May 3, 2021

Kim-Yen [Kim] Nguyen
Project Manager, OGD/ORO/DFR
Center for Drug Evaluation and Research
Office of Generic Drugs
U.S. Food and Drug Administration
Tel: 240-402-8869

Re: Suitability Petition (FDA-2019-P-5759) Information Request - Chlorzoxazone and Acetaminophen Tablets, 250 mg/300 mg

Dear Sir/Madam,

This Letter is in reference to the INFORMATION REQUEST received from the agency on March 26, 2021 for the Suitability Petition (FDA-2019-P-5759). Aavis Pharmaceuticals is submitting complete response to all the deficiencies/comments listed in the Agency's communication.

1. In accordance with 21 CFR 314.93(d), amend your petition to identify a reference listed drug (RLD) that is the subject of your petition.

Response:

As per the FDA Section 505(j)(2)(A)(iii) and 21C.F.R. §314.93, Aavis Pharmaceutical's has proposed new fixed dose combination of Chlorzoxazone and Acetaminophen Tablets, 250 mg/300 mg. Following is the reference listed drug we consider during proposing the new fixed dose combination.

Active Ingredient:	ACETAMINOPHEN; BUTALBITAL
Proprietary Name:	BUTAPAP
Dosage Form; Route of Administration:	TABLET; ORAL
Strength:	325MG;50MG
Reference Listed Drug:	No
Reference Standard:	Yes
TE Code:	AA
Application Number:	A089987
Product Number:	001
Approval Date:	Oct 26, 1992
Applicant Holder Full Name:	MIKART LLC
Marketing Status:	Prescription

Note for reviewer: - To provide the justification for bio-waiver we have proposed to generate the dissolution profile of proposed fixed dose combination with BUTAPAP (A089987) (For

Acetaminophen) and CHLORZOXAZONE (A207483) for Chlorzoxazone. (Annex-1: Orange book pages are attached along with this document).

2. Provide the RLD label based on the RLD cited in your response to comment above. If necessary, provide an updated proposed drug product label and/or reference standard label.

Response:

We have proposed new fixed dose combination of Chlorzoxazone and Acetaminophen Tablets, 250 mg/300 mg which is based on the RLD BUTAPAP (ACETAMINOPHEN; BUTALBITAL TABLETS 325MG;50MG). In-place of butalbital we proposed to use Chlorzoxazone in the new dose combination. This combination is already been approved in Canadian market.

Considering this we have prepared the proposed labeling of our new fixed dose combination based following product labeling.

1. BUTAPAP (ANDA089987) (Annex-II)
2. CHLORZOXAZONE TABLETS (ANDA207483) (Annex-III)
3. ACETAZONE FORTE (Canadian Product) (Annex-IV)

Labeling of above listed product is provide along with this document.

3. Provide a Pediatric Research Equity Act (PREA) waiver and justification.

Response:

As mentioned in the dosage and administration proposed dose is for adult patent only and not recommended for the child. Thus, we request Agency to grant us a Pediatric Research Equity Act (PREA) waiver for our proposed new fixed dose combination Chlorzoxazone and Acetaminophen Tablets, 250 mg/300 mg. The signed Pediatric Research Equity Act (PREA) waiver request is also provided along with this response (Annex-V).

During the course of the review of this application, if there are any questions or comments, please do not hesitate to contact undersigned via telephone at +1-706-684-0388, facsimile at +1-706-684-0393 or e-mail: dbarot@aavispharma.com.

Sincerely,

Digitally signed by
Dhananjay Barot
Date: 2021.05.03
10:34:28 -04'00'

Dhananjay Barot
President
Aavis Pharmaceuticals.