Beckloff Associates
Attn: Michael C. Beckloff
7400 West 110th Street
Suite 300
Overland Park, KS 66210

Docket No. FDA-2006-P-0339
(Legacy No. FDA-2006-P-0288)

Dear Michael Beckloff:

This is in response to your petition received on July 19, 2006, by the U.S. Food and Drug Administration (FDA or Agency), requesting permission to submit an Abbreviated New Drug Application (ANDA) for the following drug product: Alprazolam Orally Disintegrating Tablets, 0.25 mg. The listed drug product to which you refer in your petition is Niravam® Orally Disintegrating Tablets, 0.25 mg, 0.5 mg, 1 mg, and 2 mg, approved under New Drug Application (NDA) 021726 and held by UCB Inc.

Your petition requests "a change in strength" from that of the listed drug product (i.e., from Niravam (alprazolam) Orally Disintegrating Tablets, 0.25 mg, 0.5 mg, 1 mg, and 2 mg to alprazolam orally disintegrating tablets, 0.25 mg). A change in strength is the type of change that is permissible under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act), subject to FDA approval of a petition submitted under that section of the Act.

However, a petition to request a change from a listed drug is only required when "[a] person . . . wants to submit an ANDA for a drug product which is not identical to a listed drug in route of administration, dosage form, and strength, or in which one active ingredient is submitted for one of the active ingredients in a listed combination drug." 21 CFR 314.93(b). FDA's publication *Approved Drug Product's With Therapeutic Equivalence Evaluations* (the Orange Book), identifies as a reference listed drug (RLD) NDA 021726, for alprazolam orally disintegrating tablets, 0.25 mg.[1] Your petition states that the "drug, the route of administration, and the recommendations for use are the same" as the RLD. Further, there is no difference in the dosage form or strength between your proposed alprazolam orally disintegrating tablets, 0.25 mg, and the RLD. Therefore, FDA denies your petition because it does not propose a change from a listed drug (i.e., NDA 021726) in route of administration, dosage form, strength, or active ingredient.[2]

If you disagree with our determination concerning the approvability of your petition as originally submitted, you may seek a reconsideration of the decision not to approve your petition following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in

[1] The Agency notes that NDA 021726 is listed on the Discontinued Drug Product List in the Orange Book. See Orange Book Preface at section 1.11 for more information on the discontinued section of the Orange Book. An ANDA may be submitted that relies on a listed drug approved for safety and effectiveness under section 505(c) of the Act but has been voluntarily withdrawn from sale in the United States. See 21 CFR 314.122(a). The Orange Book also indicates that the Agency has determined that NDA 021726 was not withdrawn from sale for reasons of safety or effectiveness. FDA published this determination in the Federal Register (80 FR 1423; Jan. 9, 2015). This determination allows the Agency to approve ANDAs for the discontinued product. 21 CFR 314.161(a).

[2] See also 21 CFR 314.93(e)(1)(vi) (stating that a suitability petition will be denied if a drug product is approved in an NDA for the change described in the petition).

your original petition and must be submitted in accordance with 21 CFR 10.20, in the format outlined in § 10.33 and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information not included as part of your original submission that you would like the Agency to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

A copy of this letter will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely,
William H. Chong -S
Digitally signed by William H. Chong -S
Date: 2022.06.29 08:13:10 -04'00'

William Chong, M.D.
Director, Office of Safety and Clinical Evaluation
Office of Generic Drugs
Center for Drug Evaluation and Research