E4 Consulting

June 24, 2020

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

CITIZEN PETITION

Dear Sir or Madam:

I am submitting this Citizen Petition pursuant to the Federal Food, Drug and Cosmetic Act ("FD&C Act") and in accordance with regulations at 21 CFR §10.25(a), 10.30(b), and 314.161, on behalf of a client, to request that the Commissioner of the Food and Drug Administration determine whether a listed drug has been discontinued for safety or effectiveness reasons as outlined below.

1. Action Requested

The petition requests that the Commissioner of the Food and Drug Administration ("FDA") determine whether BACTROBAN® (mupirocin calcium) Nasal Ointment, 2%, approved under NDA 050703 (held by GlaxoSmithKline), has been discontinued from sale for safety or efficacy reasons.

2. Statement of Grounds

The Food and Drug Administration maintains a list of drug products that are eligible for submission as abbreviated new drug applications in the Approved Drug Products with Therapeutic Equivalence Evaluations ("The Orange Book"). BACTROBAN® (mupirocin calcium) Nasal Ointment, 2% approved under NDA 050703 (held by GlaxoSmithKline) on September 18, 1995. Upon approval BACTROBAN Nasal Ointment, 2% became the Reference Listed Drug (RLD) by its listing in the Orange Book against which generic equivalents can be developed and approved in an ANDA.

As verified on the Orange Book website, at the time of this petition's submission, BACTROBAN Nasal Ointment, 2% is currently in "Discontinued" marketing status. See attached page from the Orange Book (Attachment 1). However, The Orange Book does not reflect any determination to indicate if this product was discontinued for safety & effectiveness reasons. Accordingly, I respectfully request that FDA to determine whether BACTROBAN® (mupirocin calcium) Nasal Ointment, 2% was discontinued for reasons of safety or effectiveness.

15696 Oakstand Road, Poway, CA 92064-2264
Telephone: +1 858 735-0320 **Fax: +1 858 746-4343**

3. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 C.F.R. §25.31.

4. Economic Impact

Pursuant to 21 C.F.R. §10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided, if so requested.

5. 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 petition, which is unfavorable to the petition.

Sincerely,

Eric Gruff, PhD MBA
President, E4 Consulting

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