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Humanwell
Pharmaceutical US

June 28, 2024

Via Electronic Submission

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: ANDA Suitability Petition- Eslicarbazepine Acetate Oral Suspension, 50 mg/mL

Dear Sir or Madam,

Epic Pharma, LLC ("Epic"), as the Regulatory Agent, is submitting this suitability petition on behalf of Humanwell Pharmaceutical US, Inc. ("Humanwell US"), pursuant to Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act (FD&C Act), and in accordance with 21 CRF 314.93, 21 CRF 10.20, and 21 CRF 10.30, to request the Commissioner of the Food and Drug Administration (the "Agency" and/or the "FDA") declare that the proposed product, Eslicarbazepine Acetate Oral Suspension in the new strength of 50 mg/mL and new dosage form of ready for use oral suspension is suitable for submission as an abbreviated new drug application (ANDA). The regulatory agent appoint letter is attached.

1. Action Requested

Petitioner seeks to file an ANDA for Eslicarbazepine Acetate that differs in strength and dosage form from the Reference Listed Drug ("RLD") and Reference Standard ("RS"), APTIOM® (Eslicarbazepine Acetate) Oral Tablet, 200 mg, 400 mg, 600 mg and 800 mg, NDA# 022416 held by Sumitomo Pharma America Inc. This Suitability Petition requests a declaration by the Commissioner of the FDA that the proposed product, Eslicarbazepine Acetate Oral Suspension, 50 mg/mL is suitable for submission as an ANDA.

2. Statement of Grounds

The FD&C Act provides for the submission of an ANDA for a drug product that differs in dosage form and strength from that of the listed drug provided that FDA has approved a petition that proposed filling such an application.

The RLD APTIOM is an immediate-release tablet product in strengths of 200 mg, 400 mg, 600

mg and 800 mg of eslicarbazepine acetate. The proposed product is an oral suspension in a strength of 50 mg/mL, and it requires 4, 8, 12 and 16 mL of the oral suspension to provide the equivalent dose of 200, 400, 600 and 800 mg of eslicarbazepine acetate. This petition request involves a change in dosage form (oral tablet to oral suspension) and in strength (200 mg, 400 mg, 600 mg, or 800 mg to 50 mg/mL) from that of the RLD. The proposed drug product will have the same labeling as the approved labeling, only replacing the tablet with suspension measured by volume. Therefore, no further safety concerns exist for the proposed ANDA product. The draft labeling of the proposed Eslicarbazepine Acetate Oral Suspension, 50 mg/mL is provided as an attachment, which includes track changes compare with the RLD labeling. The oral suspension will provide an alternate dosage form for ease of administration for those patients who have difficulty swallowing a tablet, especially at high dose of 800 mg.

The proposed product Eslicarbazepine Acetate Oral Suspension, 50 mg/mL will be packaged in an amber glass bottle, with a 10mL syringe, and an adaptor for connecting the bottle and the syringe to draw the required dose. To pull the equivalent tablet dose of 200, 400, 600 and 800 mg drug, it requires 4, 8, 12, and 16 mL of the suspension. The strength, packaging configuration and instruction for use of the proposed oral suspension is the same as the ZEBINIX® (Eslicarbazepine Acetate) Oral Suspension, 50 mg/mL by Sunovion Pharmaceuticals, approved by the European Medicines Agency (EMA) in 2009. The packaging configuration of the proposed oral suspension is also the same as Oxcarbazepine Oral Suspension, 60 mg/mL, another marketed product indicated for the treatment of partial-onset seizures in adult and pediatric patients.

We noticed that the FDA has approved a Suitability Petition seeking a change in dosage form from Gris-PEG (griseofulvin ultramicrosize) Tablet, 250 mg to Griseofulvin ultramicrosize oral suspension 250 mg/5 mL (Docket No. FDA-2008-P-0303). The product is indicated for the treatment of fungi infections in adult and pediatric patients.

3. Pediatric Research Equity Act applicability

The proposed change in dosage form triggers the Pediatric Research Equity Act (PREA) which requires application sponsors to conduct studies in pediatric patients, if the Agency concludes that such studies would provide beneficial health data for the pediatric population. The Act specifically requires that a request for a new dosage form is subject to a pediatric evaluation. The Act also provides for a waiver from such requirement if the drug:

1) Does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients;
2) Is not likely to be used in a substantial number of pediatric patients.

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The RLD is an oral tablet that is adequately labeled for use for the treatment of partial-onset seizures in patients 4 years of age and older. Under Pediatric Use (8.4), it is stated- "Safety and effectiveness of APTIOM have been established in the age groups 4 to 17 years. Use of APTIOM in these age groups is supported by evidence from adequate and well-controlled studies of APTIOM in adults with partial-onset seizures, pharmacokinetic data from adult and pediatric patients, and safety data from clinical studies in 393 pediatric patients 4 to 17 years of age [see Adverse Reactions (6.1) and Clinical Pharmacology (12.3)]. Safety and effectiveness in pediatric patients below the age of 4 years have not been established."

According to the clinical trials disclosed on the RLD label [see Clinical Trials Experience (6.1)], in monotherapy trials in patients with partial-onset seizures in Study 1 and Study 2, 365 patients received APTIOM. Of the patients in those trials, 95% were between 18 and 65 years old. In the placebo controlled adjunctive therapy trials in patients with partial-onset seizures (Study 3, Study 4 and Study 5), 1021 patients received APTIOM. Of the patients in those trials, approximately 95% were between 18 and 60 years old.

Since the proposed oral suspension will be bioequivalent to the RLD oral tablet, it meets the waiver requirement of "Does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients". Since the pediatric patient population in the RLD clinical trials is < 5% of the recruited patient population, it meets the waiver requirement of "Is not likely to be used in a substantial number of pediatric patients."

The petitioner, hereby, requests that the agency grants a waiver from conducting pediatric studies of the proposed oral suspension when submitted as an ANDA.

4. Environmental Impact

The petitioner claims a categorical exclusion under 21 CRF 25.31.

5. Economic Impact

The petitioner will submit information on economic impact upon request by the agency if applicable.

6. 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.

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Should any additional information be needed, please do not hesitate to contact me at 347-238-2729 or e-mail to RADept@epic-pharma.com.

Sincerely,

Digitally signed by Pei Zhang
DN: cn=Pei Zhang, o=Epic Pharma, LLC, ou=Regulatory Affairs Department, email=p.zhang@epic-pharma.com, c=US
Date: 2024.06.28 10:07:44 -04'00'

Mr. Pei Zhang, Ph.D.
Director of Regulatory Affairs
Epic Pharma, LLC

Attachments:

1. Regulatory Authorization Letter
2. FDA approved Labeling for the reference-listed drug APTIOM Tablets
3. Copy of Electronic Orange Book of APTIOM Tablets
4. ZEBINIX Oral Suspension Label approved by the European Medicines Agency
5. FDA approved Labeling for TRILEPTAL (Oxcarbazepine) Oral Suspension
6. Suitability Petition Approval Letter for Griseofulvin ultramicrosize oral suspension 250 mg/5 mL (Docket No. FDA-2008-P-0303)
7. Draft Package Insert Proposed for Eslicarbazepine Acetate Oral Suspension, 50 mg/mL with track changes compare with RLD labeling.