyridine Hydrochloride Tablets for Our ANDA
Azo Gantrisin (Phenazopyridine Hydrochloride, Sulfisoxazole) approved under NDA 019358.	Tablets	Oral	50 mg
Azo Gantanol (Phenazopyridine Hydrochloride, Sulfamethoxazole) approved under NDA 013294	Tablets	Oral	100 mg
Sulfamethoxazole, Trimethoprim and Phenazopyridine Hydrochloride, Tablets approved under NDA 021105	Tablets	Oral	200 mg

Phenazopyridine Hydrochloride is indicated for the symptomatic relief of pain, burning, urgency, frequency, and other discomforts arising from irritation of the lower urinary tract mucosa caused by infection.

Phenazopyridine is compatible with antibacterial therapy and can help to relieve pain and discomfort during the interval before antibacterial therapy controls the infection.

The proposed Phenazopyridine Hydrochloride Tablet strengths are consistent with the RLD labeling in all respects as applicable to Phenazopyridine Hydrochloride indications.

Guvam Pharma LLC., believes that pediatric assessment is not applicable to the proposed Phenazopyridine Hydrochloride Tablets, drug product, because the proposed change concerns only facilitates the availability of the product for separate administration in place of combination therapy, with the active ingredient, dosage form, indication, route of administration and dosing regimen remains identical to that for Phenazopyridine Hydrochloride as approved under NDA 013294, 019358 and 021105 ***(Attachment 3).*** Therefore, Guvam Pharma LLC., does not plan to submit any pediatric assessments with its application.

Guvam Pharma LLC., proposed Phenazopyridine Hydrochloride Tablets does not pose questions of Safety or Effectiveness since the proposed strengths are the recommended product doses stated in the approved labeling of the referenced three NDA's (019358, 013294,021105). The active ingredient, dosage form, uses and route of administration of the proposed strengths are/will be the same as applicable to the Phenazopyridine Hydrochloride Tablets as approved under the referenced NDAs for combination therapy along with other active and inactives.

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Draft labeling for the proposed Phenazopyridine Hydrochloride Tablets, 50 mg, 100 mg and 200 mg is provided as ***Attachment 4.***

As summarized above, Guvam Pharma LLC., requests that the FDA find and consider that the proposed Phenazopyridine Hydrochloride Tablets, 50 mg, 100 mg and 200 mg drug product is suitable for submission as an ANDA.

C. Environmental Impact:

Guvam Pharma LLC., claims a categorical exclusion under 21 C.F.R. § 25.31.

D. Economic Impact Statement:

Guvam Pharma LLC., does not believe that this requirement is applicable at this time, but will agree to submit economic impact information, in accordance with 21 C.F.R. § 10.30(b), if requested by the Agency.

E. Certification:

Guvam Pharma LLC., 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.

Enclosures:

Attachment 1: Approved Drug Products with Therapeutic Equivalence Evaluations, accessed November 22, 2019 (Orange Book)

Attachment 2: Federal Register Notice that Azo Gantanol and Azo Gantrisin were not withdrawn from sale for reasons of safety or effectiveness

Attachment 3: NDA 21-105 Labeling

Attachment 4: Draft Package Insert Labeling for Phenazopyridine Hydrochloride Tablets, 50 mg, 100 mg and 200 mg

Sincerely,
For **Guvam Pharma LLC.**

Mahender Korapati
Chief Operating Officer (RAC-US)