DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 17 2003

SensorMedics Corporation
Attention: Barry Sugarman
15515 Sunset Blvd.
Pacific Palisades, CA 90272

Docket No. 02P-0448/CP1

Dear Mr. Sugarman:

This is in response to your petition filed on October 15, 2002, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Albuterol Base Inhalation Solution, 0.083%. Your requests include a change in strength (i.e., total drug content) for Albuterol Solution 0.083% in 4 mL, 5 mL, 6 mL, 7 mL and 8 mL "pouches", a change from the salt form to the base form of the active ingredient, and an unapproved or uncleared delivery system. The listed drug product to which you refer in your petition is Albuterol Sulfate Inhalation Solution, 0.083%, 3 mL nebulas, ANDA 72-652 held by Dey LP.

This petition was reviewed pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act). Under Sections 505(j)(2)(C)(i) of the Act, such a petition will be approved unless the Food and Drug Administration (FDA) finds that investigations must be conducted to show the safety and effectiveness of the proposed drug product or its strength which differs from the listed drug product.

Your requests involve a change in active ingredient from albuterol sulfate to albuterol (base) and a change in strength (total drug content) from that of the listed drug product (i.e., from 3 mL nebules to 4 mL, 5 mL, 6 mL, 7 mL and 8 mL "pouches"). You are also requesting a new drug and device combination (i.e., the "pouches" are designed solely to be used with a unique nebulizer system). The changes in strength (total drug content) that you request are authorized under Section 505(j)((2)(C) of the Act. However your petition proposes to utilize an unapproved or uncleared delivery system for administration of the albuterol (base) inhalation solution. The pouch will be compatible only with the unapproved or uncleared delivery system (PharmaMyst ElectroHydroDynamic Nebulizer) you intend to market. According to your petition, this unique drug delivery system could potentially allow patients to inhale a significantly lower dose of the drug while maintaining the same therapeutic effect as products currently on the market. These claims must be substantiated. You also propose to change from the sulfate salt of the active ingredient albuterol, to the base form of albuterol. This type of change in the active ingredient is not permitted. Please refer to the preamble of the Abbreviated New Drug Regulations; Proposed

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SensorMedics Corporation
Albuterol Base Inhalation Solution, 0.083%

Rule 54 FR 28878 "FDA considers a salt or ester of an active ingredient to be a different active ingredient and will not approve petitions that seek permission to submit an ANDA for a drug product which substitutes a different salt or ester of an active ingredient from that of a listed drug, unless the petition seeks a change in a combination product and the new salt or ester has been approved or is not a new drug."

Therefore, the FDA has determined that your proposed changes in strength, and active ingredient, raise questions of safety and effectiveness, and has concluded that clinical trials are required for the new strengths (total drug content) to be used with an unapproved or uncleared delivery system. Accordingly, FDA is denying the petition under Section 505(j)(2)(C)(i) because investigations are necessary to show the safety and effectiveness of the new active ingredient and the claim that the delivery system makes the drug more effective by providing the same level of effectiveness while supplying lesser amounts of the drug.

If you disagree with our determination concerning the acceptability of your petition as originally submitted, you may seek a reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR Section 10.20, in the format outlined in Section 10.33, and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information, not included as part of your original submission that you would like the FDA to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

A copy of this letter denying your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,

Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research