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20 November 2000

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

RE: Request for Withdrawal of Approval
Petition Docket Number 00P-0913/CP1
Approval Date 13 June 2000
For Albuterol Sulfate Inhalation Solution, 0.0417%

Dey hereby requests that the FDA rescind its approval, granted 13 June 2000, of the ANDA Suitability Petition filed 3 March 2000 under docket number 00P-0913/CP1. The Petition was in support of a proposed Albuterol Sulfate Inhalation Solution 0.0417% unit-dose product.

Dey's request is based on the following grounds:

On 29 January 1992 Dey filed a Suitability Petition under docket number 92P-0049/CP1. The Petition was in support of a proposed Albuterol Sulfate Inhalation Solution 0.0415% unit-dose product. In subsequent conversations with the FDA, specifically with Gordon Johnston on 20 May 1992, Dey was informed that the proposed drug product was not suitable for submission as an ANDA. Mr. Johnston told Dey that an efficacy study would be needed, thereby requiring an NDA rather than an ANDA. Because the process to prepare a written denial letter to Dey's Petition was lengthy, Mr. Johnston requested that the Petition be withdrawn. A record of the conversation is included with this Petition.

Dey complied with the withdrawal request in a letter dated 27 May 1992. A copy of the letter is included with this Petition.

In further conversations with the FDA, specifically with Cathie Schumaker of the Division of Oncology and Pulmonary Drug Products, on 5 January 1993, Dey was informed that discussion at an HFD-150 team meeting on 21 December 1992 confirmed that in order to receive approval of an alternate strength of albuterol, with or without pediatric indications, clinical studies including a dose ranging study and a three-month efficacy study would be required. A record of the conversation is included with this Petition.

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No additional evidence has been presented since the filing of Dey's Suitability Petition which would deem clinical studies unnecessary. Therefore, new petitioners should have to meet the same requirements conveyed to Dey.

Should you have any questions regarding this request, please call me at (707) 224-3200, ext. 4750.

Sincerely,

A handwritten signature in black ink that reads "Peggy J. Berry". The signature is written in a cursive style with a large, looping initial "P".

Peggy J. Berry
Director, Regulatory Affairs.

FDA TELEPHONE CONTACT

DISTRIBUTION:

FDA CONTACT: Gordon Johnston
DEY CONTACT: Katherine Gold *lk*
DATE OF FDA CONTACT: May 20, 1992

H. Burnham
B. Mozak
C. Rice
J. Siebert
J-P. Termier
M. Wells

SUBJECT: Albuterol Sulfate Inhalation Solution 0.0415%
Citizen's Petition

The FDA has determined that the drug product Albuterol Sulfate Inhalation Solution 0.0415% is not suitable for submission as an ANDA. Therefore, the Citizen's Petition submitted on January 28, 1992, has been denied.

The FDA based their decision on two issues. First, there are currently no efficacy studies on file at the FDA for the 0.0415% strength. As efficacy studies would be required, the product would require an NDA instead of an ANDA. Second, the labeling would have to be different from the referenced drug product. This issue also removes the product from the Office of Generic Drugs' jurisdiction into the NDA area.

Mr. Johnston acknowledged the literature references submitted with the Citizen's Petition that discuss the use of varying strengths of the product. He reiterated the FDA policy that use of a product does not denote approval of the product.

As the process to prepare a written denial letter to the Petition is lengthy, Mr. Johnston requested the Petition be withdrawn. It is recommended that this request be discussed at the next NPCC meeting.



DEY LABORATORIES, INC.
2751 Napa Valley Corporate Drive
Napa, California 94558
TEL (707) 224-3200 FAX (707) 224-3238

May 27, 1992

Dockets Management Branch
Food and Drug Administration
HFD-305, Room 1-23
Park Building
12420 Parklawn Avenue
Rockville, MD 20857

RE: Docket Number 92P-0049/CP 1

Dear Sir:

Dey Laboratories, Inc., is requesting the withdrawal of the referenced ANDA suitability petition dated January 28, 1992.

Sincerely yours,

Katherine A. Gold

Katherine A. Gold
Manager, Regulatory Affairs

KAG:psp

CC: Gordon Johnston
OGD/FDA

DEY LABORATORIES, INC.

~~FDA TELEPHONE CONTACT~~

FDA CONTACT:	Cathie Schumaker	Distribution:
DEY CONTACT:	Katherine Gold 	H. Burnham
DATE OF FDA CONTACT:	January 5, 1993	B. Mozak
SUBJECT:	<u>EDTA/Preservative-Free and</u>	C. Rice
	<u>Alternate Strengths of Albuterol</u>	J. Siebert
		M. Wells

Cathie Schumaker (Supervisory CSO) of the Division of Oncology and Pulmonary Drug Products (HFD-150) was contacted to request the results of the December 21, 1992, HFD-150 team meeting for the following issues:

EDTA/Preservative-Free Claim

HFD-150 Director Dr. Greg Burke does not see the need for a meeting to discuss the FDA's request to cease using the term "preservative-free". In Dr. Burke's opinion, the effects of the chemical in its entirety does not allow for the claim. According to Ms. Schumaker, Dr. Burke will not change his decision on the matter. However, when I stated that we would be interested in continuing our request for a meeting with the FDA, Ms. Schumaker requested that we continue to work with HFD-150 before contacting the FDA Ombudsman. A letter requesting a meeting with Dr. Burke will be prepared.

Alternate Strengths of Albuterol

In order to receive approval of an alternate strength of albuterol with or without pediatric indications, clinical studies are required. The studies would include a dose ranging study and a three month study to prove the efficacy of the product as defined by the labeling. Prior to the submission of an IND, Ms. Schumaker recommended a proposal outlining the product and the proposed clinical studies be submitted. The proposal will be prepared for the FDA.

KAG:ra

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ANGEL O'HALLORAN
DEY LABORATORIES
2751 NAPA VALLEY CORP DR
NAPA CA 94558

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(707)224-3200

TO: NAHM MEYER
FOOD & DRUG ADMINISTRATION
5630 FISHER LANE RM 1061
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ROCKVILLE MD 20852

(301)594-5400

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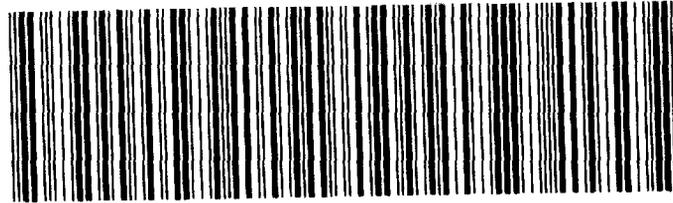
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