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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS
VIA FACSIMILE

APR 29 1999

Mr. Michael Crnkovich
President
Emergency Filtration Products, Incorporated
4335 South Industrial Road
Suite 440
Las Vegas, Nevada 89103

Re: RespAide Non-Rebreathing Mask and Valve, K980052

Dear Mr. Crnkovich:

The Food and Drug Administration (FDA) has reviewed promotional materials for the RespAide Non-Rebreathing Mask and Valve (Respaide). This product is manufactured by Emergency Filtration Products, Incorporated (Emergency Filtration) and is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The RespAide is a Non-Rebreathing Valve and Mask that has been cleared under section 510(k) of the Act and is intended for use in cardiac or respiratory arrest to assist in cardiopulmonary resuscitation. The RespAide kit includes gloves, an antiseptic towlette and a biohazard bag, in addition to the mask, filter, and mouthpiece.

The original labeling for RespAide submitted by Emergency Filtration to the Office of Device Evaluation (ODE) included claims that the device could reduce the transmission of Ebola, HIV, tuberculosis, meningitis, and pneumonia. Additionally, your materials included the statement that RespAide is "the best available technology for mouth-to-mask CPR available today." The 510(k) record indicates that on June 24, 1998, Mr. Doug Beplate, Emergency Filtration contact person, indicated in a facsimile to Ms. Christy Foreman, an ODE reviewer, that claims for reducing the above bacterial and viral organisms would be removed from your promotional materials and that the claim indicating RespAide is "the best available technology" would also be removed from these materials.

However, our review of your web site at the internet address: http://www.respaide.com continues to make claims for the protection of specific viral and bacterial organisms i.e., "RespAide is a CPR isolation mask, a device designed to protect both the patient and

rescuer from infectious viral and bacterial disease such as HIV, Hepatitis, and Tuberculosis, in mouth-to-mouth resuscitation."

Promotion of RespAide for claims of protecting the patient and/or rescuer from the transmission of HIV, hepatitis, tuberculosis, or any other pathogenic organsisms, represents a major modification in the intended use of the device and requires the submission of a new 510(k) as described under the provisions of 21 CFR 807.81(a)(3)(ii).

Continued promotion of RespAide by Emergency Filtration for such claims causes your device to be adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

The RespAide is also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use of the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the device was not found to be substantially equivalent to a predicate device.

Additionally, we have also reviewed an Emergency Filtration press release dated April 12, 1999, which includes the statement, "It is the only CPR mask to be awarded an FDA 510(k) number and has obtained military stocking numbers." Since there are, in fact, other CPR masks which have received clearance from the agency, we believe this statement is misleading and should be removed from your promotional materials.

This letter is not intended to be an all-inclusive list of deficiencies associated with your RespAide Non-Rebreathing Mask and Valve. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's San Francisco District Office. Please send a copy of your response to the District Director, Food and Drug Administration, San Francisco District Office (HFR-PA100), 1431 Harbor Bay Parkway, Alameda, California 94502-7070.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

bcc:

Drafted: SBudabin: 4/28/99
Reviewed: BTart: 4/28/99
Notified: SAN-DO: SKendall: 4/29/99
Final: SZB:
Files: c:\Emergency Filtration.WL

HFA-224	(Records)
HFC-130	
HFC-210	(DCarroll)
HFC-230	
HFC-240	(COMSTAT)
HFI-20	(Press Office)
HFI-35	(with purged cc orig. ltr)
HFR-PA1	(Richard Baldwin)
HFR-PA100	(Patricia Ziobro)
HFR- 140	(Steven Kendall)
HFZ-1	(Elizabeth Jacobson)
HFZ-300	(Lillian J. Gill)
HFZ-302	(c/f, s/f, SBudabin FBP (2) # 79049)
HFZ-305	(Precedent File)
HFZ-306	(Cathy Condon)
HFZ-450	(Christy Foreman)
HFZ-343	(Edgardo Santiago)