Citizen Petition

Date: 11/06/2019

The undersigned submits this petition under CFR 21 314.161 §§10.25(a) and 10.30 of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to disclose whether a listed drug has been voluntarily withdrawn or withdrawn for safety or effectiveness reasons.

A. Action Requested

Disclose whether a listed drugs ANDA 040063, ANDA 088606 and ANDA 084476 have been voluntarily withdrawn or were withdrawn for safety or effectiveness reasons.

B. Statement of Grounds

I was unable to find any such notification in the Federal Register. I have grouped 3 related items in one petition because I thought that it would save your agency time and effort. I will submit individually if required.

Specifically, listed in the Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations is:

Product Details for ANDA 040063
ACETIC ACID 2% IN AQUEOUS ALUMINUM ACETATE (ACETIC ACID, GLACIAL; ALUMINUM ACETATE) 2%;0.79% Marketing Status: Discontinued
Active Ingredient: ACETIC ACID, GLACIAL; ALUMINUM ACETATE
Proprietary Name: ACETIC ACID 2% IN AQUEOUS ALUMINUM ACETATE
Dosage Form; Route of Administration: SOLUTION/DROPS; OTIC
Strength: 2%;0.79%
Reference Listed Drug: No
Reference Standard: No
TE Code:
Application Number: A040063
Product Number: 001
Approval Date: Feb 25, 1994
Applicant Holder Full Name: BAUSCH AND LOMB PHARMACEUTICALS INC
Marketing Status: Discontinued

Product Details for ANDA 088606

BOROFAIR (ACETIC ACID, GLACIAL; ALUMINUM ACETATE) 2%;0.79% Marketing Status: Discontinued
Active Ingredient: ACETIC ACID, GLACIAL; ALUMINUM ACETATE
Proprietary Name: BOROFAIR
Dosage Form; Route of Administration: SOLUTION/DROPS; OTIC
Strength: 2%;0.79%
Reference Listed Drug: No
Reference Standard: No
TE Code:

Application Number: A088606
Product Number: 001
Approval Date: Aug 21, 1985
Applicant Holder Full Name: PHARMAFAIR INC
Marketing Status: Discontinued

Product Details for ANDA 084476

DOMEBORO (ACETIC ACID, GLACIAL; ALUMINUM ACETATE)
2%;0.79% Marketing Status: Discontinued
Active Ingredient: ACETIC ACID, GLACIAL; ALUMINUM ACETATE
Proprietary Name: DOMEBORO
Dosage Form; Route of Administration: SOLUTION/DROPS; OTIC
Strength: 2%;0.79%
Reference Listed Drug: No
Reference Standard: No
TE Code:
Application Number: A084476
Product Number: 001
Approval Date: Approved Prior to Jan 1, 1982
Applicant Holder Full Name: BAYER PHARMACEUTICALS CORP
Marketing Status: Discontinued

C. Environmental Impact

"We claim categorical exclusion under 25.30, 25.31, 25.32, 25.33, or 25.34 of this chapter or an environmental assessment under 25.40 of this chapter."

D. Economic Impact

The economic impact information will be submitted upon request of the commissioner.

E. 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.

_____(Signature)

James Grote _____(Name of petitioner)

(b) (6) [redacted] _____(Mailing address)

_____(Telephone number)