

Beckloff Associates

7400 West 110th Street, Suite 300
Overland Park, Kansas, 66210
913.451.3955 tel
913.451.3846 fax

www.beckloff.com

 **Beckloff Associates**
a Cardinal Health company

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July 18, 2006

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

SUITABILITY PETITION

The undersigned submits this petition under 21 CFR 10.20 and 10.30, as provided for in 21 CFR 314.93 and Section 505(j)(2)(c) of the Federal Food, Drug, and Cosmetic Act, to request the Commissioner of Food and Drugs to declare that the drug product alprazolam orally disintegrating tablets for oral administration in a 0.25-mg strength is suitable for submission as an ANDA.

A. Action Requested

The petitioner requests the Commissioner of the FDA to declare that alprazolam orally disintegrating tablets, 0.25 mg, is suitable for submission as an ANDA. The reference listed drug upon which this petition is based is Schwarz Pharma's Niravam™ (alprazolam orally disintegrating tablets) 2.0 mg. Niravam was approved in 0.25-, 0.5-, 1.0-, and 2.0-mg dosage strengths under NDA No. 21-726. This petition is submitted for a change in dosage strength from the reference listed drug strength of 2.0 mg. Alprazolam orally disintegrating tablets will be marketed in dosage strengths of 0.25, 0.5, 1.0 and 2.0 mg. The drug, the route of administration, and the recommendations for use are the same as those of the reference listed drug. The proposed product would only differ in dosage strength from the reference listed drug (Niravam 2.0 mg).

B. Statement of Grounds

The Federal Food, Drug, and Cosmetic Act provides for submission of an ANDA for a new drug that differs in dosage strength from that of a reference listed drug, provided the FDA has approved a petition that proposed the filing of such an application. This petition requests a change in strength for the proposed drug from that of the reference listed drug.

The reason for this request is the desire to market 0.25, 0.5, 1.0, and 2.0 mg alprazolam orally disintegrating tablets, matching the approved dosage strengths for Niravam. The 0.25 mg dosage strength is not dose-proportional to the 0.5, 1.0, and 2.0 mg dosage strengths. Therefore a bioequivalence study will be required in order to demonstrate bioequivalence to the Niravam 0.25 mg orally disintegrating tablet. As the Niravam 2.0 mg orally disintegrating tablet is the Reference Listed Drug, FDA must state that alprazolam 0.25 mg orally disintegrating tablets are suitable for submission in an ANDA.

The proposed package insert for alprazolam orally disintegrating tablets will be consistent with the reference listed drug labeling. The indications, route of administration, intended patient population, and recommendations for use will remain the same as for the reference listed drug product, Niravam.

In summary, the proposed change in strength of alprazolam orally disintegrating tablets from that of the reference listed drug (i.e., a change from 2.0 to 0.25 mg) will not raise questions of safety or efficacy.

The package insert for the reference listed drug is provided in Attachment 1 of this petition. The proposed draft package insert for alprazolam orally disintegrating tablets is provided in Attachment 2, with changes highlighted for ease of review.

C. Environmental Impact

A claim for a categorical exclusion of an environmental assessment report based upon 21 CFR 25.31 is hereby made.

D. Economic Impact

The petitioner does not believe that this is applicable in this case but will agree to provide such an analysis if requested by the agency.

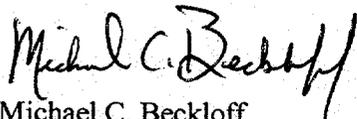
E. Pediatric Use Information

The Pediatric Research Equity Act, passed in December 2003, requires that applications submitted under Section 505 of the Act be evaluated for safety and efficacy in pediatric populations when the application is submitted for the following: a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration. The proposed petition seeks a change in dosage strength from that of the reference listed product, and therefore under the provisions of the Pediatric Research Equity Act, it is not necessary to evaluate the safety or efficacy of this drug in pediatric populations or seek a waiver or deferral for pediatric studies.

F. 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.

Sincerely,



Michael C. Beckloff
President
Beckloff Associates, Inc.
7400 West 110th Street, Suite 300
Overland Park, KS 66210
(913) 451-3955

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Enclosures

cc: G. Buehler, Director, Office of Generic Drugs