



October 14, 2002

VIA FEDERAL EXPRESS

Dockets Management Branch (HFA-305)
Food and Drug Administration (Phone: 301-827-6860)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

ANDA SUITABILITY PETITION

SensorMedics Corporation hereby submits this ANDA Suitability Petition under the provisions of section 505 (j)(2)(C) of the Federal Food, Drug and Cosmetic Act, and the corresponding regulation under 21 CFR 314.93 requesting that the Commissioner of Food and Drugs allow the submission and filing of an Abbreviated New Drug Application (" ANDA ") for Albuterol Base Inhalation Solution, 0.083% (0.83 mg/mL), in 4 mL, 5 mL, 6 mL, 7 mL, and 8 mL pouches delivered by the PharmaMyst™ ElectroHydroDynamic (EHD) Nebulizer, which is more specifically presented below, and with attachments to this petition.

A. Action Requested

The Petitioner requests that the Commissioner of Food and Drugs allow the submission and filing of an ANDA for Albuterol Base Inhalation Solution, 0.083% (0.83 mg/mL), in 4 mL, 5 mL, 6 mL, 7 mL, and 8 mL pouches pursuant to Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act. Specifically, the proposed product is formulated as a pre-diluted, non-preserved, base form version of Schering's product, Proventil®, Albuterol Sulfate Inhalation Solution 0.083%, 3 mL, NDA No. 19-243. This dosage form is intended for both adult and pediatric use. Draft labeling is enclosed with this petition. SensorMedics proposes to use the Dey labeling and indications, which appear to be the same as those indications used in the Ventolin® labeling, along with added appropriate instructions for the use of our delivery device. The Dey product, which is currently on the market under ANDA No. 72-652, contains the labeling and indications used in the Ventolin® product. In the approved petition under Docket No. 01P-0353/CPI, FDA designated Proventil® and Ventolin® both as reference listed drugs on 5/23/2002.

B. Statement of Grounds

The Food, Drug, and Cosmetic Act as amended provides, in relevant part, that any person may file an ANDA for the approval of a new drug that is the "same"

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as a listed drug. 21 U.S.C. § 355(j)(2)(A), (j)(6); 21 C.F.R. § 314.92(a)(l). Abbreviated applications also may be submitted for a new drug, which differs from a listed drug in one or more specified aspects, provided that FDA has declared the product suitable for ANDA submission through the petition process. 21 U.S.C. § 355(j)(2)(A), (j)(2)(C); 21 C.F.R. § 314.92(a)(3). Permitted product changes include, among other things, a different route of administration, dosage form, or strength from that of a listed drug. Id. FDA must approve a petition seeking one or more of these product changes, unless the proposed product change(s) presents questions of safety or effectiveness. 21 U.S.C. § 355 (j)(2)(C)(i); 21 C.F.R. § 314.93.

This petition accordingly seeks FDA authorization to submit an ANDA for an Albuterol Base Inhalation Solution, 0.083% (0.83 mg/mL), in 4 mL, 5 mL, 6 mL, 7 mL, and 8 mL pouches. The proposed ANDA will reference the listed drug, Proventil[®], which is manufactured by Schering. The proposed drug product will differ from the listed drug in strength (base form) and dosage form (EHD ready solution), both of which are changes that are permitted by the Act. Specifically, the proposed product will contain the same active ingredient, in base form, for the same labeled use as the reference listed drug, but as a solution for inhalation in an EHD device, and at a strength of 0.083% (0.83 mg/mL), in 4 mL, 5 mL, 6 mL, 7 mL, and 8 mL pouches. SensorMedics proposes, and will show bioequivalence to Proventil[®] utilizing pulmonary lung function testing (FEV₁ = Forced Expired Volume in One Second; FEV_C = Forced Vital Capacity; FEV₁/FEV_C Ratio; and PEF_R = Peak Expiratory Flow Rate). It is expected that a significantly lower dose delivered by our product specific device nebulization device will result in the same lung function responses as the innovator product due to its ability to produce a specific, single particle size nebulization at near-zero velocity. The innovator has conducted both adult and pediatric studies in support of their indication for relief of reversible bronchospasm and acute attacks of bronchospasm, and the labeling for the listed drug contains the appropriate adult and pediatric information. Therefore, the safety and effectiveness of albuterol in adult and pediatric patients has been established, so there are no questions of safety or effectiveness. In view of this, SensorMedics intends to label its device for the adult and pediatric population.

The availability of an EHD Inhalation solution dosage, and the unique dispensing method will maximize the drug delivery to the airways, and minimize the patient's oropharyngeal deposition because of the narrow particle size and near-zero forward velocity of the nebulization. Also, the proposed drug product will provide physicians and patients with an extremely accurate dosage as well as speed and ease of administration compared to traditional nebulization devices. And, all of this is accomplished while providing the same therapeutic and safety benefits as that of the listed drug. Further, the proposed drug should improve patient compliance because the need for additional compounding or any handling of the



solution will be completely eliminated since the immediate drug container is not opened by the patient; it is simply place into the easy-to-use EHD device.

Due to the lower total dose needed, it is also expected that there will be less side effects traditionally associated with albuterol for inhalation. The labeling of the proposed drug product will be the same as the currently approved labeling for the listed drug, with a few minor changes which are required because of differences approved under this petition; ie., dosage form and administration instructions. See Attachments. In light of the above, and the fact that albuterol has been marketed in the U.S. for many years, there is no reason to question the safety or efficacy of the proposed albuterol inhalation solution product for its intended uses.

C. Environmental Impact

The Petitioner claims a categorical exclusion under 21 CFR §25.31.

D. Economic Impact

It is proposed that usage of the SensorMedics EHD albuterol will result in greater patient compliance, better physician records, and less side effects due to a lower dose needed to achieve bioequivalent lung function benefit. Therefore, a significant corresponding economic savings to the doctor, the patient, and society are expected. Further information under this section 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. Further, to the best of its knowledge and belief at this time, the petitioner is not aware of any information unfavorable to this petition.

Thank you very much.

Sincerely,

Barry Sugarman, B.S.ENGR.
Consultant, Advanced Technologies

Attachments: EHD Technology PowerPoint Slides, Lung Function Textbook Definitions, Dey Albuterol Sulfate for Inhalation, 0.083% Product Insert, and SensorMedics Product Insert Differences.